Generally Recognized As Safe:
Understanding How Food Ingredients Enter the U.S. Food Supply

International Food Information Council

Key Points

- The safety of the United States (U.S.) food supply is maintained through a robust regulatory framework designed to ensure all food ingredients are safe before they are consumed.
- The U.S. government is responsible for ensuring the safety of the food supply. Specifically, the U.S. Food and Drug Administration (FDA) is the government agency responsible for this oversight.
- Generally Recognized as Safe (GRAS) is one of the regulatory pathways through which new or novel use food substances can enter the U.S. food supply.
- All food substances which are generally recognized as safe must meet the safety standard of "reasonable certainty of no harm," which is based on comprehensive scientific data including toxicology, dietary exposure, and metabolism studies.
- The U.S. takes a risk-based approach to food ingredient safety, which combines both hazard and real-world exposure. A risk-based approach helps ensure food safety while allowing access to a wider variety of ingredients used within safety limits.

Introduction

The safety of the United States (U.S.) food supply is maintained through a robust regulatory framework designed to ensure all food ingredients meet established safety standards before reaching consumers. This system relies on rigorous scientific evaluation, regulatory oversight, and established procedures to identify and mitigate potential risks. Still, consumer confidence in the safety of the foods and beverages they consume has dropped over the past ten years, according to the 2025 IFIC Food & Health Survey.[1]

Today, if a food or beverage manufacturer intends to use a new food ingredient or a previously approved ingredient in a novel way, the substance must be evaluated for compliance through one of three processes: Generally Recognized As Safe (GRAS), Food Additive Petition (FAP), or if a color, a Color Additive Petition (CAP). By default, a food ingredient that has not been approved through one of these processes is deemed unsafe and cannot be legally imported or marketed in the United States.

Understanding these various approval processes as well as recent federal policy action related to GRAS is key to accurately communicating about food ingredient safety. Despite rigorous testing and regulatory processes, consumers may have questions, concerns and/or curiosity about certain food ingredients in the U.S. food supply.

This resource details the evolution of U.S. food ingredient approval and scientific requirements for approval as well as the regulatory and policy landscape. It also clarifies misperceptions and provides key messages for communicators.

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The History & Evolution Of Food Ingredient Approval In The United States

While there are many individual foods available for consumer purchase, such as frozen single-ingredient fruits and vegetables, fresh seafood, or bagged sugar, many foods we eat are comprised of multiple components, ingredients or substances.

Ingredients can include everyday components like flour, sugar, salt and oils; functional ingredients like vitamins, protein isolates or fiber sources; and substances added to foods for specific technical and/or functional purposes such as preserving freshness, enhancing flavor or appearance or improving texture. A food additive is defined in the Federal Food, Drug, and Cosmetic Act as "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."[2] An additive is a type of ingredient not typically consumed on its own as a food. For example, xanthan gum—used in salad dressings, chocolate milk, bakery fillings, puddings and other foods—is a direct additive used to add texture.[2]

In the early 20th century, food adulteration and contamination were widespread in the U.S. with minimal oversight, limited testing capabilities, and few resources to support food safety regulation. Since then, the U.S. has built a comprehensive and science-based regulatory framework that has drastically improved food safety; today's food supply is significantly safer and more transparent than it was a century ago.[3]

In the U.S., all substances added to food are subject to safety standards and must either be approved by the FDA through a formal FAP process or determined to be GRAS for their intended use.

Prior to 1958, ingredients were considered safe until proven otherwise. The Food Additives Amendment of 1958—part of the Food, Drug, and Cosmetic Act (FD&C Act) —defined a specific additive approval process and established a premarket approval system for most new food additives. This new process shifted the burden of proof of an ingredient's safety to the manufacturer prior to entering the market. This amendment dictates that if a substance qualifies as a new food additive, it may not be used unless and until FDA approves the additive through the FAP process.

The amendment also created the concept of GRAS, which allows substances widely considered safe by experts based on rigorous scientific evidence or a history of safe use to be used in food without premarket approval.[4] Finally, FDA was assigned as the regulatory agency responsible for evaluating the safety of food additives, as well as establishing and enforcing the regulations established based on the 1958 amendment. While FDA manages the day-to-day regulatory rules and procedures that implement the law, only Congress can change the provisions codified within the law of the FD&C Act and the Additives Amendment.

The Current United States Food Additive Approval Process

If a manufacturer wishes to market a new food additive or use a food additive in a different way than previously approved, the manufacturer must submit a Food Additive Petition (FAP) to the FDA. The petition must provide scientific evidence demonstrating that the substance is safe under its proposed conditions of use, including the specific foods in which it will be added and the intended use levels. Complete reports on safety studies are required. The FAP process requires the submission of detailed information, including manufacturing methods, production facilities and sample specifications. It can also include proprietary and confidential/unpublished information. FDA may also request additional data or physical samples during the review if needed.[5]

FDA then publishes a petitions notice in the Federal Register, which publicly discloses safety and functionality data.[4] Information such as manufacturing methods or process are not made publicly available if they represent a trade secret or confidential commercial information.[5] FDA evaluates the petition, and other available data and information, to determine if the data demonstrates that the food additive is safe under the proposed conditions of use. A food additive is determined to be safe if it can be scientifically demonstrated that its use meets the FDA's safety standard—a reasonable certainty of no harm. FDA determines an Acceptable Daily Intake (ADI), which is the amount of a substance considered safe to consume each day over a person's lifetime. As a final step,

the FDA issues a regulation in the U.S. Code of Federal Regulations (CFR) that authorizes the use of the food additive.

The Food Additives Amendment requires FDA to act on a petition within 180 days, yet in practice, the timeline may pause when additional information or new data is submitted. Sometimes, approvals can take years.

FDA also oversees the color additive approval process, which is more stringent than that for other food additives and requires premarket approval by the FDA. Under the FD&C Act, all color additives must be tested for safety and listed by the FDA before they can be used in food. Unlike most other food ingredients or substances, all approved color additives are subject to ongoing certification, batch-by-batch for synthetic colors, ensuring quality and compliance with safety standards.

The FEMA GRAS™ program refers to the process by which a standing expert panel of the Flavor and Extract Manufacturers Association (FEMA) independently determines whether flavor ingredients are GRAS for use in food. Established in 1960 following the Food Additives Amendment, the program evaluates the safety of flavoring substances based on scientific evidence and common use in food prior to 1958. FEMA publicly discloses the identity of flavoring substances that its Expert Panel has determined to be GRAS and submits the supporting safety data to the FDA; these substances are then listed in the FDA's Substances Added to Food Inventory (formerly Everything Added to Foods in the United States, or EAFUS).

The United States GRAS Process

Within the Food Additives Amendment of 1958, Congress expressly exempted substances considered GRAS from the statutory definition of a food additive, meaning they are not subject to the premarket approval requirements. It also defined GRAS substances in two ways:

- Common Use: For substances used in food prior to January 1, 1958, there is general recognition of safety based on substantial history of consumption by a significant number of consumers.[6] Examples of these types of ingredients include vinegar, vegetable oil, baking powder, and many spices, flavors, gums, and preservatives.
- Qualified Expert Substantiation: The substance "is generally recognized, among qualified experts, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use."[6]

While there are no statutory requirements that dictate the process or procedures for GRAS affirmation separate from prior sanction, it can take one of two different approaches—FDA-Notified GRAS or Self-Affirmed GRAS.

- FDA-Notified GRAS: Any entity or individual, although typically an ingredient or food manufacturer, voluntarily submits an application to the FDA, providing a substance description, use history, the applicable conditions of use, and scientific support of the

ingredient's safety. Pivotal safety data must be publicly available (published), but corroborative or supportive data can be unpublished, although full study reports must be provided. The submitted information is reviewed by FDA experts, and their response can be one of three possibilities, indicating acceptance, insufficiency, or ceasing of evaluation. A successful review culminates in an official "no further questions" letter from the FDA. A database of these GRAS ingredients is maintained by the FDA.

- Self-Affirmed GRAS. This process requires the same scientific scrutiny as FDA-Notified GRAS yet permits individuals to conclude that their product is safe without the final conclusion going to the FDA for review. While this route offers more autonomy, it also places a heavy onus on the GRAS determiner to ensure the ingredient's safety, sometimes based on a review by an expert panel. Public notification of these GRAS self-determinations is not required, but FDA has a voluntary notification option and encourages manufacturers to inform the agency on GRAS conclusions. At any time, the FDA retains the authority to challenge self-affirmed GRAS determinations, particularly if safety concerns arise, where the full safety dossier used to conclude GRAS status must be provided.

FDA clarified approval of substances generally recognized as safe in a final rule effective on October 17, 2016.

Scientific Requirements For Approval

The Food Additives Amendment of 1958 established the standard of "reasonable certainty of no harm" for food additives, and in various communications and regulations, the FDA has clearly stated that the safety standard for a GRAS substance is identical to the safety standard for a food additive. The scientific support considered for GRAS or FAPs include, but are not limited to the following:[5,7]

Dietary exposure to the substance	Based on the substance's intended use and all dietary sources, including natural sources, the amount consumers are likely to eat or drink must be provided. Food consumption data used to estimate this exposure must be detailed.
Self-limiting ingredient levels	If the addition of a particular level of the substance would become unpalatable or impractical from a food development standpoint, this information must be provided.

Safety under its intended use conditions

Data supporting the safety of the notified substance, considering all dietary sources and any chemically- or pharmacologically-related substances in the diet, must be detailed and cited, focused on sources that are publicly available. FAPs can use unpublished data in reports submitted to FDA.

In the GRAS process, non-public data can be corroborative only.
Scientific support typically includes the following:

- Substance chemical composition, purity and specifications.
- Safety studies (both animal and human) that evaluate potential adverse effects of the substance for toxicity, damage to DNA, harm to reproductive organs or developing fetuses and/or carcinogenicity. Short-term exposure as well as repeat exposure must be addressed.
- Metabolic research to understand how the body absorbs, metabolizes, distributes and excretes the substance.

Manufacturing process

A manufacturing process description, including controls and facilities, must be provided.

Environmental assessment

If a substance has potential for environmental impacts, an environmental assessment may be included.

Risk Vs. Hazard

A key difference in how the U.S. evaluates food ingredients scientifically—compared to some other countries—is the distinction it makes between hazard and risk. A hazard is a potential source of harm, injury, or illness. Risk, on the other hand, is the likelihood that harm will occur from the hazard. The FDA utilized a risk-based approach to its scientific evaluation— a combination of the hazard (the potential for harm) with exposure (how much of a substance people are likely to consume). Ingredients are approved, as long as the actual exposure level is considered safe for the general population. This allows for low-level use of certain substances having strict usage limits, with an understanding that outside of specified use, the substance could become hazardous.

In contrast, the European Union (EU) applies a hazard-based approach—banning or restricting ingredients solely because they contain or may produce a harmful substance, regardless of real-world exposure. The EU follows the precautionary principle, generally erring on the side of extreme caution by restricting ingredients when there is uncertainty about safety, even without definitive risk.

Emerging Applications for AI In Scientific Review Process

Given that data from varying scientific disciplines is required to approve a new substance for use in the food supply, scientific review can require hundreds of staff hours by individuals trained in toxicology, chemistry, biology and other disciplines. To help streamline scientific review processes, artificial intelligence (AI) tools are being explored within scientific and medical fields, though current technologies are not yet sufficiently advanced or specialized in ensuring the accuracy required for scientific evaluation.

AI technologies show strong potential to enhance the evaluation of scientific studies by rapidly analyzing large data sets, identifying patterns and assessing study quality more efficiently than manual methods. Tools like natural language processing can extract key details, such as study design, sample size, outcomes and conclusions, helping standardize data extraction and reduce bias. Machine learning can assist in screening studies, flagging inconsistencies and predicting evidence strength. When used with expert oversight, AI can improve transparency and support timely, data-driven decisions in areas like food safety. However, many AI models operate as “black boxes” with unclear decision-making processes. Risks of bias, particularly when trained on incomplete or low-quality data, underscore the need for expert interpretation and caution against overreliance. Ensuring AI systems are properly validated and their results are reproducible remain key challenges. While this field shows promise, proof of concept is essential to ensure models can accurately analyze and prioritize scientific studies and the weight of the evidence.

In June of 2025, the FDA launched Elsa, an (AI) tool designed to help employees from scientific reviewers to investigators work more efficiently. Elsa is described as a large language model–powered AI tool designed to assist with reading, writing, and summarizing. This tool can summarize adverse events to support safety profile assessments, perform faster label comparisons and generate code to help develop databases for nonclinical applications. It is not evident that Elsa is currently being used in the FAP or GRAS process; still, FDA has indicated this is the start of their AI journey.

Notable Regulatory & Policy Shifts

The Office of Food Chemical Safety, Dietary Supplements and Innovation within U.S. FDA Unified Human Foods Program oversees the GRAS process. For ingredients used in meat and poultry, FDA consults with the U.S. Department of Agriculture (USDA) during the review process.

However, as noted above, in self-affirmed GRAS, entities determine the safety of food ingredients without FDA oversight or mandatory notification. Critics argue that the GRAS process raises transparency concerns and potential conflicts of interest, as industry-funded expert panels may be biased; they also note potential risks such as insufficient safety data, undisclosed health effects

(like endocrine disruption or carcinogenicity), and a “revolving door” between industry and regulators. Critics cite that the lack of FDA oversight may hinder the agency’s ability to monitor cumulative exposures or respond quickly to emerging food safety issues.

Proponents of self-GRAS suggest that food companies are committed to using strong scientific evidence and robust safety data when making self-GRAS determinations, recognizing that rigorous safety standards are essential to protect their reputation, build consumer trust and reduce the risk of future liability. Proponents note that investing in credible, transparent science not only supports responsible product innovation but also helps safeguard long-term brand value in an increasingly health- and safety-conscious marketplace.

Once an ingredient enters the food supply—whether through the FAP process or GRAS affirmations—the FDA has mechanisms to monitor and reassess its safety on a post-market basis. The FDA conducts post-market reviews of food additives and GRAS substances by monitoring scientific research, adverse event reports and emerging safety concerns. For approved food additives, the FDA can reassess safety, update regulations or remove approvals if new risks are identified. The FDA can take enforcement actions, such as issuing warnings or banning substances, if evidence shows a product is unsafe. In June of 2025, FDA released for public comment their proposed method intended to provide a transparent, systematic and science-based approach to determine which chemicals the agency would prioritize for post-market assessments.

Additionally, on March 10, 2025, Robert F. Kennedy, Jr., the Secretary of the U.S. Department of Health and Human Services directed the FDA to "explore potential rulemaking to revise its Substances Generally Recognized as Safe (GRAS) Final Rule and related guidance to eliminate the self-affirmed GRAS pathway."[8] This could potentially mean entities would no longer be able to self-declare ingredients as safe without notifying the FDA, as the agency would review all GRAS determinations. This change is intended to enhance transparency and ensure all food ingredients are adequately vetted for safety.

The pathway to revising the self-GRAS processes remains unclear, especially given various elements would require congressional action and are not within FDA's regulatory control. Additionally, the potential added work that would be required if FDA reviewed all GRAS notifications as well as the corresponding and necessary resources must be considered. The press release following Secretary Kennedy's March announcement did indicate HHS would work “with Congress to explore ways legislation can completely close the GRAS loophole.”[8] Until a new pathway is determined and confirmed by FDA, the current approach will continue to be used.

Key Messages For Experts & Educators

For educators and communicators, understanding FAP and GRAS means more than knowing the law and the approval process; it means being able to explain it in a way that builds trust, supports informed choices, and helps bridge the gap between science, policy, and public perception.

The key messages shared below are designed to equip educators and experts with clear, science-based information to address common questions and misconceptions about food ingredients and additives.

The IFIC Spotlight Survey: American’s Perceptions of Food Ingredient Safety found that Americans want more facts (38%) and practical actions (33%) than science (14%) when

making food decisions. Whether communicating through social media, educational programs, media interviews, or community outreach, these messages provide a foundation to engage audiences with balanced, accurate, and practical information.

The Role Of Food Ingredients & Additives

- Food ingredients and additives serve important roles in the foods we enjoy every day —helping deliver improved taste, safe storage, appealing appearance and convenience.
- Some food additives help maintain freshness and prevent spoilage, improve texture, enhance color and flavor and allow food to remain safe and affordable.
- Consumers benefit from foods that are more accessible, convenient and consistent without sacrificing safety due to new and innovative food ingredients.
- Novel food ingredients allow for innovation, such as products that meet special dietary needs, support nutrition goals or reduce food waste.

Can I Safely Consume Food Ingredients & Additives?

- Yes, these ingredients are backed by rigorous science and regulatory oversight by the U.S. Food and Drug Administration (FDA).
- Before introducing new additives and similar ingredients into foods, manufacturers invest in strong scientific data to protect human health as well as their brand.
- Communicators can reassure families that the food system is built on multiple layers of safety assessment, monitoring, and regulation designed to protect public health.

How Is Food Ingredient Safety Evaluated?

- Ingredients must be proven safe before use. Whether an ingredient is an everyday staple like flour or a functional component like a preservative, it must meet strict safety standards set by the U.S. Food & Drug Administration (FDA) before being used in food.
- All food substances which are Generally Recognized as Safe (GRAS) must meet the safety standard of “reasonable certainty of no harm,” which is based on comprehensive scientific data including toxicology, dietary exposure, and metabolism studies.
- Food ingredient safety in the U.S. is based on scientific consensus, not guesswork.
- No ingredient can legally be added to food in the U.S. without a safety determination through premarket FDA approval, GRAS status, or a prior exemption.
- U.S. ingredient safety decisions are based on risk, combining both hazard and real-world exposure. This risk-based approach helps ensure food safety while allowing access to a wider variety of ingredients when used within defined consumption levels.

- Consumers want simple, actionable information about ingredients, not complicated science. Educators can build trust by explaining what ingredients do, why they're used, and how to make informed food choices.

Who Is Responsible For Evaluating Food Ingredient Safety?

- The Office of Food Chemical Safety, Dietary Supplements and Innovation within U.S. Food and Drug Administration (FDA) Unified Human Foods Program oversees the Generally Recognized As Safe (GRAS) and Food Additive Petition (FAP) processes.
- Even after new substances are introduced into foods, FDA monitors ingredient safety and updates approval status as necessary.
- Different countries apply different safety standards—while the U.S. focuses on risk (hazard + exposure), other countries may ban ingredients based solely on hazard using the precautionary principle, even when actual risk is low.
- Food and beverage as well as supplement manufacturers have a fundamental responsibility to ensure the safety of the ingredients used in their food and beverage products as quality and safety are top priorities.

What Is The GRAS Process & How Does It Work?

- GRAS (Generally Recognized as Safe) means that qualified experts, and sometimes the U.S. Food and Drug Administration (FDA), agree a food ingredient is safe to eat based on scientific evidence or a long history of common use.
- GRAS was created to streamline approval of substances with established safety profiles, reducing regulatory burden without compromising consumer safety.
- FDA encourages transparency through voluntary notification and maintains authority to intervene if safety concerns emerge.
- Recent policy discussions are focused on increasing transparency in GRAS determinations, including potential reforms to limit self-affirmed GRAS.

Educators can play a key role in explaining how food ingredients are reviewed for safety and regulated, as well as how the U.S. food system protects public health. For more information, visit: ific.org/GRAS

Appendix A: Glossary Of Terms

Acceptable Daily Intake (ADI): The amount of a substance that can be consumed daily over a lifetime without appreciable health risk, as determined by the FDA.

Color Additive Petition (CAP): A regulatory submission required for approval of color additives in food. CAPs are reviewed more stringently than general food additives and require premarket FDA approval.

Delaney Clause: A provision in the Food Additives Amendment of 1958 that prohibits the approval of any food additive shown to cause cancer in humans or animals, regardless of the level of exposure. While it reflects a zero-risk standard for carcinogenicity, the clause has been controversial due to advances in toxicology and risk assessment, and it has limited application today as modern regulatory approaches focus on actual exposure and risk rather than the mere presence of a hazard.

Dietary Exposure: The estimated amount of a substance that individuals consume through their diet, based on intended use and occurrence in food.

Exposure (in Risk Assessment): The amount of a substance that a person is likely to ingest, which, when combined with hazard information, forms the basis of FDA's risk evaluation.

FDA-Notified GRAS: A voluntary submission to the FDA in which a manufacturer presents data supporting that an ingredient is Generally Recognized as Safe (GRAS). FDA reviews the information and responds with one of several possible outcomes.

FEMA GRAS: A safety evaluation program led by the Flavor and Extract Manufacturers Association to determine if flavoring substances are GRAS, based on expert panel review.

Food Additive: Any substance that is not normally consumed as food itself but is added to food for a specific function (e.g., preservation, texture, flavor enhancement).

Food Additive Petition (FAP): A required submission to the FDA to request approval for a new food additive or a new use of an existing additive. Includes detailed scientific and manufacturing data.

Generally Recognized as Safe (GRAS): A regulatory status for substances widely acknowledged by qualified experts to be safe under intended use conditions, allowing exemption from the formal FAP process.

Hazard vs. Risk: Hazard refers to the potential of a substance to cause harm, while risk considers both the hazard and the likelihood of exposure to determine actual danger.

Premarket Approval: Regulatory authorization that must be obtained before marketing a new food additive, typically through the FAP process.

Post-Market Review: Ongoing FDA surveillance of food additives and GRAS substances after they enter the food supply, using adverse event reports, research, and safety data.

Precautionary Principle: A regulatory approach in which substances are restricted or banned when safety is uncertain, even if risk is not definitively demonstrated.

Reasonable Certainty of No Harm: The FDA's safety standard for approving food substances, meaning there is a high level of confidence that no harm will result from intended use over a lifetime.

Risk Assessment: A scientific evaluation that combines hazard identification and exposure estimates to determine whether a substance poses a risk under specific conditions.

Self-Affirmed GRAS: A process by which companies independently determine an ingredient is GRAS without FDA review. Often involves expert panels but is not publicly disclosed unless voluntarily submitted.

For more science-based resources, visit ific.org

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