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Legal Sidebar

# Food Additives and GRAS Substances: A Legal Framework

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Over the past few decades, the Food and Drug Administration's (FDA's) regulation of food additives has provoked debate. In general, food additives, which include substances such as spices, emulsifiers, and preservatives, are added to foods to improve taste, texture, shelf life, or for other reasons. While the Federal Food Drug & Cosmetic Act (FD&C Act) includes a requirement for manufacturers to obtain premarket approval from FDA for food additives, manufacturers are not required to use the premarket approval process for certain substances that are generally recognized as safe (GRAS), as set out in the statute. Pursuant to existing law, GRAS substances are not considered food additives and are exempt from FDA's premarket review. Current FDA regulations permit a manufacturer to market products with substances the manufacturer concludes are GRAS, with the option to submit a voluntary notice to FDA stating it believes a substance is not subject to premarket approval accompanied by support for that belief. Food safety groups and commentators have criticized FDA's treatment of GRAS substances, arguing that it allows the food industry to "bypass crucial safety checks for new ingredients" and to "regulate itself." Others are skeptical that FDA has sufficient resources to take on the review of GRAS assessments and have expressed that requiring FDA to review GRAS determinations may hamper industry innovation and "may cause disruptions in our food supply."

In recent months, the U.S. Department of Health and Human Services (HHS) has taken steps to amend the GRAS framework. In March 2025, the Secretary of HHS directed FDA to explore rulemaking to eliminate the pathway for companies to self-affirm food ingredients are GRAS. Following this announcement, on December 1, 2025, FDA submitted a proposed rule concerning GRAS substances to the Office of Management and Budget (OMB) for review. As of the date this Sidebar was published, review remained pending. While under review, the text of the rule is not public, and therefore the precise scope of any changes is unknown, but FDA's Unified Agenda (a semi-annual agenda of upcoming regulations) suggests that the proposed rule may require mandatory submissions for a conclusion that a substance is GRAS. As explained more below, FDA previously commented on potential limits on its authority over GRAS notices under the FD&C Act, which may raise questions regarding the extent of its authority over GRAS substances.

This Legal Sidebar begins with an overview of the legal regulation of food additives and GRAS substances. Then, it discusses FDA's 2016 final rule allowing for the voluntary submission of GRAS

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notices and the legal challenge to that rule. The Sidebar concludes with selected legal considerations for Congress.

## Regulation of Food Additives, GRAS Substances, and Food Contact Substances

To further FDA's mission to ensure foods are "safe, wholesome, sanitary, and properly labeled," the FD&C Act prohibits the introduction of adulterated or misbranded foods in interstate commerce. One way that a food is considered to be adulterated is if it contains an "unsafe" food additive, and a food additive is deemed unsafe unless FDA has promulgated a regulation approving the use of that additive. Any person may file a petition asking FDA to promulgate a food additive regulation, or the FDA Commissioner may propose the issuance of such a regulation. If a food manufacturer or other person files a petition, FDA is to grant such a petition and determine the relevant food additive to be "safe" if the petition has demonstrated there is a reasonable certainty of no harm under the conditions of its intended use. In making this evaluation, current FDA regulations specify that the agency considers (1) "the probable consumption of the additive," (2) "the cumulative effect of such additive in the diet of man or animals," and (3) other safety factors "generally recognized as appropriate."

The FD&C Act defines *food additive* as "any substance the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" unless the substance is GRAS. A substance is *GRAS*—and therefore not a food additive—if "experts qualified by scientific training and experience to evaluate its safety" generally recognize the intended use of the substance to be safe. According to the statutory definition, these experts must base their view of a general recognition of safety on either (1) scientific procedures or (2) common use of a substance in food prior to January 1, 1958.

The first type of GRAS substances are ones that have "been adequately shown through scientific procedures . . . to be safe under the conditions of [their] intended use." A GRAS conclusion based on scientific procedures "require[s] the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient." The GRAS conclusion is "ordinarily" based on published studies, but it can be corroborated by unpublished studies and other information. Courts have noted that a GRAS conclusion does not require the "unanimous recognition" of qualified experts but instead their "general recognition."

The second type of GRAS substances are those that were "used in food prior to January 1, 1958" and shown through "experience based on common use in food[ ] to be safe under the conditions of [their] intended use." FDA regulations provide that general recognition of safety through experience "shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information."

Even though FDA does not preapprove substances as GRAS, FDA regulates substances used in foods on the market that have not been shown to be GRAS. For example, FDA has sent untitled letters to manufacturers of certain caffeinated beverages requesting the support for their conclusion that their use of caffeine in alcoholic beverages is GRAS. Subsequently, FDA sent warning letters threatening to seize the products unless the manufacturers discontinued making the products.

In 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA), which established a mandatory notification procedure for certain food additives and a subset of GRAS substances called food contact substances. A *food contact substance* is "any substance intended for use as a component of materials used in manufacturing, packing, packaging, or holding food if such use is not intended to have any technical effect in such food." To market a food with a food contact substance, the food company must submit a notification to FDA for the substance, or there must be in effect a food

additive regulation approving the use of the substance. The food contact notification must identify the intended use of the food contact substance and information that forms the basis of the determination that the intended use of the food contact substance is safe. A company may use a food contact substance 120 days after submitting such a notification to FDA, unless FDA notifies the company that such use of the food contact substance has not been shown to be safe.

## 2016 GRAS Final Rule

In 2016, FDA finalized a rule that amended its regulations to create a voluntary notification procedure for industry to notify FDA of its GRAS determinations (2016 GRAS final rule), which remains in effect as of the publication of this Sidebar. The rule applies to GRAS substances that are not food contact substances, given that FDAMA made it mandatory to submit food contact substance notifications. Under the GRAS notification procedure, any person may submit a GRAS notice to FDA that states their view that a use of a particular substance is GRAS under the conditions of its intended use and therefore not subject to the premarket approval requirements applicable to food additives. FDA is to respond via letter within 180 days of filing, and it may extend the time frame by 90 days when it needs to do so. A submitter may also ask FDA to cease evaluation of a GRAS notice, and FDA is to respond via letter with its decision regarding the request to cease its evaluation of the notice.

In the *Federal Register* notice announcing the 2016 GRAS final rule, FDA commented on its authority to *require* the submission of GRAS notices, rather than relying on voluntary notifications. As part of the preamble to this rule, FDA addressed certain comments asking FDA to require (rather than permit) food companies to provide FDA with basic information about the conclusion of GRAS status, out of concern that "dangerous substances could enter the food supply without [FDA's] knowledge or supervision." As a part of its response to these concerns, FDA stated that it "lack[s] express statutory authority to require companies to submit GRAS notices." The agency pointed to Congress's decision to exclude GRAS substances from the definition of *food additive*, which "reflected Congress's determination that many substances intentionally added to food for specific use do not need premarket review by FDA to ensure their safety, either because their safety has been established by a long history of use in food, or because their safety has been established by information that is generally available and accepted by qualified experts." FDA also pointed to FDAMA, which required the submission of mandatory food contact substance notifications but did not require premarket notification of all GRAS substances.

In response to comments asserting that FDA has implied legal authority to require GRAS notices, FDA stated it would consider these comments and other experience in examining any further action to ensure the safety of the food supply.

## *Center for Food Safety v. Becerra*

Following FDA's issuance of the 2016 GRAS final rule, two nonprofit organizations—the Center for Food Safety and the Environmental Defense Fund—filed a legal challenge to the rule in the U.S. District Court for the Southern District of New York. The organizations argued, in part, that the rule exceeded FDA's statutory authority under the FD&C Act because the rule fails to ensure foods are safe as required by the statute. They asked the court to vacate the rule, noting concerns about food safety and FDA's lack of knowledge about the substances in the food supply.

In considering whether FDA had exceeded its statutory authority, the court applied the now-overturned *Chevron* doctrine, which required courts to determine whether the statute was "silent or ambiguous" with respect to the contested issue, and if so, defer to the agency's interpretation of the statute if the interpretation was reasonable. The court was therefore tasked with determining whether FDA's interpretation that the FD&C Act does not require the submission of GRAS notices was reasonable. FDA asserted that it "lack[ed] express statutory authority to require companies to submit GRAS notices." FDA

noted it might have implied authority to make GRAS notifications mandatory, but it argued that, even if it did, the decision to use a voluntary system was reasonable because the food industry submitted many GRAS notices voluntarily and because reviewing mandatory submissions would deplete its resources that could be better directed toward evaluating "higher priority, substances."

The court concluded that FDA's interpretation was reasonable because GRAS substances were specifically exempted from the premarket review framework for food additives and because FDA has limited resources to allocate to food safety. The court reasoned that FDA has a "long-standing record" of interpreting the FD&C Act to exempt GRAS substances from premarket review, as the systems in place before the 2016 Final Rule were also voluntary. The opinion further noted that Congress "has remained silent for more than sixty years on whether GRAS submissions should be voluntary" despite FDA's long-standing interpretation of the FD&C Act.

The organizations raised, and the court rejected, several other arguments—that the GRAS rule unlawfully subdelegates FDA's duty to ensure food safety to food companies, that the rule is arbitrary and capricious, and that the rule violates the FD&C Act. The court rejected each of these arguments, noting that FDA has "numerous cogent explanations" for the rule and that many of plaintiffs' arguments are "essentially reiterations of the issues the plaintiffs flagged in their other challenges." The court therefore granted FDA's motion for summary judgment, ending the legal challenge to the 2016 GRAS final rule. The plaintiffs opted not to appeal this decision.

## Considerations for Congress

As of the publication of this Legal Sidebar, the 2016 GRAS final rule remains in effect, but changes to this rule may be forthcoming. On December 1, 2025, FDA submitted a proposed rule concerning GRAS substances to OMB for review. To date, that review remains pending. As suggested by FDA's Unified Agenda, these new regulations may propose to alter the voluntary notification procedures for GRAS determinations, or they could potentially include other requirements related to GRAS determinations. Given the HHS Secretary's directive to "Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe," it is possible that a future proposed rule would require GRAS notice submissions.

Should any forthcoming final rule be subject to litigation, the *Center for Food Safety v. Becerra* opinion may be instructive, but it would not bind a future court. First, the opinion is not published and therefore of no precedential weight. Second, it is a district court opinion, which is generally not binding on other courts. Third, the opinion does not squarely address whether FDA is *authorized* to require the submission of GRAS notices. Instead, it holds that FDA's interpretation that the FD&C Act does not *require* FDA to mandate GRAS submissions is reasonable under *Chevron*. In other words, the court addressed the question of whether FDA *must* require GRAS submissions, but not whether it *may* require GRAS submissions.

FDA's previous interpretations of its authority to require GRAS notices under the FD&C Act may be relevant to future litigation. Following the overturning of *Chevron*, courts apply the cannons of statutory construction to find a statute's best reading, rather than defer to an agency's reasonable interpretations of ambiguous statutes. The Supreme Court's opinion in *Loper Bright* suggested that courts may look to *Skidmore* to guide their consideration of statutes. *Skidmore* is a 1944 Supreme Court case that does not require courts to defer to agencies but permits courts to give weight or respect to agency interpretations that it considers persuasive. One factor courts may consider in determining persuasiveness is an agency's "earlier and later pronouncements," and it may afford less weight to an agency's interpretation if it considers it to be inconsistent with its earlier pronouncements.

Members of the 119th Congress have introduced legislation that, if enacted, would impact the process through which food companies may obtain GRAS designations: the GRAS Oversight and Transparency

Act (H.R. 7291), the Better Food Disclosure Act of 2025 (S. 3122), the Grocery Reform and Safety Act (H.R. 4958), and the Ensuring Safe and Toxic-Free Foods Act of 2025 (S. 2341). Congress may consider these bills or other legislation that would affect the way food substances are determined to be GRAS or otherwise modify FDA's review of food safety. Congress may also consider clarifying FDA's authority (or lack of authority) to promulgate regulations requiring the submission of GRAS notices through legislation. Congress may also take no action and allow FDA to promulgate regulations and courts to determine the scope of FDA's authority in any legal challenges, if it chooses to do so.

## Author Information

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