

➤ MAINTAINING A PROVEN, SCIENCE-BASED GRAS FRAMEWORK



America's food safety system is robust, science-based, and trusted around the world. Across the supply chain, manufacturers are committed to producing safe, nutritious food and beverages that are both affordable and widely available.

A key part of America's food safety system is the **Generally Recognized as Safe** framework, which for decades has provided a safe, efficient, and effective regulatory pathway for food ingredients and packaging, making the **U.S. a world leader in innovation.**

Manufacturers support focused improvements to GRAS that increase transparency and trust without unnecessarily raising costs or inhibiting innovation. Any such modernization should fall within appropriate statutory authority and preserve the benefits the system provides to both manufacturers and consumers.

What GRAS Really Is

Congress created the GRAS concept in 1958 as part of the Food Additives Amendment to the Federal Food, Drug, and Cosmetics Act, with the **intent of exempting substances from mandatory FDA premarket approval that are already generally recognized by qualified experts as safe for their intended use(s).**

The FDA specifically states that “[b]ecause of the large number of substances...it is impracticable to list all such substances that are GRAS.” In addition, the agency has long interpreted the statute to limit its authority to expand premarket approval requirements without congressional action.

GRAS is not a loophole. It is a legal, science-based system that has an enviable safety record and is a key factor in making the United States the world leader in science-based and trusted food innovation.

The Risk of Major Disruption

Proposals that would require FDA approval for every ingredient use or manufacturing change prior to commercialization **would risk straining agency resources and disrupting food and agriculture supply chains.** Such proposals would also misalign the U.S. with other global regulatory authorities, which would have significant effects on small and mid-sized food manufacturers. Compliance costs would increase, and food prices would likely rise. **The pace of innovation would slow, and the U.S would likely lose its first to market advantage.**

A Better Approach

Manufacturers support principles that modernize and strengthen the GRAS framework without dismantling it, including:

- A centralized, public listing of substances subject to self-GRAS determinations
- Systematic, risk-based post-market assessment by FDA
- Clear scientific standards and best practices for expert review
- Continued protection of confidential business information
- A uniform national standard to avoid a patchwork of state laws that undermine business certainty and federal law

These measures would improve transparency and trust and preserve flexibility and innovation without breaking a system that already works. Further, any major changes to GRAS should be made by Congress—not through regulatory shortcuts—to ensure that FDA's authorities remain clear, predictable, and grounded in statute.

› THE BOTTOM LINE:

A stable, predictable GRAS framework helps keep manufacturers at work providing safe, affordable, and available food and beverage products for all American families.