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FDA's Statutory Authority to Require Premarket Notification and Review of GRAS Substances Under the Food, Drug, and Cosmetic Act



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Executive Summary

This report explains the legal authority by which the Food and Drug Administration (FDA) can amend its regulations to require premarket notification and other premarket procedures before substances that are considered "generally recognized as safe" (GRAS) are allowed to be used in the U.S. food supply. The FDA's authority to take these steps derives from the Federal Food, Drug, and Cosmetic Act (FDCA) and its 1958 Food Additives Amendment (FAA). While the FAA prescribes detailed procedures for approving food additives, it exempts GRAS substances, leaving discretion for oversight of them to the FDA and creating space for the agency to design oversight for such substances.

Congress enacted the FAA to close a dangerous gap in prior law that allowed untested substances to be added to food and remain on the market for years before the government could prove harm. The statute establishes a broad default: any substance added to food is a "food additive" and is deemed unsafe unless it has gone through a detailed premarket additive approval process set out in the statute. Congress provided for a narrow exception to this process for GRAS substances: defined as those with a well-established history of safe use (e.g., sugar, salt, butter, lard, pepper) or a strong, generally recognized scientific consensus of safety. As analyzed in this report, the legislative history makes clear that Congress did not envision GRAS as an open-ended alternative pathway for novel chemicals, but as a practical exception for well-known ingredients and subject to ongoing FDA oversight and reevaluation.

Over time, and due to permissive FDA regulations that have allowed use of GRAS substances without mandatory FDA oversight, industry reliance on the GRAS pathway has largely supplanted the food additive petition process. Because GRAS notification is voluntary, FDA frequently does not know which chemicals are being added to food until after they are widely marketed and consumed. This outcome undercuts the central purposes of the FDCA and FAA. Thousands of substances now have entered the food supply through self-GRAS, without any FDA notification, and the overwhelming majority of new food chemicals have bypassed the traditional food additive process. Some of these GRAS substances, like tara flour, have been discovered to pose serious health risks after use in the food supply.

In August 2026, the U.S. Food and Drug Administration (FDA) proposed a rule to refine its requirements for the use of substances that are "generally recognized as safe" (GRAS) in food.[1] Despite proposing to make GRAS notifications to FDA mandatory, the proposed rule does not require these notification to be made prior to using the GRAS substances in food products. But as this report explains, FDA has ample authority to require such notifications to be premarket, which would better align with the statutory purpose, legislative history, and public health mission of the FDA.

Under current administrative law jurisprudence post-*Loper Bright*, courts no longer apply *Chevron* deference but require an independent analysis of the "best reading" of the statute and may accord *Skidmore* respect to agency interpretations. As described in this report, a reviewing court should find that the best reading of the FAA permits, and even strongly supports, FDA adoption of mandatory premarket procedures for GRAS substances. The text and legislative history show Congress intended premarket review to be the default for new food substances, with GRAS as a limited exception. A regime that allows companies to self-certify safety without meaningful FDA engagement recreates the precise premarket gap the FAA was enacted to close in the first place.

Courts have also repeatedly held that the FDCA should be interpreted broadly, in light of its overriding public health purpose. Courts have been loath to allow gaps in the law that create public health risks or harms, instead supporting FDA interpretations of the FDCA that aim to protect consumers. Viewed in this light, any FDA regulations that are within its authority to ensure food safety and public health should be supported by the courts.

Finally, the FDA has the authority to ensure "efficient enforcement" of the FDCA. Together with the FDA's duty to keep unapproved food additives out of the food supply, that authority supports requiring anyone who invokes the GRAS exception to notify the FDA, and share the basis for the determination, before the substance is used in food. Courts have long upheld the FDA's power to find that a substance or a certain use of a substance is not GRAS and is therefore an unapproved additive. The FDA cannot make those findings about substances it does not know exist, and voluntary notification under the 2016 GRAS rule leaves many substances unknown. Taken together, this supports FDA's authority to require premarket procedures for GRAS substances.

There is a limiting principle: FDA may not create a GRAS review process that is identical to the food additive petition process. This is because Congress created a category of GRAS substances and explicitly stated that they would be exempt from the food additive definition and thus the food additive petition process. However, the FDA can still require premarket GRAS notification, prescreening to determine whether a substance properly belongs in the GRAS or additive pathway, and submission of evidence showing general recognition of safety, all without collapsing GRAS into the additive approval process.

In sum, the structure, legislative history, and purpose of the FDCA and FAA, together with modern administrative jurisprudence and related FDCA case law, strongly support FDA's authority to require mandatory premarket notification and related procedures for GRAS substances. A well-crafted rule that preserves a procedural distinction from the food additive petition process would be a lawful response to growing evidence that the current voluntary GRAS system allows unsafe chemicals to enter and remain in the U.S. food supply without adequate oversight.



Issue

In August 2026, the U.S. Food and Drug Administration (FDA) proposed a rule to refine its requirements for the use of substances that are "generally recognized as safe" (GRAS) in food.[2] While the proposed rule would make GRAS notifications mandatory, it would not require that such notification take place prior to using the substance in foods being marketed in the United States. Some stakeholders have questioned FDA's authority to require premarket notice or other premarket procedures for GRAS substances. However, as described in this report, FDA has additional authority and could require premarket notification for GRAS substances. This report answers the question: Does the FDA have the authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to require premarket notification or other premarket procedures for substances that are considered by food industry actors to be GRAS?

Brief Answer

Yes. Under the Food Additive Amendment (FAA) to the FDCA, the FDA can establish premarket procedures to ensure GRAS status before a substance is used in food. These can include mandatory premarket notification or review of a GRAS determination or premarket screening of a substance to determine whether it can use the GRAS process or must use the additive approval process, provided that the premarket notification and review process for GRAS substances differs from the food additive petition process set out by Congress in the in the FAA.

Background

In recent years, concern has grown about additives and chemicals in the U.S. food supply.[3] There are thousands of ingredients in the U.S. food supply, but many of these substances have never been reviewed by the FDA for safety.[4] Under current FDA regulations, the majority of such substances can legally enter the market with limited or no FDA oversight, based solely on a determination by the food or ingredient manufacturer that the substance is "generally recognized as safe" (GRAS). If a food or ingredient manufacturer determines that a substance is GRAS (a "self-GRAS" determination or "self-certified" GRAS), they may voluntarily notify the FDA of the determination, in which case the FDA can issue a "no questions" letter, stating they do not question that determination. The manufacturer may alternatively make a confidential GRAS determination, sometimes colloquially described as "secret-GRAS"[5] and add the substance to food without ever notifying the FDA or the public.

Over time, the use of GRAS determinations—including those where the FDA has been notified and those where it has not—has overtaken the use of the Congressionally-created additive approval process. Research published in 2011 by Pew Health Group found that between 1990 and 2010, many new substances in food did not go through FDA review: those researchers discovered an estimated 1000 GRAS decisions were self-determined and never reported to the FDA, and another 2072 substances were determined GRAS by an

industry panel of experts (frequently through the Flavors and Extracts Manufacturers Association).[6] A 2025 study by the Environmental Working Group (EWG) found that nearly 99% of the new chemicals added to food between 2000 and 2025 (863 chemicals) bypassed the statutorily-created additive process and were instead used following voluntary notification to the FDA, a much less onerous process with limited FDA review; in that time period, only 10 chemicals were added to food via additive petition to FDA..[7] EWG research in 2026 also identified 111 food chemicals added to food using secret-GRAS in recent years, of which 49 are in common use and are listed as ingredients in thousands of food products as extracts, supplements, and alternative proteins.[8] Importantly, a growing body of scientific evidence suggests that many substances in use under the GRAS designation—either with notification to the FDA or through self-GRAS determinations—pose health risks.[9] Mounting concern over many of these substances has led to calls for the FDA to take action.[10] In 2025, the agency announced that it would be exploring an update to its GRAS rule,[11] and in August 2026, the agency published a proposed rule that aims to strengthen agency review of GRAS substances.[12] This section lays out the statutory definitions of food additives and GRAS substances, along with the history of FDA regulation and further detail on some of the concerns that are prompting FDA to take action now.

In 1938, Congress enacted the Food, Drug, and Cosmetic Act (FDCA), which built upon and replaced its predecessor, the 1906 Pure Food and Drug Act, and more fully empowered the FDA as a regulatory agency with oversight over the safety and labeling of food, drugs, medical devices, and cosmetics.[13] The FDCA allows the FDA to establish minimum standards for foods and prohibits the sale of foods that are adulterated or misbranded.[14] The FDCA is the core federal legislation relating to the FDA's authority, and all subsequent legislation on food, drugs, medical devices, and cosmetics are enacted as amendments to the FDCA.[15]

One such amendment was enacted by Congress in 1958 to increase regulatory oversight for food additives. The Food Additives Amendment (FAA) added provisions to the FDCA stating that any food containing unapproved additives is considered "adulterated."[16] The FAA added the following definition of a "food additive": "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of any food."[17] This definition was intentionally quite broad and aimed to require oversight for all substances added to food intentionally or unintentionally. However, in the FAA, Congress also included an exception to the definition of "additive" that exempts any substance considered "generally recognized as safe" (GRAS). The exception states that a substance is not an additive if it 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[.][18]

Congress's purpose in enacting the FAA was two-fold: first, to protect the health of consumers by requiring manufacturers of food additives and food processors to ensure the safety of any substances that will be added to food before those substances are used on the market; and second, to advance food technology by permitting the use of food additives to support innovation in food taste, handling, or storage.[19] In light of these two objectives, the FAA prohibited the use of food additives unless authorized by the FDA via a rigorous premarket food additive petition process.[20]

The additive petition process prescribed by Congress is data-intensive and lengthy. The FAA requires anyone who intends to use a food additive to first seek approval from the FDA by submitting a food additive petition.[21] The burden is on the petitioner to prove safety, and the petition must provide evidence that the substance is safe for the ways in which it will be used, including the foods in which it will be used and the intended levels of use.[22] After a petition is submitted, the FDA must publish a notice of the petition in the federal register, allowing the opportunity for public comment.[23] The FDA must then evaluate the petition and the public comments to determine if the data demonstrate that the food additive is safe under the proposed conditions of use.[24] For every food additive the FDA approves, the agency must promulgate a regulation authorizing the approved uses of the additive that meet the safety standard for food use.[25] Additives cannot be used except as authorized by such a regulation.

GRAS was intended as a relatively narrow exemption from the food additive definition (and thus from the premarket additive petition process). The legislative history, fleshed out in more detail below in Section IV. A., shows that members of Congress intended that food additives go through rigorous premarket review, and that only a narrow set of substances that had been commonly used in food prior to 1958 or were generally known to be safe for consumption be exempt. Statements from the Department of Health, Education and Welfare (precursor to the Department of Health and Human Services) also confirmed the Department's understanding that the GRAS exemption would only apply to common substances, like "sugar, salt, butter, lard, pepper."[26]

In contrast to its detailed description of the procedures required for additive approvals, the FAA includes no information about procedures for GRAS substances or GRAS determinations. The FAA does not state whether industry or the FDA is responsible for determining general recognition among experts that a substance is safe. Nor does the FAA detail any procedural mechanism for determining whether a substance is GRAS.[27]

Under the general authority granted to it by the FDCA, the FDA has consistently demonstrated its authority over the procedures required for GRAS. However, the FDA's regulatory oversight of GRAS has undergone several changes in the decades since the FAA was enacted. In 1958, shortly after the enactment of the FAA, the FDA created "the GRAS list," where it confirmed the GRAS status of a multitude of food substances that were used in food prior to 1958.[28] However, the FDA acknowledged it was impossible to list every safe substance, and many substances that were considered GRAS by the food industry were not included in the GRAS list.[29] Thus, manufacturers often asked the FDA for informal, non-binding "opinion letters" to confirm a substance's status as GRAS, which the FDA would issue.[30]

After cyclamates were linked to cancer and removed from the GRAS list in 1969, President Nixon ordered a comprehensive safety review of all presumed GRAS substances that same year.[31] As a result, in 1970, the FDA established formal criteria to determine if a substance should be "affirmed" as GRAS, regulated as a food additive, or be listed in an interim food additive regulation.[32] In 1972, the FDA created a "GRAS affirmation petition" process, allowing a manufacturer to voluntarily request the FDA to review and verify the safety of a substance.[33] Unfortunately, the affirmation petition process was slow and resource-intensive for both the government and industry, as the FDA utilized notice-and-comment rulemaking for each such substance, similar to the additive petition process.[34] Thus, the FDA began to allow industry entities to self-certify new substances as GRAS without informing the agency, a rule it proposed in 1997 and formally adopted with very little modification in 2016.[35]

Under its 1997 Proposed and 2016 Final Rule on Substances Generally Recognized as Safe ("2016 Final GRAS Rule"), the FDA allows companies to voluntarily notify the FDA of a GRAS designation.[36] The FDA then has several options as to how it responds. First, the FDA can issue a "no questions" letter, saying it does not question the GRAS designation and thus allows it to stand.[37] Second, the FDA can issue a letter rejecting the GRAS designation.[38] Lastly, the FDA can issue a notice that it has ceased to evaluate the substance at the request of the manufacturer. In practice, the FDA will generally cease to evaluate a substance after it writes privately to the manufacturer raising questions about the safety or scientific process used to assess safety, which prompts the manufacturer to withdraw its GRAS notice.[39] Yet, since the GRAS notification process is voluntary, companies may use a substance in food without notifying the FDA (sometimes called self-GRAS), or even if the FDA has raised serious questions about its safety and the GRAS notice was withdrawn.[40]

Without mandatory premarket review or notification, the FDA lacks the means to know when a new substance is used in food. Because manufactures may use generic terms on the food label (e.g., flavors),[41] there is often no way for the FDA (or the public) to know that a new substance was added to food through this self-GRAS process.[42] If FDA does identify a substance added to food through this self-GRAS process, it would only discover it after the product has already been manufactured, marketed, sold, and consumed.

FDA unquestionably has the post-market authority to review and revoke the GRAS and food additive status of ingredients in the food supply.[43] There are numerous examples of substances used under a GRAS designation that were later revoked due to health harms. For example, in 2022, the novel ingredient tara flour led to the illness and hospitalization of hundreds of people for gastrointestinal symptoms and abnormal liver function.[44] Tara flour was never submitted to FDA via a food additive petition or a voluntary GRAS notification. Instead, the substance was used in food products after a supplier self-determined its GRAS status.[45] . However, reports allege that only one toxicity study was conducted at the Universidad Peruana Cayetano Heredia prior to the self-designation of tara flour as GRAS.[46] Food safety attorney Bill Marler pointed out in a 2023 letter to the FDA's Deputy Commissioner for Foods:

> The study begs the question as to how [the manufacturer] knew to specifically test for liver function and whether there were prior indications or concerns about the potential for tara [flour] to cause liver injury. It also raises questions as to why [the distributor] proceeded with the import and distribution of tara flour, especially given the absence of GRAS status for tara flour, the restricted scope of [the distributor's] study, and the paucity of other studies at the time.[47]

The FDA investigated the outbreak, but could not prove that tara flour was the cause; however, it spurred the FDA to conduct its own assessment of the evidence, and eventually the FDA officially revoked tara flour's GRAS status based on absence of data to support its safe use in food.[48] This action occurred in 2024, two years after the outbreak, despite the fact that the outbreak injured more than 400 people, in some cases resulting in organ damage.[49]

The FDA has acknowledged the need for better oversight of additives and GRAS substances pre- and post-market in statements[50] and in its 2026 proposed rule.[51] Congress has also considered action to address the GRAS loophole.[52] While Congress has the clear power to amend the FAA to change its food additives and GRAS definitions and procedures more holistically, as this report argues, the FDA also has authority to revise its GRAS regulations and implement mandatory premarket procedures for GRAS substances.

This report addresses the FDA's statutory authority to revise its existing GRAS regulations and enact a new rule requiring premarket notification and review procedures for GRAS substances. This authority will be broadly referred to throughout this report as the authority to establish "premarket procedures." First, this report will demonstrate that the text and legislative history show Congressional intent that the GRAS definition be a narrow exception to the clear default that substances added to food must go through premarket review. Second, it will discuss why current administrative law jurisprudence under *Loper Bright Enterprises* would not bar the FDA from requiring premarket GRAS procedures. Third, it will discuss the broader purpose of the FDCA and how courts have historically interpreted this purpose and addressed the scope of the FDA's authority over food safety. Fourth, it will show that the FDA has a duty to ensure unapproved additives are not used in food and undisputed authority to determine that a substance or a particular use of a substance is not GRAS and is thus an unapproved food additive. That authority, coupled with the FDA's rulemaking power, gives it authority to implement premarket GRAS requirements. Finally, this report will outline what the FDA has the authority to require in terms of premarket procedures in GRAS rulemaking.

Legal Authorities and Discussion

A. The Language and Legislative History of the FAA Weigh in Favor of GRAS Premarket Procedures and Clear FDA Oversight

As discussed in this section, the FAA establishes a broad default rule subjecting all substances added to food to premarket safety review, carves out a narrowly drawn exemption for GRAS substances, and leaves the procedural implementation of that exemption up to the FDA. The legislative history confirms that Congress enacted the FAA to prevent unreviewed substances from entering the food supply without oversight.[53] The FAA also provides the statutory foundation for the FDA's authority to oversee the safety of GRAS substances and to implement premarket procedures governing their use.

The text and structure of the FAA, along with its legislative history, provide strong evidence that Congress intended that new substances being added to the food supply go through premarket review. The FAA was enacted to more clearly define and regulate food additives. The amendment added the term "food additive" to the FDCA and defined it broadly as "any substance the intended use of which results or may result . . . in its becoming a component or otherwise affecting the characteristics of any food."[54] This definition establishes a default rule that any substance added to food is a food additive and is presumptively unsafe without FDA approval. The statute then carves out a narrow exemption to this definition for substances "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . (or experience based on common use in food) to be safe under the conditions of its intended use."[55] These elements are codified at 21 U.S.C. §321(s). The language of the FAA describes two ways for a substance to be GRAS: either by means of scientific procedures or, in the case of substances in use prior to the passage of the FAA, by means of experience based on common use in food.[56] A substance that fails to meet these conditions should fall back within the default category of "food additive" and be presumed unsafe, absent successful completion of the statutorily-mandated additive review process and FDA-prescribed conditions of safe use.[57] The FDA is under no obligation to consider any substance GRAS until a general recognition of safety has been shown to the FDA.

The legislative history of the FAA provides insight into Congressional intent. There are two primary takeaways about the GRAS definition and purpose that emerge from reviewing this history. First, Congress enacted the FAA to ensure that harmful substances were not used in food for extended periods of time before the FDA could prove their harm and remove them. Second, Congress intended premarket additive review for new substances used in food to be the default, with GRAS serving as a narrow exception, rather than an alternative regulatory pathway.

As numerous statements in the legislative record show, members of Congress were concerned that harmful substances were being in food for years before the FDA knew about their harm. Representative Delaney, Chairman of the House Select Committee to Investigate the Use of Chemicals in Food and Cosmetics, explained on the House floor that the legislation was enacted to respond to the rapid pace of food technology development in the 1950s, which demanded better safeguards to protect public health: "[t]he safeguarding of the health of the American public should ever be uppermost in our minds. In these fast moving times, food technology changes almost from day to day and it is difficult to keep up with developments."[58] Representative McDonough noted, "I favor this legislation as one means of protecting the public because I think that many of these chemicals are very dangerous in many instances and may be harmful to the health of many people throughout the Nation. These additives should be pretested before they are used."[59]

The Senate Report submitted by the Committee on Labor and Public Welfare—the Committee to which the bill was referred—was also direct about the specific harms Congress sought to prevent by enacting the legislation:

> [E]xisting law permits any processor who chooses to pay no heed either to the public's health or to his continuance in one particular line of business to unfairly compete with responsible processors, to defy the Food and Drug Administration and to endanger the health of millions by using an untested additive for as long a time as it may take for the Government to suspect the deleteriousness of his additives, schedule research into its properties and effects, and, finally—perhaps years later—to begin the years-long experiments needed to prove the particular additive safe or unsafe.[60]

Senator Hill similarly worried that a chemical "may be added to foodstuffs and used for a considerable period of time before anyone begins to suspect that it may be having ill effects" and that by the time suspicion arose, still more time would pass before the FDA could schedule an investigation.[61] The record also shows that Congress intended the FAA to protect against "any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability."[62]

The GRAS exemption was not conceived as an alternative pathway for novel substances to enter the food supply, but as a practical carve-out for ingredients with a well-established history of safe use or common scientific agreement of their safety, subject to FDA oversight and evaluation. A letter from the Department of Health, Education, and Welfare (precursor to the Department of Health and Human Services) submitted during a 1958 House floor debate on the FAA clarified its understanding of what would be covered by the definition:

> Another provision of [the bill] . . . is the one that would exempt from the definition of food additive substances used in food prior to January 1, 1958, that have been adequately shown through experience based on common use in food to be safe under the conditions of intended

> use. Our Department believes that it is not necessary to good public health protection to have chronic toxicity studies conducted of common food chemicals, such as salt, sugar, vinegar, baking soda, and a great many other materials that have been in common use for a long time. As a matter of fact, these substances have been established as suitable food ingredients through feeding to generations of human beings. . . .
>
> But this is not a grandfather clause either. If later developments show that a substance previously considered safe because of common use in food were [] subject to question and not generally recognized as safe, then the substance would become subject to the definition of a food additive and would have to be cleared under the procedures of the proposed law.[63]

FDA Commissioner Larrick submitted a partial list to Congress of what the FDA would consider "GRAS," including items such as butter, coffee, gelatin, lemon juice, mustard, paprika, salt, vinegar, and wine.[64] Likewise the Congressional record gives as examples common ingredients like "sugar, salt, butter, lard, [and] pepper,"[65] because they are known to be "suitable food ingredients through feeding to generations of human beings."[66]

In contrast with GRAS based on common use, the legislative history describing GRAS based on scientific procedures is comparatively sparse.[67] However, given Congress's concern about new ingredients and the plain language of this section instituting a more rigorous review for all additives going forward, it is reasonable to presume that Congress viewed it as being at least as protective as GRAS based on common use, if not even more stringent, requiring a level of expert consensus and public data equivalent to or better than historical certainty.

Indeed, the FDA's GRAS regulations in place today and since the 1970's have stated its view that GRAS using scientific procedures be more rigorous than GRAS based on prior use. FDA's GRAS regulations explain that "an ingredient not in common use in food prior to January 1, 1958 may achieve general recognition of safety *only* through scientific procedures."[68] As to the scientific procedures required, the FDA regulations have stated since that time that:

> General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General 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, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.[69]

In all of this history, there is no indication that Congress intended to provide the food industry a "loophole" to add ingredients into the food supply without FDA oversight or knowledge. In fact, the legislative history points to the exact opposite purpose in passing the FAA. The Senate Report by the Committee on Labor and Public Welfare states that:

> This huge loophole [in which a processor may use an untested additive for as long as time as it may take for the Government to suspect the deleteriousness of the additives and subsequently review and research its effects] is 1 of 2 flaws in existing law which, through this measure, we are attempting to fill.[70]

A regime that permits manufacturers to self-determine that novel substances are GRAS without any premarket notification to FDA recreates the precise harm Congress sought to prevent: the public unknowingly consuming unreviewed and unsafe substances for years before suspicion of harm arises. This is at odds with Congress's key concerns and goals in enacting the FAA: to ensure that substances would be reviewed for safety before being added to the food supply.

B. Applying Current Administrative Law Jurisprudence, a Court Should Uphold an FDA Rule Requiring Premarket GRAS Notifications

The legislative history of the FAA demonstrates the narrow scope that was intended for the GRAS exemption, however, any action taken by the FDA must be evaluated in light of how a court would interpret it using current administrative law jurisprudence. As explained in this section, a court reviewing FDA action using that jurisprudence should uphold an FDA rule establishing mandatory premarket procedures for GRAS substances. The Supreme Court recently announced a change in how courts should review an agency action. Previous jurisprudence on agency rulemaking applied the doctrine in C*hevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, requiring that courts defer to an agency's permissible interpretation of an ambiguous statute.[71] *Chevron* set up a two-step process, whereby courts would first identify whether Congress had directly spoken to the issue, and if not—if the court determined the statute to be ambiguous on the specific issue—the court would move to the second step and would defer to a reasonable agency interpretation of the statute.[72] The FDA's existing GRAS voluntary notification rule has been upheld by a court applying *Chevron* deference.[73] However, the U.S. Supreme Court's ruling in *Loper Bright Enterprises v. Raimondo* abandoned *Chevron* deference and held that the power to interpret statutes is squarely in the domain of the judiciary.[74] Thus, any analysis of a future GRAS rule's success must apply the court's reasoning under *Loper.*[75]

Loper holds that every statute has a "single, best meaning" that "is fixed at the time of [its] enactment."[76] To find this meaning, courts are directed to use every tool at their disposal to resolve any ambiguity.[77] While courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority,[78] agency interpretations can still be given weight or respect depending on certain factors described in the 1944 case *Skidmore v. Swift & Co*.[79] Alternatively, a court may determine that a "statute's meaning may well be that the agency is authorized to exercise a degree of discretion,"[80] and when the "statute delegates authority to an agency . . . courts must respect the delegation, while ensuring that the agency acts within it."[81]

In reviewing an FDA rule requiring premarket GRAS procedures under *Loper,* a court would therefore determine whether: (1) FDA's required premarket procedures for GRAS substances is the best meaning of the statute at the time of its enactment; (2) an FDA rule requiring premarket GRAS procedures should be entitled to respect under *Skidmore*; or (3) the FDCA delegated discretionary authority over GRAS substances to the FDA, which should be respected by courts under *Loper* by upholding an FDA rule requiring premarket procedures. Under any of these interpretive methods, a court should uphold an FDA rule requiring premarket procedures for GRAS substances. Each of these arguments will be addressed below in turn.

i. The best meaning of the FAA is that it requires a premarket notification requirement for GRAS substances.

Loper first tells reviewing courts to take steps to determine the "best reading" of a statute, or to determine

whether Congress clearly delegated discretion over the provision at issue to the agency. *Loper* holds that statutes:

> no matter how impenetrable, do—in fact, must—have a single, best meaning. That is the whole point of having written statutes: "every statute's meaning is fixed at the time of enactment." So instead of declaring a particular party's reading 'permissible' in such a case, courts use every tool at their disposal to determine the best reading of the statute and resolve the ambiguity.[82]

The GRAS clause of the FAA covers substances "generally recognized, among experts . . . to be safe under the conditions of [their] intended use[.]"[83] However, the clause is silent on the specifics of how to determine whether something is GRAS. For example, it does not describe how the general recognition of safety among experts needed to establish GRAS status is created, established, or verified. It also does not specify how many experts and which experts (e.g., industry, government, consumer, academic experts) are needed to establish general recognition among experts.

An interpretation that premarket procedures are required for GRAS substances aligns with the purpose of the FAA and the GRAS exemption, as detailed in the FAA's legislative history above, in Section IV.A. *Loper* holds that a statute's meaning is fixed at the time of its enactment.[84] At the time of enactment of the FAA, Congress and the FDA both agreed that premarket review should be the norm for any additives entering the food supply,[85] and that the less rigorous GRAS pathway was intended only for substances already in the food supply before January 1, 1958, such as sugar, salt, butter, lard, and pepper, that "have been established as suitable food ingredients through feeding to generations of human beings,"[86] or for which there is clear expert consensus and public data on their safety.

By contrast, the existing FDA rule reproduces the very deficiencies in the law which the FAA sought to remedy with required premarket review of additives. Contrary to Congressional intent, virtually all new substances now enter the market through the GRAS exception rather than the Congressionally-specified additive process.[87] This turns the GRAS exception into the default, allowing new, untested chemicals to enter the food supply with little or no FDA oversight, and thus to bypass Congress's intended scrutiny.

Increasing scientific evidence that suggests that many GRAS substances may pose substantial health risks only further emphasizes this reading as the "best meaning" of the statute.[88] While some substances cause acute effects within hours or days,[89] others are associated with chronic risks that may take years to develop (e.g., cardiovascular diseases, reproductive harms, harms to the microbiome), with early changes remaining unnoticed for many years.[90] Reviewing GRAS substances only postmarket, after their introduction into the food supply, does not achieve the purposes of the FAA, which is to keep unapproved additives out of the food supply. Additionally, without any premarket procedures, the FDA's uncontroverted postmarket review authority[91] is severely hampered, as the FDA cannot know that a new substance is in use—and thus should be examined for any potential negative health effects—until it is already marketed, sold, and consumed. These factors weigh in favor of a "best meaning" that would require premarket notification to the FDA of a GRAS determination.

In reviewing the existing GRAS rule, even while upholding the FDA's voluntary notification regime, the district court judge in the 2021 case *Center for Food Safety v. Becerra* acknowledged that a rule requiring premarket notification may actually represent the best reading of the statute.[92] However, *Center for Food Safety* was decided when *Chevron* was still the applicable framework; thus, the court was constrained by *Chevron* to defer to the FDA's policy choice, rather than independently selecting the best statutory

interpretation.[93] If *Center for Food Safety* had been decided under *Loper*, the same court would likely have held that mandatory GRAS notifications were required by statute.

In *Center for Food Safety*, the issue was whether the FDA's chosen approach to administering the GRAS exemption was within its statutory authority.[94] Plaintiffs challenged the FDA's 2016 GRAS rule on grounds that the rule violated the express language of the FAA and also exceeded the FDA's statutory authority under the FDCA.[95] The court rejected both arguments and upheld the rule as a lawful exercise of the FDA's discretion.[96] Applying the C*hevron* doctrine, the court found that the FDCA "is silent or ambiguous" on whether GRAS notifications must be mandatory and accordingly deferred to the FDA's choice of the voluntary notification regime as, according to the FDA, the "best use of its resources to effectuate Congressional intent and the core statutory purpose."[97]

This holding carries two important implications in the argument for the FDA's premarket GRAS authority. First, by reaching step two of the *Chevron* analysis, the court found the statute ambiguous, which also means that it found that nothing in the statute prohibits mandatory premarket GRAS procedures. The court did not say that a premarket notification requirement would be impermissible—such a finding would mean the statute was unambiguous and the court would stop at the first step of the *Chevron* analysis.[98] In addition, the FDA's acknowledgment during rulemaking that "even without express authorization from the FDCA, it could potentially make GRAS notifications mandatory" was noted approvingly by the court.[91]

Second, the court explicitly acknowledged that the FDCA's broad food safety mandate—to "protect the public health" by ensuring "foods are safe, wholesome, sanitary, and properly labeled" actually "cuts in favor of Plaintiffs' argument, as the FDA may be hindered in carrying out this objective if it does not have access to all GRAS determinations."[99] The court thus acknowledged that mandatory premarket notification may represent the best reading of the statute, but was constrained by *Chevron* to defer to the FDA's contrary policy choice rather than independently selecting the best interpretation.

Finally, the legislative history of the FAA forecloses a construction of the statute that would bar the FDA from requiring premarket procedures as a condition of invoking the GRAS exemption, further contributing to the notion of the "best reading" of the statute being one requiring premarket GRAS procedures. As mentioned, a regime that permits manufacturers to self-determine novel substances as GRAS risks recreating the precise harm Congress sought to prevent: the public unknowingly consuming unreviewed and unsafe substances for years before suspicion of harm arises.[100] The FAA was enacted to close that gap. The text of the FAA plus the legislative history strongly supports an FDA rule requiring premarket GRAS procedures as the best reading of the FAA.

ii. Post-Loper, an FDA rule requiring premarket GRAS notifications would still be entitled to respect under Skidmore.

As discussed in the previous subsection, courts can apply *Loper* to conduct a *de novo* review to determine a single "best reading" of a statute. If a court conducts a strictly textual analysis of the FAA, the best reading would be one that requires premarket GRAS procedures. However, in determining the best reading, *Loper* also exhorts courts to consider whether the agency's interpretation is entitled to respect from the court.

As noted above, *Loper* holds that "[c]ourts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority."[101] Courts may no longer defer to an agency's interpretation

of a statute simply because it is ambiguous, as they did under *Chevron*.[102] While agency interpretations of ambiguous text are no longer entitled to the deference they received under *Chevron*, they can still be persuasive, according to *Loper*.[103] In overturning *Chevron*, *Loper* resurrected the doctrine in *Skidmore v. Swift & Co.*, where the Court explained that the "interpretations and opinions" of the relevant agency, "made in pursuance of official duty" and "based upon . . . specialized experience," "constitute[d] a body of experience and informed judgment to which courts and litigants [could] properly resort for guidance," even on legal questions.[104] The revival of *Skidmore* means that pre-*Chevron* case law, in which courts were largely inclined to defer to the FDA's judgment in order to effectuate the FDCA's purpose to protect public health, is now particularly relevant and supports respecting the FDA's authority should it decide to implement mandatory premarket procedures for GRAS substances.[105]

A court applying the *Skidmore* analysis to an FDA rule requiring premarket GRAS procedures would likely conclude that respect is warranted. The following *Skidmore* factors are used to determine whether an agency's interpretations are entitled to respect or weight: (1) the thoroughness of the agency's interpretation; (2) the validity of the interpretation's reasoning; (3) the interpretation's consistency with earlier and later pronouncements; and (4) other factors that give the interpretation the power to persuade.[106] Here, the four factors would, on the whole, likely weigh in favor of *Skidmore* respect, especially if the FDA could show how it believes the new rule would increase public health and safety.

The first *Skidmore* factor, thoroughness, depends on whether the agency's interpretation underwent rigorous consideration and public scrutiny.[107] Therefore, the evaluation of this factor will depend on how scrupulously the FDA discusses its considerations and analysis of the statutory text of the FDCA and FAA, as well as how such a rule would support public health and safety, in any GRAS rule revision. All of FDA's proposed and final rules on GRAS substances have been lengthy, thorough, and subject to rigorous public input, including its 2016 final rule and its 2026 proposed rule.[108] Based on these proposed and final rules, thoroughness should not pose an obstacle to *Skidmore* respect.

As to the second factor, validity, courts have required that an agency pronouncement be "well-reasoned, substantiated, and logical."[109] Courts have said that this validity inquiry focuses on "whether the agency has consulted appropriate sources, employed sensible heuristic tools, and adequately substantiated its ultimate conclusion."[110] Here, premarket requirements for GRAS will likely satisfy the validity factor. There are many reasons, explored above, that support an FDA decision to impose more stringent requirements for GRAS than it currently does. The legislative history of the GRAS exemption also confirms that Congress understood it to be narrow in scope and intended the FDA to have an active enforcement role.[111] Consequently, the second *Skidmore* factor also weighs in favor of respect.

The third *Skidmore* factor refers to whether the agency's interpretation is consistent with its earlier and later pronouncements.[112] Here, a proposed GRAS rule to require premarket procedures would be a departure from the GRAS rules allowing voluntary premarket notification that have governed since the 1970s. However, changes in FDA GRAS procedures over time should not diminish from *Skidmore* respect. FDA initially exercised greater oversight by creating "the GRAS list," to confirm the GRAS status of food substances used in food prior to 1958.[113] It was not until it met resource constraints that the FDA abandoned this practice to issue informal "opinion letters" to confirm a substance's status as GRAS, and eventually moved to voluntary notification.[114]

Moreover, while the FDA has changed the specifics of GRAS procedures over time, it has been consistent in asserting its authority to oversee and promulgate regulations for GRAS substances—via the GRAS list, the GRAS voluntary affirmation process, and the current voluntary notification framework.[115] First, in its *Center for Food Safety* reply brief, the FDA itself acknowledged the breadth of its authority.[116] The FDA has therefore been consistent in its assertion that it has general, broad regulatory authority over GRAS and can change the regulatory process for GRAS as needed. Second, while the FDA also has not previously required mandatory GRAS notices, it has never taken the position that it lacks authority to do so. At most, the FDA has taken the position that Congress does not require "premarket engagement" in any form for GRAS substances, but it has not argued that Congress *prohibited* it from imposing premarket requirements.[117] To the contrary, the FDA implied that it could have such authority in the 2016 Final GRAS Rule, where it stated that "mandating submission of GRAS notices would need to be done in a separate rulemaking to ensure adequate notice and comment."[118] Third, courts have held that "confronting a new problem is not the same thing as acting inconsistently."[119] While the FDA may have perceived voluntary notification to be sufficient in the past,[120] the FDA is now arguably confronting a problem that has only recently been identified: as the court acknowledged in *Center for Food Safety*, the number of additives has been increasing rapidly, and nearly all new substances now enter the market through GRAS rather than the additive petition process.[121] Finally, consistency has been deemed less dispositive than other *Skidmore* factors.[122] Also, diet-related diseases of various sorts have continued to rise in prevalence nationally.[123] FDA must confront this growing challenge with a revised rule. Because the other *Skidmore* factors weigh heavily in favor of respect, any finding of inconsistency should not bar respect here.

The final *Skidmore* factor is a catch-all for other elements that enhance the persuasiveness of the agency's interpretation, such as the agency's expertise in a regulated area, or lack thereof, which may do the opposite.[124] In the area of food safety and public health, courts have consistently recognized the FDA's expertise and authority, as described below in Section IV.C., and should therefore give respect to its interpretations of FDCA provisions like the FAA.[125]

In summary, the *Skidmore* factors weigh in favor of respect for FDA's interpretation of its authority. Thus, a court that decides to apply *Skidmore* respect to an FDA rule requiring GRAS premarket procedures should uphold such a rule.

iii. In the alternative, courts could use Loper to find that Congress delegated broad rulemaking authority to the FDA, including the authority to require premarket GRAS notifications, and thus the best reading of the statute is that the court should defer to the FDA.

As discussed above, a court could apply *Loper* to find that the "best reading" of the FAA is one that requires premarket GRAS notification or could uphold such a rule by using *Skidmore* respect for FDA's interpretation of its authority. A court could separately uphold a rule by finding that Congress clearly delegated discretion over GRAS substances to the FDA. *Loper* specifies that:

> "[w]hen the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court [is] to independently interpret the statute and effectuate the will of Congress subject to constitutional limits. The court fulfills that role by recognizing constitutional delegations, fixing the boundaries of the delegated authority . . . and ensuring the agency has engaged in 'reasoned decisionmaking' within those boundaries."[126]

The *Loper* court explained that statutes may delegate discretionary authority by empowering an agency to prescribe rules to "fill up the details" of a statutory scheme, or to regulate subject to the limits imposed by a term or phrase that "leaves agencies with flexibility," such as "appropriate" or "reasonable."[127]

While the best reading of the FAA would be one that requires premarket GRAS notification, a court could alternatively uphold a premarket GRAS requirement rule based on a finding that the best reading of the statute is that Congress clearly delegated discretion to the FDA. Under 21 U.S.C. § 371(a), Congress granted the FDA "authority to promulgate regulations for the efficient enforcement" of the FDCA.[128] Courts have acknowledged this authority means the FDA can enact a broad array of regulations, both substantive and procedural to fulfill the public health and food safety purpose of the FDCA.[129] In enacting the FAA, as discussed above, Congress's desired result was to protect the public health by requiring new, untested substances to be evaluated for safety before entering the food supply.[130] While the FDA may have previously concluded that mandatory GRAS submissions would be too resource-intensive and a voluntary system was preferable, the FDA has now acknowledged the negative public health impacts of a voluntary GRAS system, and has the authority to regulate in order to better support public health and safety.

Post-*Loper*, courts have interpreted statutory language analogous to the FAA in a way that similarly finds Congress delegated the agency discretion. The most pertinent example is the Federal Circuit's decision in *Lesko v. United States*.[131] There, the overtime statute obligated the Office of Personnel Management (OPM) to pay for overtime "officially ordered or approved," but did not specify what this phrase means or expressly delegate to the agency the authority to define this phrase.[132] The Federal Circuit held that the plain language of the phrase presupposes a process for authorizing overtime but provides no guidance as to the mechanics.[133] Because OPM was granted the authority to "prescribe regulations . . . necessary for the administration [of the overtime statute]," the Federal Circuit concluded that Congress expressly delegated regulatory discretion to the OPM to define the phrase, so long as it is necessary for administration.[134]

Like the overtime statute in *Lesko*, the FAA exempts substances "generally recognized" as safe from the additive process but does not specify what the phrase means or expressly delegate authority to define it to the FDA within the FAA. The GRAS provision presupposes a procedure for determining whether there has been general recognition and thus an exemption from the statutorily-mandated additive procedures, but does not provide guidance as to the mechanics. Because the FDA was granted the "authority to promulgate regulations for the efficient enforcement" of the FDCA,[135] including the GRAS provision, it is expressly delegated regulatory discretion to define GRAS procedures, so long as they efficiently enforce the FDCA.

Under *Loper,* a court must exercise its independent judgment to determine the single best meaning of a statute. Agencies no longer receive automatic deference for their definition of ambiguous terms, as they did under *Chevron*. A court may uphold a rule based on the fact that the court believes it matches the "best reading" of the statute. Or, a court may extend *Skidmore* respect based on the agency's specialized knowledge, thoroughness, validity of their reasoning, and consistency of their interpretation. Alternatively, a court may uphold an agency action by determining the statute clearly delegated discretionary authority to the agency. Ultimately, a court using any of these interpretative methods should uphold an FDA rule requiring premarket procedures for GRAS substances.

C. Courts Have Consistently Construed the FDCA Broadly to Support FDA's Food Safety Mandate, Which Supports FDA Efforts to Improve GRAS Oversight

Courts have consistently interpreted the FDCA expansively, recognizing that it confers a broad public-health mandate on the FDA. A broader statutory analysis of the FDCA and the FDA's authority under it supports the argument that the FDA has the authority to change the requirements for GRAS substances to mandate premarket procedures for GRAS substances if it believes they are required to fulfill its food safety mandate. The FDCA establishes the FDA as the primary federal agency responsible for ensuring the safety of the nation's food supply by ensuring that "foods are safe, wholesome, sanitary, and properly labeled."[136] The Act specifies that the term "safe" as used in the food additive definition, "has reference to the health of man or animal."[137] Notably, this broad definition is not limited by any cost-benefit analysis or other constraints.

It would certainly frustrate the FDA's purpose if it were prevented from having a reliable means of knowing what substances are entering the food supply. A reading of the FAA that forecloses FDA action to close this gap is inconsistent with Congress's clearly-articulated purpose of the FDCA and, as the cases below demonstrate, with the interpretive principle applied by the Supreme Court and circuit courts that show the FDCA should be construed broadly to give effect to its protective purpose. The Supreme Court established that interpretive principle soon after the FDCA's enactment, in *U.S. v. Dotterweich*.[138]

In *Dotterweich*, the Supreme Court, in interpreting whether the FDCA's criminal penalties provisions could reach a corporate officer involved in the interstate shipment of misbranded and adulterated drugs, grounded its construction of the FDCA in the social realities the legislation was designed to address.[139] The Court noted that in the circumstances of modern industrialism, consumers are "largely beyond self-protection" with respect to the safety of what they eat and consume.[140] From that premise, the Court drew an important conclusion that has defined FDCA jurisprudence since. According to the *Dotterweich* court, "[r]egard for [keeping impure and adulterated food and drugs out of commerce] should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."[141] This is a directive that, where two readings of the FDCA are available, courts should choose the one that makes the statute function so that the FDA can do what Congress created it to do: protect the public health through ensuring food safety.

The Court reaffirmed this approach in *United States v. Sullivan*.[142] In *Sullivan*, the Court rejected the argument that Congress could not have intended the FDCA's labeling requirements and penalties to reach downstream retail drug transactions.[143] The Court held that no argument of textual inconvenience or practical burden "justifies a distortion of the congressional purpose," which the Court notes is to "protect consumers from dangerous products."[144] The Court also recognized that the FDCA confers on the FDA "rather broad discretion—broad enough undoubtedly to enable [the FDA Administrator] to perform his duties fairly."[145] The Court reaffirmed this interpretation twenty years later, after the passage of the FAA, in *United States v. Bacto-Unidisk*.[146] The Court rejected the defendant's narrow reading of the FDCA, articulating the governing principle for the FDCA as a whole: "remedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."[147]

Although *Dotterweich*, *Sullivan*, and *Bacto-Unidisk* each arose in the drug context, the interpretive principle they establish is not drug-specific—it is a rule of construction for the FDCA, rooted in the statute's overriding purpose and applied uniformly across its provisions. This rule of construction has been applied in the

food context.[148] For example, the Second Circuit applied this principle in *United States v. Nova Scotia Food Products Corp.*, which sustained the FDA's time-temperature-salinity regulations for smoked fish processing against a challenge that the agency had exceeded its authority.[149] The court held that the FDA's regulations will be sustained so long as they are "reasonably related to the purposes of the enabling legislation" and that courts are generally unwilling to prohibit administrative action necessary to achieve the agency's statutory objectives absent compelling evidence of contrary congressional intent.[150] Drawing on *Dotterweich* and *Bacto-Unidisk*, the court confirmed that "when we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively."[151] The court rejected a challenge to the FDA's action premised on the absence of express statutory authorization, noting "[t]he public interest will not permit invalidation simply on the basis of a lack of delegated statutory authority in this case. A gap in public health protection should not be created in the absence of a compelling reading based upon the utter absence of any statutory authority[.]"[152] This principle supports the proposition that the absence of express authorization is not a sufficient basis to invalidate FDA action to ensure public health.

Taken together, these cases establish a consistent interpretive principle that where two readings of the FDCA are available, courts choose the one that upholds FDA's efforts to make the statute function broadly as an effective instrument of public health protection. As mentioned, Congress granted the FDA broad authority to promulgate rules needed to enforce the FDCA.[153] In the context of the FAA, proper administration of food additive and GRAS oversight is directly related to the FDCA's core food safety purpose. Mandatory premarket GRAS procedures would not expand or alter the statutory criteria for GRAS, it would merely require submission of the scientific evidence required for a GRAS determination to the FDA before the substance is used in food. The lack of premarket notification has frustrated the FDA's ability to ensure food safety, as it has no reliable means of knowing what substances are entering the food supply. The FDA must have the procedural tools to enforce the substantive standards the statute sets, and to meet its statutory mandate to ensure food safety and public health.

D. The FDA's Duty to Keep Unapproved Additives Out of Food, Coupled with its Power to Promote "Efficient Enforcement" of the FDCA, Confirm Its Authority to Require Premarket Procedures for GRAS Substances

Section 701(a) of the FDCA, codified at 21 U.S.C. § 371(a), vests the Secretary of HHS and by delegation, the FDA, with "[t]he authority to promulgate regulations for the efficient enforcement of this chapter."[154] This provision empowers the FDA to issue substantive rules so long as they are "reasonably related to the purposes of the enabling legislation."[155] Requiring anyone who invokes the GRAS exception to notify the FDA of that GRAS determination and its basis before the substance is used in food is a reasonable exercise of that power. It enables the FDA to fulfill its duty to keep unapproved food additives off the market,[156] rather than rely predominantly on postmarket enforcement after consumers have already been exposed to the unapproved additives.[157] It also reduces the costly burdens of identifying substances postmarket and the uncertainty of postmarket enforcement for the FDA and food manufacturers.

A substance whose intended use is not GRAS is a food additive. Under the FAA, a food additive used without FDA approval, or in a manner the FDA has not approved, is deemed "unsafe" and renders any food that contains it adulterated.[158] In *Southeastern Minerals, Inc. v. Harris,* the Fifth Circuit recognized FDA's undisputed authority to determine that a product requires a food additive regulation, explaining that "[t]he FDA . . . cannot intelligently and rationally perform its regulatory duties unless it determines what products are 'food additives' under 21 U.S.C. § 321(s) and what products, because of their GRAS status, are

exempt from regulation."[159] But the FDA cannot make that determination for substances it does not know are in use. Because the 2016 GRAS rule made notification voluntary, countless substances are now in the food supply without the FDA's knowledge.[160] Lack of knowledge of these substances impedes the FDA from implementing its statutory mandate to ensure that these substances and their uses are GRAS and are not unapproved food additives.

Since the FAA's enactment in 1958, the FDA has exercised its authority to declare that substances or their uses are not GRAS and are therefore unapproved food additives.[161] Courts have consistently upheld FDA's authority to determine that the use of a substance was not GRAS and therefore was an unapproved food additive. In *United States v. An Article of Food (FoodScience Laboratories)*, the Seventh Circuit noted that "a food additive is presumed to be unsafe unless the Secretary of Health and Human Services has promulgated a regulation 'prescribing the conditions under which such additive may be safely used,'"[162] and agreed with the FDA that the substance at issue was not GRAS but was an unapproved food additive.[163] In *United States v. Articles of Food & Drug, Coli-Trol 80*, the Fifth Circuit supported FDA's finding that a substance was not GRAS and was thus an unapproved food additive, as there were "no . . adequate studies of any kind" related to the substance's safety, and thus no recognition of safety.[164] In *United States v. An Article of Food (Coco Rico)*, the First Circuit agreed with FDA that a particular use of a substance was not GRAS—and was therefore an unsafe food additive—even if other uses of that substances were GRAS.[165] Taken together, these cases establish three principles. First, GRAS status requires expert consensus grounded in adequate scientific evidence, and GRAS status for one use does not automatically extend to another. Second, the proponent of a substance's GRAS status must possess, and be able to produce, evidence of general recognition of safety. Lastly, the FDA can determine that a substance, or a particular use of it, is not GRAS—and is therefore an unapproved food additive—when that evidence is lacking.

Requiring premarket procedures for GRAS substances would allow the FDA to ensure that the GRAS exception is correctly used at the very moment the statute already demands compliance. A substance that is not "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . (or experience based on common use in food) to be safe under the conditions of its intended use" is a food additive, requiring FDA premarket approval,[166] and these conditions must be satisfied when a substance enters the U.S. food supply.[167] Premarket procedures would thus let the FDA fulfill its statutory mandate to ensure that foods "are safe, wholesome, sanitary, and properly labeled"[168] before they reach consumers. Because a manufacturer that lawfully invokes the GRAS exception must already possess the data supporting its GRAS determination before using the substance in food, the only added cost of premarket notification is that of submitting that evidence to the FDA.

A GRAS regime under which the FDA learns of a substance or its use only after consumers fall ill recreates the pre-1958 evil Congress sought to cure in enacting the FAA. The Delaney Committee, whose recommendations led to enactment of the FAA, identified precisely this problem: that the government could "take no action until after the food has been placed upon the market and injury may have occurred."[169] As the Committee concluded, "the public is entitled to greater protection with respect to the foods it must necessarily consume."[170] Congress charged the FDA with ensuring that no unapproved additives enter the food supply. That duty, coupled with its authority to promulgate regulations that ensure "efficient enforcement," gives the FDA ample power to require premarket procedures for GRAS substances prospectively, rather than merely policing unapproved food additives after the fact.[171]

Regulatory Options Available to the FDA

As described throughout this report, there is strong legal justification for the FDA's authority to issue a new rule requiring premarket procedures for GRAS substances, based on the text, structure, and legislative history of the FAA, current administrative law jurisprudence, and prior case law regarding the FDCA and FAA. This section will address what such premarket GRAS procedures can entail.

While FDA can require premarket notification and other procedures for GRAS substances, there is a limiting principle on FDA's authority inferred from the wording of the FAA. Because the GRAS category operates to exempt substances from the definition of additive, and thus from the food additive approval process, the FDA may not impose premarket review requirements on GRAS substances that are identical to those prescribed by Congress for food additives. Requiring premarket notification or other premarket procedures for GRAS substances, however, is not the same as requiring affirmative approval under the prescribed food additive petition process. Premarket notification procedures merely allow the FDA to track what substances are entering the food supply and verify that the statutory criteria for the GRAS exemption are satisfied. These procedures would also enable better postmarket enforcement by equipping the FDA with a list of substances that have entered the food supply. The procedures would also allow the FDA to identify substances that, rather than being eligible for the GRAS exemption, are more accurately identified as additives that should thereby be subject to the additive review process.[172] FDA regulations can also define who constitutes an expert, minimum qualifications for such experts, and what representative group of experts are needed to establish a general recognition of safety among "experts qualified by scientific training and experience."[173]

Because the FAA made an explicit distinction between GRAS substances and food additives, Congress legislated a distinction between the process for establishing GRAS and the food additive premarket approval process. However, this does not mean that the FAA prohibits the FDA from requiring any premarket review of GRAS substances. The statutory distinction merely requires that the GRAS review process and the food additive approval process be different. Additives have a detailed process prescribed in the FAA that includes a petition and rulemaking process with notice and comment, by contrast, required notification to and review by the FDA without those other rulemaking steps is sufficiently different. Implementing premarket notifications in this manner would not make GRAS determinations the same nor equally as onerous as the food additive petition process.

As a necessary corollary to its authority to require premarket GRAS notifications, the FDA also has the authority to "prescreen" a substance to determine the proper regulatory pathway for that substance (i.e., whether it should be subject to GRAS procedures or should instead utilize the food additive petition process). Given its expansive authority for determining GRAS status and protecting food safety, there is no reason the FDA cannot enforce mandatory prescreening.

While the FDA can implement a premarket notification requirement in various ways, the requirement should cover all substances used in food, meaning not only new substances that have not yet been marketed, but also substances that are already being used in food under preexisting GRAS determinations. The FDA may thus require manufacturers to submit a notification if they want to continue using a substance that was previously determined to be GRAS before the implementation of the new rule.

In addition to requiring premarket GRAS notifications or mandatory "prescreening," the FDA can continue to monitor compliance and safety postmarket and revoke a substance's GRAS status postmarket, even if the agency previously allowed the substance to be used in food. The FDA has exercised that authority to revoke GRAS status for at least twenty substances,[174] and courts have generally upheld the FDA's decisions in these instances.[175]

Conclusion

The FDA has ample authority to promulgate a rule requiring premarket notification and other premarket procedures for GRAS substances. The legislative history to the FAA confirms that Congress wanted the default rule to be premarket review of substances added to food, and that it understood the GRAS exemption to be narrow in scope. This would support a GRAS rule that requires premarket notification before market entry, along with clearer limits on what substances qualify as GRAS and what should instead be regulated as additives. Under a *Loper* analysis, a court likely would find the best reading of the statute is that the FAA allows and arguably even mandates the FDA to require premarket procedures for GRAS substances. More generally, the FDCA supports an expansive reading of the FDA's authority, as courts have consistently interpreted the FDCA (which includes the FAA) to further the FDA's mission to protect public health. The FDA also has a duty to ensure no unapproved additives enter the food supply, which includes the authority to require premarket GRAS procedures using its rulemaking authority to ensure those substances are indeed GRAS and not unapproved additives. Given all the foregoing, the FDA is well within its authority to promulgate a rule requiring mandatory premarket notification and related procedures for every GRAS substance, and the courts should uphold such a rule.



Endnotes

[1] *See generally* Substances Generally Recognized as Safe, 91 Fed. Reg. 51,834 (proposed Aug. 11, 2026).

[2] *See generally id.*

[3] *See Trust in Public Health Agencies Declines,* IPSOS (Oct. 16, 2025), https://www.ipsos.com/en-us/axios-ipsos-american-health-index [https://perma.cc/9UFF-9KAD] (stating 56% of Americans believe unsafe additives in food pose moderate to large risks to their health).

[4] Thomas G. Neltner et al., *Navigating the U.S. Food Additive Regulatory Program*, 10 Comprehensive Rev. Food Sci. & Food Safety 342, 355 (2011), https://doi.org/10.1111/j.1541-4337.2011.00166.x (noting that the overall number of additives, GRAS substances, and other substances added to food examined in their study totaled 10,787, with an estimated 9% self-determined GRAS but not reported to FDA and 25% determined GRAS by an industry panel).

[5] *See, e.g.*, Melanie Benesh, *Secret GRAS: How 100+ food chemicals bypassed government safety review*, Env't Working Grp. (Mar. 3, 2026), https://www.ewg.org/research/secret-gras-how-100-food-chemicals-bypassed-government-safety-review [https://perma.cc/B9UU-S3AH].

[6] *Id.*

[7] *See* Melanie Benesh and Bennet Rosenberg, *EWG analysis: Almost All New Food Chemicals Greenlighted by Industry, Not the FDA*, Env't Working Grp. (July 22, 2025), https://www.ewg.org/news-insights/news/2025/07/ewg-analysis-almost-all-new-food-chemicals-greenlighted-industry-not-fda [https://perma.cc/CLR6-KR2U] ("Since 2000, food and chemical companies have petitioned the FDA only 10 times to approve a new substance. By contrast, they have added 863 chemicals, through the "generally recognized as safe," or GRAS, loophole. That's 98.8% of new food chemicals. . . . Because submission of a GRAS notice is voluntary, this may be an undercount.")

[8] *See* Melanie Benesh, *supra* note 5.

[9] Numerous studies show that GRAS substances like nitrites, nitrates, soy lecithin, titanium dioxide, aspartame, and carrageenan are associated with health risks. *See, e.g.*, John O. Warner, *Artificial Food Additives: Hazardous to Long-Term Health?*, 109 Archives Disease Childhood 882 (2024), https://doi.org/10.1136/archdischild-2023-326565; Leonardo Trasande et al., *Food Additives and Child Health*, 142 Pediatrics (2018) https://doi.org/10.1542/peds.2018-1410 (discussing increased risk of harm to neurologic developmental processes from nitrites and nitrates); L. Kavitha & M. K. Sangeetha, *The Role of Food Additives in Reproductive Endocrine Disruption: a Revised Perspective*, 11 Current Pharmacology Reps. (2025), https://doi.org/10.1007/s40495-024-00389-5 (discussing potential fertility impairment of commonly used additives, including soy lecithin, titanium dioxide, and aspartame); Laury Sellem et al., *Food Additive Emulsifiers and Risk of Cardiovascular Disease in the Nutrinet-Santé Cohort: Prospective Cohort Study*, BMJ (Aug. 2023), https://doi.org/10.1136/bmj-2023-076058 (finding positive association between widely used food additive emulsifiers, including carrageenan and lecithins, and risk of cardiovascular disease); Barbara Borsani et al., *The Role of Carrageenan in Inflammatory Bowel Diseases and Allergic Reactions: Where Do We Stand?,* 13 Nutrients 3402 (2021), https://doi.org/10.3390/nu13103402; Paulina Komisarska et al., *Carrageenan as a Potential Factor of Inflammatory Bowel Diseases*, 16 Nutrients 1367 (2024), https://doi.org/10.3390/nu16091367; Dale Lee et al., *Children with Crohn's Disease Frequently Consume Select Food Additives,* 63 Digestive Diseases Scis. 2722 (2018), https://doi.org/10.1007/s10620-018-5145-x (noting that individuals with conditions like Crohn's disease and ulcerative colitis were found to have a higher exposure to food additives like carrageenan and soy lecithin).

[10] *See, e.g.*, Jennifer L. Pomeranz, Emily Broad Leib & Dariush Mozaffarian, *Regulation of Added Substances in the food Supply by the Food and Drug Administration Human Foods Program*, 114 Am. J. Pub. Health 1066 (2024), https://doi.org/10.2105/AJPH.2024.307755; Melanie Benesh and Bennet Rosenberg, *supra* note 7.

[11] *HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe*, U.S. Dep't of Health & Hum. Svcs. (March 10, 2025), https://www.hhs.gov/press-room/revising-gras-pathway.html [https://perma.cc/U3QT-2P62]; *see Foods Program Regulations Under Development,* U.S. Food & Drug Admin. (July 9, 2026), https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-regulations-under-development [https://perma.cc/A5FZ-X35Z].

[12] *See* Substances Generally Recognized as Safe, 91 Fed. Reg. 51,834, 51,835 (proposed Aug. 11, 2026) ("The proposed rule would require any person introducing a substance into interstate commerce under the GRAS provision of section 201(s) of the FD&C Act to notify FDA of the basis for their conclusion that the substance is GRAS under the conditions of its intended use unless an exception to the requirement to submit a GRAS notice applies.").

[13] Jennifer A. Staman, Cong. Rsch. Serv., R43609, Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues 7 (2018) ("Established under FD&C Act Section 1003, the U.S. Food and Drug Administration (FDA) is the primary agency that administers and enforces the Act.").

[14] *See generally* 21 U.S.C. § 331.

[15] *See, e.g.*, Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958); Drug Amendment of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (commonly referred to as the Kefauver-Harris Amendments); Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353. Note that meat, poultry, and certain egg products are regulated by the U.S. Department of Agriculture instead of the FDA and thus are subject to other federal statutes and USDA regulations. *See, e.g.*, Federal Meat Inspection Act, codified at 21 U.S.C. §§ 601–695; Poultry Products Inspection Act, 21 U.S.C. §§ 451–472; Egg Products Inspection Act, 21 U.S.C. §§ 1031–1056.

[16] *See* 21 U.S.C. § 342(a)(2)(C) ("A food shall be deemed to be adulterated . . . if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title[.]"); *id.* § 348(a) (providing that a food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe unless its use conforms to an exemption or a regulation issued prescribing conditions under which the additive may be safely used).

[17] Federal Food, Drug, & Cosmetic Act § 201(s) (codified at 21 U.S.C. § 321(s)).

[18] *Id.*

[19] H.R. Rep. No. 85-2284, at 1 (1958); 104 Cong. Rec. 17,412 (1958) (statement of Rep. Harris) (stating that "[t]he purpose of the legislation is twofold: First, to protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and second, to advance food technology by permitting the use of food additives at safe levels"); *id.* at 19,358 (statement of Sen. Hill) (explaining the objective of the bill is to correct two deficiencies in existing laws; first, to "require the processor of foodstuffs who proposes to add to the food any new chemical additive to first prove that the proposed addition will be safe," and second to "permit American industry to promote new technological developments in food handling calculated to make foods more tasteful and appetizing, to enable them to be kept longer, or to otherwise improve them, through the use of additives now proscribed under a blanket provision of existing law.").

[20] *See* 21 U.S.C. § 348; *Understanding How the FDA Regulates Food Additives and GRAS Ingredients*, U.S. Food & Drug Admin. (June 6, 2024), https://www.fda.gov/food/food-additives-and-gras-ingredients-information-consumers/understanding-how-fda-regulates-food-additives-and-gras-ingredients [https://perma.cc/4N88-Q3M3].

[21] *See* 21 U.S.C. § 348(b)–(g); U.S. Food & Drug Admin., *supra* note 20.

[22] *See* 21 U.S.C. § 348(b)(2); U.S. Food & Drug Admin., *supra* note 20.

[23] *See* 21 U.S.C. § 348(b)(5), (f); U.S. Food & Drug Admin., *supra* note 20.

[24] *See* 21 U.S.C. § 348(c)(3), (5); U.S. Food & Drug Admin., *supra* note 20.

[25] *See* 21 U.S.C. § 348(c); U.S. Food & Drug Admin., *supra* note 20.

[26] 104 Cong. Rec. 17,414 (1958) (statement of Rep. Harris reading a letter from the Department of Health, Education, and Welfare).

[27] *See* Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d 519, 534 (S.D.N.Y. 2021) (finding FDCA silent on question of whether it requires FDA to be made aware of GRAS conclusions).

[28] *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570).

[29] *See id*.

[30] *See id.*

[31] *See id.*; Richard Nixon, *Special Message to the Congress on Consumer Protection*, 1969 Pub. Papers 421 (Oct. 30, 1969), https://www.presidency.ucsb.edu/documents/special-message-the-congress-consumer-protection-0 [https://perma.cc/VWC8-AGZZ] ("[A full review of food additives] should move as fast as our resources permit, re-examining the safety of substances which are now described by the phrase, 'generally recognized as safe' (GRAS).").

[32] *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570). When a substance is listed in an interim food additive regulation, it is allowed to stay on the market pending completion of additional studies. *See* 35 Fed. Reg. 18,623 (Dec. 8, 1970).

[33] *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963–64 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570); GRAS and Food Additive Status Procedures, 37 Fed. Reg. 25,705 (Dec. 2, 1972).

[34] *See* Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,941 (proposed Apr. 17, 1997) ("However, the GRAS affirmation petition process involved the resource-intensive rulemaking process . . . FDA believes that, in practice, this resource-intensive process deters many persons from petitioning the agency to affirm their independent GRAS determinations").

[35] *See id.* at 18,938–41 (proposed Apr. 17, 1997); Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,964 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570) ("In the Federal Register of April 17, 1997 . . . we proposed to . . . replace the GRAS affirmation petition process with a notification procedure whereby any person may notify us of a conclusion that a particular use of a substance is GRAS."). The 2016 rule is nearly identical to the 1997 proposal. *See FDA Issues Final Rule on Food Ingredients that May Be "Generally Recognized as Safe"*, U.S. Food & Drug Admin. (Aug. 12, 2016), https://www.fda.gov/food/hfp-constituent-updates/fda-issues-final-rule-food-ingredients-may-be-generally-recognized-safe [https://perma.cc/7EVE-L8KL] ("The final rule also formalizes the voluntary GRAS notification procedure, which was originally established under an interim policy and pilot program for human food in 1997 and animal food in 2010.").

[36] U.S. Food & Drug Admin., 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 5–6 (2017), https://www.fda.gov/media/109117/download.

37 *Id.* at 25–26.

38 *How U.S. FDA's GRAS Notification Program Works,* U.S. Food & Drug Admin. (Jan. 2006), https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works [https://perma.cc/GV9Z-U5SS].

39 *See id*; *see also Broken GRAS: How the FDA Lets Unsafe Ingredients Into Our Food*, Env't Def. Fund, https://www.edf.org/broken-gras-how-fda-lets-unsafe-ingredients-our-food [https://perma.cc/2YS5-RMHS] (explaining how a company can withdraw its GRAS notification and still market the product as GRAS).

40 Tom Neltner & Maricel Maffini, Nat. Res. Def. Council, Generally Recognized as Secret: Chemicals Added to Food in the United States 2, 9 (2014), https://www.nrdc.org/sites/default/files/safety-loophole-for-chemicals-in-food-report.pdf ("But when a company withdraws a notice and asks FDA to stop further review, the agency issues a letter confirming the withdrawal without publicly explaining any of the concerns that could have prompted the withdrawal."). The FDA maintains a database of GRAS substances for which it has received and reviewed a voluntary notification. *See GRAS Notices*, U.S. Food & Drug Admin., https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&sort=Date_of_closure&order=DESC&type=basic&search= [https://perma.cc/9EL8-GXSK] (last visited Mar. 6, 2025). This database does not contain substances that were self-determined GRAS by manufacturers, only substances submitted to FDA for review. In addition, there is a several year gap between this database and its predecessor, meaning any substances determined GRAS during that time period—even with FDA notification—are not captured.

41 21 C.F.R. § 101.4(b)(1)–(2), (h)(1).

42 Tom Neltner, *Broken GRAS: a scary maze of questions a corn oil producer couldn't answer*, EDF Health (Mar. 25, 2022), https://blogs.edf.org/health/2022/03/25/broken-gras-a-scary-maze-of-questions-a-corn-oil-producer-couldnt-answer/ [https://perma.cc/SDC7-WTHY]; Thomas Galligan, *What's in 'flavor'? No one knows—and that's a problem*, Ctr. for Sci. in the Pub. Int. (Mar. 12, 2024), https://www.cspi.org/cspi-news/whats-flavor-no-one-knows-and-thats-problem [https://perma.cc/6QGA-9STK].

43 *See, e.g.*, United States v. An Article of Food (FoodScience Laboratories), 678 F.2d 735 (7th Cir. 1982); United States v. Articles of Food & Drug, Coli-Trol 80, 518 F.2d 743, 747 (5th Cir. 1975); United States v. An Article of Food (Coco Rico), 752 F.2d 11, 15 n. 6 (1st Cir. 1985); Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d 519, 534 (S.D.N.Y. 2021).

44 *See FDA Update on the Post-market Assessment of Tara Flour,* U.S. Food & Drug Admin. (May 15, 2024), https://www.fda.gov/food/hfp-constituent-updates/fda-update-post-market-assessment-tara-flour [https://perma.cc/BRE3-C3MT] [hereinafter FDA, *Tara Flour*) (declaring tara flour not GRAS two years after it was introduced into the market); *Investigation of Adverse Event Reports: French Lentil & Leek Crumbles,* U.S. Food & Drug Admin. (Oct. 25, 2022), https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-adverse-event-reports-french-lentil-leek-crumbles-june-2022 [https://perma.cc/ZP9A-W26S] [hereinafter FDA, *Lentil & Leek Crumbles*) (reporting 393 total adverse illness events and 133 hospitalizations from consumption of tara flour product).

45 Elizabeth Segran & Amy Farley, *Daily Harvest recall: How a rare new ingredient sent customers to the ER*, Fast Company (June 22, 2023), https://www.fastcompany.com/90908456/daily-harvest-food-startup-toxic-tara-flour-recall [https://perma.cc/R4V7-L38R] ("[Ricky] Silver [the Chief Supply Chain Officer of Daily Harvest] says that Daily Harvest's supplier, Smirk's, confirmed that tara flour was GRAS. 'The supplier shared with us documentation and positioned [tara flour] as Generally Recognized as Safe,' he says.").

46 Letter from William D Marler to James Jones, Deputy Comm'r for Hum. Foods at U.S. FDA (Dec. 27, 2023), https://www.foodpolitics.com/wp-content/uploads/Letter-to-Deputy-Commissioner-Jones-12.27.23.pdf; Coral Beach, *FDA Determines That Tara Flour Is Not Safe; 500 Were Sickened by the Ingredient*, Food Safety News (May 16, 2024), https://www.foodsafetynews.com/2024/05/fda-determines-that-tara-flour-is-not-safe-500-were-sickened-by-the-ingredient/ [https://perma.cc/5B3M-4Z48].

47 Letter from William D Marler to James Jones, Deputy Comm'r for Hum. Foods at U.S. FDA (Dec. 27, 2023), https://www.foodpolitics.com/wp-content/uploads/Letter-to-Deputy-Commissioner-Jones-12.27.23.pdf.

48 FDA, *Tara Flour*, *supra* note 44.

49 Elizabeth Segran & Amy Farley, *supra* note 45.

50 *See* U.S. Food & Drug Admin., *supra* note 11; *FDA Finalizes Food Chemical Safety Post-Market Assessment Program, Launches Reassessment of BHT, ADA*, U.S. Food & Drug Admin. (May 12, 2026), https://www.fda.gov/news-events/press-announcements/fda-finalizes-food-chemical-safety-post-market-assessment-program-launches-reassessment-bht-ada [https://perma.cc/7Z8N-Y63A].

51 Substances Generally Recognized as Safe, 91 Fed. Reg. 51,834, 51,840–45 (proposed Aug. 11, 2026) (describing the justification for its proposal of a mandatory GRAS notification).

52 *See, e.g.*, Ensuring Safe and Toxic-Free Foods Act of 2025, S. 2341, 119th Cong. (2025); Better FDA Act of 2025, S. 3122, 119th Cong. (2025); GRAS Act, H.R. 4958, 119th Cong. (2025).

53 *See, e.g.*, 104 Cong. Rec. 17,422 (1958) (statement of Mr. McDonough) (explaining the bill is necessary to protect the public from dangerous additives that "should be pretested before they are used.").

54 21 U.S.C. § 321(s)

[55] *Id.*

[56] *Id.*

[57] *Id.* (defining food additive, and providing that substances are not food additives if they fall under the GRAS exclusion); *id.* § 348(a)–(c) (describing that food additives be deemed unsafe unless there is an effective food additive regulation prescribing approved conditions of use).

[58] 104 Cong. Rec. 17,419 (1958) (statement of Rep. Delaney).

[59] *Id.* at 17,422 (statement of Rep. McDonough)

[60] S. Rep. No. 85-2422, at 2 (1958).

[61] 104 Cong. Rec. 19,358 (1958) (statement of Sen. Hill).

[62] S. Rep. No. 85-2422, at 11 (1958); *see also* Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650, 34,658 (June 17, 2015) (The FDA cited this language in their Final Determination revoking GRAS status for partially-hydrogenated oils to reject the argument that the food additive provisions do not reach health risks related to chronic disease.).

[63] 104 Cong. Rec. 17,420 (1958).

[64] Food Additives: Hearings Before the Subcomm. on Health and Science of the House Comm. on Interstate and Foreign Commerce on Bills to Amend the Federal Food, Drug, and Cosmetic Act with Respect to Chemical Additives in Food, 85th Cong., 1st Sess. 461–462 (1957).

[65] 104 Cong. Rec. 17,414 (1958) (statement of Rep. Harris reading a letter from the Department of Health, Education, and Welfare).

[66] *Id.* at 17,420.

[67] Neither the report of the House committee that proposed the passage of the FAA nor the Congressional record discuss GRAS based on scientific procedures other than to say that "[an] additive may be shown to be [GRAS] either by means of scientific procedures (including a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food." *See, e.g.*, *id.* at 17,416 (1958) (statement of Rep. Harris), 17,418 (statement of Rep. Poff).

[68] 21 C.F.R. § 170.30(c)(1) (emphasis added); 42 Fed. Reg. 14,302, 14,487 (March 15, 1977).

[69] 21 C.F.R. § 170.30(b); 42 Fed. Reg. 14,302, 14,487 (March 15, 1977).

[70] S. Rep. No. 85-2422, at 2 (1958).

[71] Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[72] *Id*. at 843 ("First, always, is the question 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. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, . . . rather if 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.").

[73] *See* Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d 519 (S.D.N.Y. 2021) (upholding the voluntary GRAS notification procedure as a valid reading of the statute under *Chevron*).

[74] Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024).

[75] We do not discuss the major questions doctrine (MQD) in detail in this report, as it does not apply to FDA action on GRAS substances and therefore does not warrant extended treatment. The doctrine addresses agency assertions of unprecedented power in domains not traditionally within the agency's purview, or transformative expansions of regulatory authority derived from vague ancillary language. *See* West Virginia v. EPA, 597 U.S. 697, 724 (2022) (quoting *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 159–60 (2000)); *Loper Bright Enterprises*, 603 U.S. at 405 (quoting *West Virginia* and holding *Chevron* does not apply if question is of "deep economic and political significance," in which case delegation is expected to be express and not merely through "modest words, vague terms, or subtle devices"). The doctrine asks not merely whether Congress provided "clear congressional authorization" in the abstract, but whether Congress "meant to confer the power the agency has asserted." *Brown & Williamson,* 529 U.S. at 159. None of the triggering conditions are present here. FDA has regulated food additives and GRAS substances continuously since the FAA's enactment in 1958; food safety is well-documented as FDA's core statutory mission, *see* 21 U.S.C. § 393(b)(2), and the authority at issue derives from the FAA's central definitional provision, *see id.* § 321(s), not from a vague ancillary clause. *West Virginia* further distinguished EPA's contested action—an "unprecedented" attempt to restructure the national electricity grid—from incremental exercises of authority within an agency's established domain. 597 U.S. at 724. The significant MQD cases involved an agency claiming power over an industry or activity outside its traditional purview or invoking an oblique statutory provision to assert sweeping new authority. *See, e.g.*, *id.*; Nat'l Fed'n of Indep. Bus. v. Dep't of Labor, Occupational Safety and Health Admin., 595 U.S. 109 (2022); Biden v. Nebraska, 600 U.S. 477 (2023). A procedural notification requirement for an ingredient category FDA has regulated for nearly seventy years is, by definition, not a "transformative expansion" of agency authority. Additionally, a new premarket notification rule would not have "deep economic and political significance" because current GRAS rules already require an adequate showing of safety; the only new cost to the regulated community would be the cost of providing such evidence of safety to the FDA prior to marketing a substance.

[76] *Loper Bright Enterprises*, 603 U.S. at 400.

[77] *Id.*
[78] *Id.* at 412.
[79] *Id.* (referencing *Skidmore v. Swift & Co.,* 323 U.S. 134 (1944)).
[80] *Id.* at 395.
[81] *Id.* at 413.
[82] *Id.* at 400.
[83] 21 U.S.C. § 321(s).
[84] *Loper Bright Enterprises*, 603 U.S. at 400.
[85] *See, e.g.*, 104 Cong. Rec. 19,358 (1958) (statement of Sen. Hill).
[86] *See, e.g.*, *id.* at 17,420 (Letter from the Department of Health, Education, and Welfare).
[87] *See* Thomas G. Neltner et al., *supra* note 4; Melanie Benesh, *supra* note 5.
[88] *See* Tom Neltner & Maricel Maffini, *supra* note 40, at 9–10 (detailing that many companies' GRAS safety determinations are seriously flawed); Melanie Benesh, *What is GRAS?*, Env't Working Grp. (Mar. 5, 2024), https://www.ewg.org/news-insights/news/2024/03/what-gras [https://perma.cc/WX3Z-3TRM] (explaining the health concerns of hundreds of chemicals that have been added to food products through the GRAS loophole); John O. Warner, *supra* note 9 (discussing artificial additives, particularly attractive to children, have resulted in adverse health effects); Env't Def. Fund, *supra* note 39 (explaining how the current broken GRAS system lets in harmful substances into the American food supply).
[89] FDA, *Lentil & Leek Crumbles*, *supra* note 44 (reporting 393 total adverse illness events and 133 hospitalizations from consumption of tara flour product).
[90] *See* Tom Neltner & Maricel Maffini, *supra* note 40, at 12 (explaining difficulty of determining source of illness *ex post*); Marilyn Urrutia-Pereira et al., *Food Additives and Their Impact on Human Health*, 53 Allergologia et Immunopathologia 26 (2025), http://dx.doi.org/10.15586/aei.v53i2.1149 (verifying association of food additives with systemic autoimmune and cardiometabolic conditions, as well impacts on microbiota); L. Kavitha & M. K. Sangeetha, *supra* note 9 (discussing impacts of certain commonly-used additives on fertility impairment).
[91] See, e.g., United States v. An Article of Food (FoodScience Laboratories), 678 F.2d 735 (7th Cir. 1982); United States v. Articles of Food & Drug, Coli-Trol 80, 518 F.2d 743, 747 (5th Cir. 1975); United States v. An Article of Food (Coco Rico), 752 F.2d 11, 15 n. 6 (1st Cir. 1985); Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d 519, 534 (S.D.N.Y. 2021).
[92] *Ctr. for Food Safety*, 565 F. Supp. 3d at 538 (acknowledging validity of concerns raised in a Government Accountability Office (GAO) report that FDA did not have the information to vouch for the safety of many chemicals added to food).
[93] *Id.* (holding that under the second step of the *Chevron* analysis, FDA's interpretation need not be the only possible interpretation, but simply one reasonable interpretation).
[94] *Id.* at 543.
[95] *Id.* at 531–32, 538–39.
[96] *Id.*
[97] *Id.* at 535.
[98] *Id.*
[99] *Id.* at 534; *see also* 21 U.S.C. § 393(b)(2) (identifying FDA's mission to "protect the public health by ensuring that -- . . . foods are safe, wholesome, sanitary, and properly labeled".).
[100] S. Rep. No. 85-2422, at 2 (1958) ("This huge loophole [in which a processor may use an untested additive for as long as time as it may take for the Government to suspect the deleteriousness of the additives and subsequently review and research its affects, taking years] is 1 of 2 flaws in existing law which, through this measure, we are attempting to fill.").
[101] Loper Bright Enterprises v. Raimondo, 603 U.S. 369, 412 (2024).
[102] *Id.* at 413.
[103] *Id.* at 402.
[104] *Id.* at 370, 388, 394, 399, 402 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) several times to hold that courts may seek aid from interpretations of those responsible for implementing particular statutes).
[105] *See, e.g.*, Fmali Herb, Inc. v. Heckler, 715 F.2d 1385, 1390–91 (9th Cir. 1983) (holding that because FDCA's overriding purpose is to protect the public health, an FDA regulation establishing a rigorous threshold of evidence needed to constitute sufficient proof of safety based on common use would be entitled to substantial judicial deference); United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977) (upholding FDA's time-temperature-salinity requirement on whitefish processing and noting, "when we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively, but rather as "consistent with the Act's overriding purpose to protect the public health" (citing *U.S. v. Bacto-Unidisk*, 398 U.S. 784, 798 (1969)).
[106] *Skidmore*, 323 U.S. at 140.
[107] *See id.*; De La Mota v. U.S. Dep't of Educ., 412 F.3d 71, 80 (2d Cir. 2005) (implying *Skidmore* thoroughness requires rigorous consideration and public scrutiny).
[108] *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25,

170, 184, 186, 570); Substances Generally Recognized as Safe, 91 Fed. Reg. 51,834 (proposed Aug. 11, 2026).

109 *De La Mota*, 412 F.3d at 80–81; *see also Skidmore*, 323 U.S. at 140.

110 Doe v. Leavitt, 552 F.3d 75, 82 (1st Cir. 2009).

111 *See supra* Section IV. A.

112 *Skidmore*, 323 U.S. at 140.

113 *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570).

114 *See id.*

115 *See, e.g.*, *id.* at 54,971 ("To administer the provisions of the FD&C Act with respect to the use of GRAS substances, we are retaining the voluntary nature of the GRAS administrative procedure. This rule replaces one longstanding voluntary administrative procedure with a different voluntary administrative procedure.").

116 Defendants' Reply Memorandum of Law in Further Support of Their Cross-Motion for Summary Judgment at 2–3, Ctr. for Food Safety v. Becerra, No. 17 Civ. 3833 (S.D.N.Y. Sept. 19, 2019), 2019 WL 6463638 ("Congress's broad textual command leaves FDA discretion to determine how to best implement the GRAS provision.").

117 *Id.* at 5–6.

118 Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,981–82 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570) ("We agree that we lack express statutory authority to require companies to submit GRAS notices . . . We recognize that some comments suggest that such a requirement might be within our legal authority, even if not expressly required by the FD&C Act. We will consider these comments and our experience under this final rule in evaluating what, if any, further action is needed with respect to ensuring the safety of the food supply. However, mandating submission of GRAS notices would need to be done in a separate rulemaking to ensure adequate notice and comment.").

119 *See* Gemini Fishing Inc. v. United States Dep't of Homeland Sec., 783 F. Supp. 3d 465, 485–86 (D. Mass. 2025) (citing *Doe v. Leavitt*, 552 F.3d 75, 82 (1st Cir. 2009)) (granting *Skidmore* deference to the agency even when seemingly changing its interpretation on a term as it was still validly reasoned and done earnestly in the face of an unprecedented application).

120 *See* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,970 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570) ("These regulations provide . . . a more efficient procedure"); Defendants' Reply Memorandum of Law in Further Support of Their Cross-Motion for Summary Judgment at 6, Ctr. for Food Safety v. Becerra, No. 17 Civ. 3833 (S.D.N.Y. Sept. 19, 2019), 2019 WL 6463638 (arguing FDA reasonably determined voluntary notification to be efficient enforcement because it simplified process and would not excessively consume FDA's resources).

121 *See* Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d 519, 539 (S.D.N.Y. 2021) (holding that the court is "cognizant of [the] reality" that circumstances have changed since the enactment of the FAA and the number of additives in the food supply has spiked from 800 to more than 9,000); Melanie Benesh and Bennet Rosenberg, *supra* note 7 (finding nearly 99% of the new food chemicals introduced to U.S. food supply between 2000 and 2025 bypassed the federal additive review process through the GRAS designation).

122 *Gemini Fishing Inc.*, 783 F. Supp. 3d at 486 (citing Kristin E. Hickman & Matthew D. Kreuger, *In Search of the Modern Skidmore Standard*, 107 Colum. L. Rev. 1235, 1286 (2007)) (explaining that the "consistency' factor seems less dispositive than other Skidmore factors").

123 U.S. Gov. Account. Off., Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts 16 (August 2021), https://www.gao.gov/assets/gao-21-593.pdf (noting that the "prevalence of diet-related chronic health conditions was higher in 2018 than 2009.").

124 *Cf.* Gonzales v. Oregon, 546 U.S. 243, 269 (2006) (holding *Skidmore* deference could be tempered due to agency's lack of expertise in the regulated area); King v. Burwell, 576 U.S. 473, 486 (2015) (citing *Gonzales* in holding it unlikely that Congress delegated health insurance policy decisions to Internal Revenue Service which had no expertise in the area).

125 *See, infra* Part IV.C.; *see also, e.g.*, United States v. Sullivan, 332 U.S. 689, 694 (1948) ([T]he FDCA confers on the FDA "rather broad discretion—broad enough undoubtedly to enable [the Administrator] to perform his duties fairly."); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 177 (D.D.C. 2000) (holding question of whether substance should be accorded GRAS status is within FDA's technical expertise).

126 Loper Bright Enterprises v. Raimondo, 603 U.S. 369, 395 (2024).

127 *Id*.

128 21 U.S.C. § 371(a).

129 Nat'l Ass'n of Pharm. Mfrs. v. Food & Drug Admin., 637 F.2d 877, 879 (2d Cir. 1981) ("Reading the language of [21 U.S.C. § 371(a)] . . . one would have little difficulty in concluding that the words suffice to empower the Commissioner of the FDA, to issue regulations, substantive as well as procedural, having the force of law."); *see also* United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977) ("We read [21 U.S.C. § 371(a)] as analogous to the provision 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,' in which case 'the validity of a regulation promulgated thereunder will be sustained so long as it is reasonably related to the purposes of the enabling legislation.'").

130 *See supra* Section IV.A.

[131] Lesko v. United States, 161 F.4th 1352 (Fed. Cir. 2025).
[132] *Id.* at 1358–59.
[133] *Id.*
[134] *Id.* at 1358–61.
[135] 21 U.S.C. § 371(a).
[136] *Id.* § 393(b)(2)(A). Meat, poultry, and processed egg products are subject to premarket inspection by the USDA's Food Safety and Inspection Service (FSIS) under the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act, 21 U.S.C. § 60, Poultry Products Inspection Act, 21 U.S.C. § 451, and the Egg Products Inspection Act, 21 U.S.C. § 1031. However, under a Memorandum of Understanding between FDA and FSIS, FDA retains authority over the safety of food additives, GRAS substances, color additives, and food contact substances used in the production of meat, poultry, and egg products, while FSIS conducts a simultaneous suitability review. *See* Memorandum of Understanding Between the Food Safety and Inspection Service, U.S. Department of Agriculture, and the Food and Drug Administration, U.S. Department of Health and Human Services, MOU 225-00-2000 (Jan. 31, 2000), as amended.
[137] 21 U.S.C. § 321(u).
[138] United States v. Dotterweich, 320 U.S. 277 (1943).
[139] *Id.*
[140] *Id.* at 280.
[141] *Id.*
[142] United States v. Sullivan*,* 332 U.S. 689 (1948)
[143] *Id.* at 693.
[144] *Id.* at 696.
[145] *Id.* at 694.
[146] United States v. Bacto-Unidisk, 394 U.S. 784 (1969).
[147] *Id*. at 789.
[148] *See, e.g.*, United States v. Nova Scotia Food Products Corp., 568 F.2d 240 (2d Cir. 1977); United States v. 250 Jars of U.S. Fancy Pure Honey, 218 F. Supp. 208, 212 (E.D. Mich. 1963) (refusing to accept a narrow construction that "would do violence to the noble purpose of the Food, Drug and Cosmetic Act," and declining to "open a loophole through which those who prey upon the weakness, gullibility and superstition of human nature can escape the consequences of their actions"); United States v. Blue Ribbon Smoked Fish, Inc., 56 F. App'x 542, 543–44 (2d Cir. 2003) (citing *United States v. Diapulse*, 457 F.2d 25, 28 (2d Cir.1972)) (sustaining an FDA injunction against a smoked fish processor whose plant conditions created a risk of listeria contamination noting that "The reach of the FDCA is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction.").
[149] *Nova Scotia Food Products Corp.*, 568 F.2d at 240.
[150] *Id*. at 246.
[151] *Id.*
[152] *Id.* at 248.
[153] 21 U.S.C. § 371(a).
[154] 21 U.S.C. § 371(a). "This Chapter" refers to 21 U.S.C. Chapter 9, which is the FDCA in its entirety.
[155] Nat'l Ass'n of Pharm. Mfrs. v. FDA, 637 F.2d 877, 889 (2d Cir. 1981) (quoting *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973)).
[156] 21 U.S.C. § 348 (a).
[157] The Second Circuit has confirmed that this kind of authority is precisely what general rulemaking grants like 21 U.S.C. § 371(a) are designed to confer. In *National Nutritional Foods Ass'n v. Weinberge*r, 512 F.2d 688, 697–98 (2d Cir. 1975), the court upheld FDA's authority to reach binding determinations through informal notice-and-comment rulemaking under FDCA § 701(a) (21 U.S.C. § 371(a)) and rejected the argument that Congress's provision of more formal procedures elsewhere in the statute foreclosed FDA from using that general grant. The specific procedures, the court held, were "in addition to and not in derogation of" the general rulemaking power, under which FDA "may follow streamlined procedures designed to avoid the endless delays that have tended to paralyze adjudicatory hearings." *Weinberger*, 512 F.2d at 697. The court further emphasized that in areas requiring scientific expertise, courts have "learned from experience to accept a general delegation as sufficient," recognizing that FDA, "by reason of its expertise, [is] better equipped to make such determinations than a court which is 'without chemical or medical background." *Id.*; *see also* United States v. Ewig Bros. Co., 502 F.2d 715, 719 (7th Cir. 1974) (holding that that "the allocation of decision-making responsibility between the agency and the judiciary" enables FDA to make determinations systematically, "without having to rely upon the decisions—possibly inconsistent with one another—of different federal judges determining danger to health on a case-by-case basis").
[158] *See, e.g.*, United States v. An Article of Food (FoodScience Laboratories), 678 F.2d 735, 737 (7th Cir. 1982) (quoting 21 U.S.C. §§ 342, 348 by stating that "[a] food shall be deemed to be adulterated if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title . . . a food additive is presumed to be unsafe unless the Secretary of Health

and Human Services has promulgated a regulation 'prescribing the conditions under which such additive may be safely used.'").

159 Se. Mins., Inc. v. Harris, 622 F.2d 758, 767 (5th Cir. 1980).

160 *See, supra* notes 5–12 and accompanying text.

161 *See, e.g.*, Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,961 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570) ("Since the 1970s, we have had regulations clarifying the statutory provision for eligibility for classification as GRAS"); *id.* at 54,963 ("when a use of a substance does not qualify for GRAS status or other exceptions provided under section 201(s) of the FD&C Act, that use of the substance is a food additive use subject to the premarket approval mandated by the FD&C Act. In such circumstances, we can take enforcement action to stop distribution of the food substance and foods containing it on the grounds that such foods are or contain an unlawful food additive"); *Statement of Policy: Foods Derived From New Plant Varieties*, 1992 WL 12145394 (F.D.A., 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."); *Post-market Determinations that the Use of a Substance is Not GRAS*, U.S. Food & Drug Admin. (May 8, 2025), https://www.fda.gov/food/generally-recognized-safe-gras/post-market-determinations-use-substance-not-gras [https://perma.cc/T2B8-396U] (listing sixteen recently posted memos documenting FDA's determination that the use of a substance in food does not meet the statutory criteria for GRAS).

162 *An Article of Food (FoodScience Laboratories)*, 678 F.2d at 737.

163 *See generally id.*

164 United States v. Articles of Food & Drug, Coli-Trol 80, 518 F.2d 743, 747 (5th Cir. 1975); *see also* United States v. Naremco, Inc., 553 F.2d 1138, 1142 (8th Cir. 1977) ("scattered lay opinion" cannot substitute for expert scientific consensus under the "generally recognized among experts" standard).

165 United States v. An Article of Food (Coco Rico), 752 F.2d 11, 15–16 (1st Cir. 1985).

166 21 U.S.C. § 321(s).

167 *Id.* § 170.30(a)–(b); Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,973 (Aug. 17, 2016) (to be codified at 21 C.F.R. pts. 20, 25, 170, 184, 186, 570).

168 21 U.S.C. § 393(b)(2)(A).

169 H.R. Rep. No. 82-2356, at 27 (1952).

170 *Id.*

171 21 U.S.C. § 371(a).

172 Se. Mins., Inc. v. Harris, 622 F.2d 758, 767 (5th Cir. 1980).

173 21 U.S.C. § 321(s).

174 *See* U.S. Food & Drug Admin., *supra* note 161; *Post-market Determinations that the Use of a Substance is Not GRAS*, U.S. Food & Drug Admin., https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=Postmarket [https://perma.cc/CNK8-EXM6] (last accessed April 2, 2026).

175 *See, e.g., An Article of Food (FoodScience Laboratories)*, 678 F.2d; *Articles of Food & Drug, Coli-Trol 80*, 518 F.2d; *An Article of Food (Coco Rico)*, 752 F.2d.



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FDA's Statutory Authority to Require Premarket Notification and Review of GRAS Substances Under the Food, Drug, and Cosmetic Act

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