Reforming the U.S. Food and Drug Administration's Generally Recognized As Safe (GRAS) Process
Policy Guidance
July 2026

Overview

The U.S. Food and Drug Administration's (FDA) "Generally Recognized as Safe" (GRAS) framework allows a substance to be used in food without FDA premarket review, provided it is generally recognized as safe by qualified experts. In practice, though, it has allowed substances to enter the United States (U.S.) food supply without adequate safety review. While some companies may voluntarily notify FDA of GRAS determinations, most rely on a self-affirmed pathway that operates without agency knowledge, oversight, or access to data that ostensibly supports the safety of the ingredient.

In 2012, the American Heart Association underscored the need for a more thorough approach to food chemical regulation via the GRAS process in public comments to FDA,[1] with a specific focus on sodium (salt). The Heart Association recommended that FDA have greater involvement in GRAS determinations, increase its level of enforcement, and implement a process to periodically review the science supporting GRAS claims.

Since then, there has been a growing concern about the widespread consumption of ultraprocessed foods (UPFs) and their potential population-level health risks. UPFs are industrially processed products made with additives or ingredients not commonly used in home cooking.[2] Many ingredients used in UPFs enter the U.S. food supply through the GRAS framework.[3,4] Thus, revising this framework is an important policy approach for ensuring a safe food supply and mitigating population health risks associated with consuming UPFs. The following policy guidance summarizes an updated, more comprehensive position for the Heart Association on this issue.

Background

The GRAS process was established by the 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act. The amendment created requirements that "food additives" must be approved by FDA before products containing these additives could be marketed to the public. However, the definition of additives excludes substances that are "generally recognized as safe" under the conditions of their intended use or based on common usage in food prior to 1958.[5] This means that substances that are GRAS under conditions of their intended use are not food additives and do not require premarket approval by FDA.

For a substance to be considered GRAS, there must be a consensus among qualified experts that establishes that the substance is safe under the conditions of its intended use. Congress did not specify how substances would be determined to be GRAS, but since 1997, FDA has operated under a voluntary notification process that allows food manufacturers to notify FDA of a new GRAS determination, but also allows manufacturers to make their own determination and use a substance in food without notifying FDA.[6]

If industry chooses to notify FDA, the agency has 30 days to respond in writing either by (1) stating that the agency has no questions about the notifier's GRAS conclusion, (2) concluding that the notice does not provide a sufficient basis for a GRAS determination, or (3) ceasing to evaluate the notice at the notifier's request.[3,7] When industry self-affirms that substances are GRAS, there should be the same quantity and quality of scientific evidence as a food additive petition.[8] However, because companies are not required to notify FDA or publicly disclose their GRAS determinations, it is difficult to verify whether these standards have been met. Only about 75 GRAS notices are evaluated by FDA each year,[9] and experts believe most GRAS determinations occur outside FDA review.[3,10,11]

In contrast, FDA reviews the safety data for food additives to determine whether the substance is safe under the conditions of its intended use; it also opens a public comment process where outside experts and members of the public can provide additional data or concerns.[7] It is important to highlight that GRAS status applies to the use, not the substance itself, meaning a substance can be GRAS for one use and not another (e.g., a certain amount of caffeine used in regular soda may be GRAS, but not the same amount of caffeine used in alcoholic beverages).[12]

Limitations of the GRAS Framework

The GRAS exception was originally intended to allow a small number of ingredients already used in foods prior to 1958 to remain in use and encourage new substances to be reviewed through the food additive pathway. In practice, though, it has allowed substances to enter our food supply without premarket safety approval and often without the public's knowledge.[3] One analysis found that 99% of new food chemicals introduced between 2000 and 2021 entered the market through the GRAS pathway, rather than FDA additive review.[13] In 2010, the U.S. Government Accountability Office (GAO) issued a report calling for FDA to strengthen its oversight of food ingredients determined to be GRAS.[5] The report noted that substances previously considered GRAS have later been banned and expressed concerns about the safety of newer substances.

A significant limitation of the current GRAS framework is that companies are not required to notify the FDA of their GRAS determinations.[5] FDA only has that information if a company voluntarily shares it with the agency. Once a company concludes that an ingredient is GRAS for its specific use, it can immediately and legally begin using it in products. Theoretically, this ingredient could

be added to hundreds of products nationwide, without the FDA having reviewed its safety data – or knowing that it is being added to the food – unless the company voluntarily notifies the agency.

Second, when a company decides on its own that an ingredient is GRAS, FDA has no mechanism for confirming whether the experts making that decision are truly independent from conflicts of interest or whether the scientific review that was conducted was sufficient.[5] One study found that 100% of GRAS notifications voluntarily submitted to FDA between 1997 and 2012 were decided by individuals with a conflict of interest.[14] A more recent study found that food industry GRAS panels are largely composed of experts who earn income from GRAS panel participation, including seven individuals who occupied almost half of all available panel positions, essentially leaving safety determinations of our food supply to a small number of potentially biased people.[15] Moreover, the types of available evidence used in determining whether a substance is GRAS can vary widely. Unlike the food additive process, companies can rely on unpublished or industry-generated studies, rather than peer-reviewed publications, and are not required to provide FDA with evidence addressing long-term or cumulative exposure effects.[10,16] An unfortunate example occurred in 2022, when nearly 400 people became seriously ill after consuming products made with tara flour, an ingredient self-affirmed as GRAS. It was not until the health harms had already occurred that FDA became aware of tara flour's potential safety issues.[17]

Finally, FDA has no way to ensure the continued safety of GRAS substances in post-market review and has no process in place for systematically reviewing new information that shows potential risk of these substances. This is exacerbated because FDA does not have a comprehensive list of all substances used in food, due to the self-affirmed GRAS process. As a result, FDA has been historically slow to act in response to new evidence or concerns about existing GRAS uses of substances. A prime example affecting cardiovascular health is industrially-produced *trans* fats. For many decades, partially hydrogenated vegetable oils (PHOs) — the primary source of industrially-produced *trans* fats — were present in the U.S. food supply, despite scientific concerns about their harmful effects on health. PHOs entered our food system and were considered GRAS through the pre-1958 pathway and through FDA affirming GRAS status for specific oils and uses.[18] Evidence about the potential health harms of PHOs began accumulating in the 1950s and was strengthened by pivotal epidemiological studies in the 1990s that linked the consumption of those fats with coronary artery disease.[19] In the early 1990s, consumer and advocacy groups began petitioning the FDA to review the safety status of PHOs, but it was not until 2013 that FDA proposed revoking the GRAS status of PHOs, and in 2016 when the determination was finalized.[18,19] This example illustrates the challenges of FDA's reactive approach to oversight of substances previously considered GRAS.

Policy Context

In 2011, FDA and the Food Safety and Inspection Service (FSIS) solicited public comments on approaches to reduce population sodium consumption. Among other recommendations, the American Heart Association urged FDA to modify the GRAS status for salt and strengthen the overall GRAS process. The Heart Association recommended that the agency have greater involvement in GRAS determinations, increase its level of enforcement, and implement a process to periodically review the science supporting GRAS claims.[1] In 2025, the Heart Association released a Science Advisory on UPFs, which acknowledged the need to re-evaluate substances currently in use under a GRAS determination and improve monitoring of both existing and emerging food additives.[2] Because many ingredients in UPFs enter the U.S. food supply through the GRAS framework, reforming this system is a key policy lever for protecting food safety and reducing population health risks associated with excess UPF consumption.

Some states have already banned ingredients due to potential safety concerns. While many of those ingredients are currently considered GRAS, others are permitted food and color additives. In 2023, California passed the California Food Safety Act (AB 418), which prohibited the manufacture and sale of food products containing four additives: brominated vegetable oil, potassium bromate, propylparaben, and Red Dye No. 3—due to safety concerns.[20] A year later, California passed AB 2316 to ban certain dyes from school foods.[21] Quickly, other states began to follow, passing legislation to prohibit selling or serving foods containing certain dyes or additives. In 2025, at least 30 states considered bills limiting the use of certain additives and dyes in food products.[22,23] Many of these substances are already restricted or banned in the European Union, United Kingdom, and other countries.[24] The European Union, in particular, applies a precautionary approach to food chemical regulation, meaning an ingredient can be restricted or banned when there is credible evidence of potential harm.[25] In contrast, the United States uses a risk-based approach, allowing ingredients to be used when available evidence shows a reasonable certainty of no harm at current exposure levels.[26]

More recently, states began advancing legislation to close the GRAS loophole in the absence of federal action. In April 2026, the New York legislature became the first to pass legislation (S1239F) requiring companies to publicly disclose the safety basis for substances self-affirmed as GRAS. It has not yet been signed by the Governor. The state would also maintain a public database of all self-affirmed GRAS ingredients used in New York.[27] If signed by the Governor, this legislation could have significant ripple effects on food safety nationwide.[28] Other states are considering similar legislation, including California, Pennsylvania, and New Jersey.[29] In addition to requiring companies to submit evidence supporting GRAS determinations and publicly disclose that evidence, the California bill would require that substances introduced after 1958 either undergo

FDA safety review or new state-level review, effectively preventing the use of ingredients based only on self-affirmed GRAS determinations.[30]

At the federal level, the current Administration and Congress have signaled a willingness to reform aspects of the GRAS framework. In March 2025, the U.S. Department of Health and Human Services (HHS) publicly directed FDA to explore rulemaking to eliminate the self-affirmed pathway for GRAS.[9] In a press announcement, HHS stated that self-affirmed GRAS status was a "loophole" by which new ingredients can enter the U.S. food supply, often with unknown safety data.[9] Meanwhile, the Make America Healthy Again (MAHA) Commission released the *Make Our Children Healthy Again Strategy Report*, which listed GRAS reform—specifically closing the "GRAS loophole" —as a key priority of the Administration.[31] Later that year, FDA responded by developing a Notice of Proposed Rulemaking and sending it to the Office of Information and Regulatory Affairs (OIRA) for review with the intention of releasing the proposed rule for public comment.[32] Based on FDA's description of the rulemaking, it may fall short of needed reforms to the premarket and post-market review of current and future GRAS substances. Congress has introduced several key bills to reform the GRAS framework, including the "Grocery Reform Safety Act" (H.R. 4958), "Better Food Disclosure Act of 2025" (S. 3122), "Ensuring Safe and Toxic-Free Foods Act" (S. 2341), "GRAS Oversight and Transparency Act" (H.R. 7291), and the recent discussion draft "FDA Review and Evaluation for Safe, Healthy and Affordable Foods Act of 2026." Some provisions in those bills would improve transparency and food safety, but other concerning provisions could further exacerbate the GRAS limitations. As of May 2026, none of the GRAS reform bills have passed out of committee.

American Heart Association Policy Guidance

Given the increasing policy activity and interest in reforming the GRAS framework, the American Heart Association recommends the following:

1. **FDA must have greater oversight of GRAS determinations and already has the statutory authority to do so.**
   As experts in the field responsible for the nation's food chemical safety, FDA scientists should be a critical component of a chemical's general recognition of safety among experts. FDA has clear authority to conduct post-market reviews and revoke a substance's GRAS status if safety concerns are identified. Additional congressional action to reinforce FDA's existing authority to conduct premarket reviews would protect the FDA from industry lawsuits and disputes.

2. **FDA should require premarket safety reviews and disclosure for all new substances and their intended uses, as well as mandatory disclosure of GRAS substances already in the food supply.**
   FDA should now require companies to submit GRAS notices for any substance they intend to market as GRAS for human or animal food use, effectively ending the self-affirmed GRAS pathway. In addition, FDA should require mandatory disclosure of GRAS substances already in the food supply. FDA should conduct a rigorous safety review (or call on an objective third party, such as the National Academies of Sciences, Engineering, and Medicine, to conduct the review) for all new substances and their intended uses, expanding the types of evidence required. This evidence should include data on medium and long-term health effects on humans drawn from well-designed prospective cohort studies, as well as findings from clinical studies assessing short-term health effects, biomarkers for chronic diseases, and other validated metabolic, genetic, and physiologic intermediate measures and outcomes. Companies should not be allowed to use new substances unless issued a final "no questions" letter by the agency. FDA should also allow for public comment prior to awarding GRAS status, which ensures transparency and scientific rigor. This process will require additional resources and time but will eventually ensure a safer food supply. To improve transparency, FDA should expand, update, and maintain a publicly accessible inventory of (1) all GRAS notices and their conditions of intended use, (2) FDA determinations/approvals or denials, (3) safety data provided, and (4) rational for FDA determinations.

3. **FDA should establish post-market safety triggers with enforceable timelines.**
   Given the sheer volume of substances currently used in the food supply, FDA should establish a review framework that identifies, prioritizes, and assesses GRAS substances in need of safety reviews. This includes substances with a GRAS determination, as well as those that have been previously self-affirmed GRAS by industry. For example, FDA should conduct an expedited mandatory reassessment of safety that is triggered by international regulatory action on that substance or when there is credible peer-reviewed evidence of harm. FDA should also consider a post-market review when petitioned by the public and respond by either conducting the review or providing a written explanation as to why a review is not needed. FDA should also develop a process for public participation in prioritizing substances for review and input on review findings. FDA should conduct a minimum number of post-market reviews each year. In May 2026, FDA finalized a food chemical safety post-market assessment program,[33] and further evaluation will be needed to determine whether it addresses the limitations above.

4. **FDA should have adequate resources to support reasonable timelines and rigorous GRAS reviews.**
   Congress should appropriate adequate funding to strengthen the FDA's ability to conduct pre-and post-market oversight. If federal funding remains insufficient, Congress may also consider granting FDA additional authorities, such as authorizing industry-funded user fees, which would complement Congressional appropriations.[34]

5. **Innovative state policies are important complementary strategies to ensure a safe food supply, motivate industry to seek FDA review, and spur federal GRAS reform.**
   State policies requiring public disclosure of ingredients that have not undergone FDA pre-market review, or warning labels for potentially harmful ingredients, can be important complementary strategies to federal action and catalyze product reformulation. While FDA should be the central body leading rigorous safety reviews to determine an ingredient's GRAS status, states can encourage federal reform through policy action. As in all cases where states innovate through public policy, evaluation will be an important consideration. It is also imperative that Congress does not preempt state policies in this domain.

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The American Heart Association wishes to thank the following individuals who contributed their expertise to this policy guidance. The recommendations in this statement do not necessarily represent the views of the organizations listed.

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