FACT SHEET | Healthy America

Take Back Your Health: Closing the GRAS Loophole

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THE "GENERALLY RECOGNIZED AS SAFE" PATHWAY

All Americans deserve to know what is actually in their food, not just be told to trust that their food products are safe. Unfortunately, many Americans don't know what they are consuming or even how to pronounce most of the ingredients on the label. Nearly 60% of the American diet is made up of ultra-processed foods, with unknown ingredients. Addressing this issue starts with modernizing our food system and creating a clear federal definition of "ultra-processed", so Americans can better understand how to make the best decisions for them and their family.

THE GRAS LOOPHOLE

Before 1958, the Food and Drug Administration (FDA) had no authority to require pre-market safety reviews for food additives. This was reversed by the 1958 Food Additives Amendment, which created the Generally Recognized As Safe (GRAS) pathway. This pathway allowed food companies to exempt certain foods from the FDA's full pre-market approval process if the ingredient had a documented history of safe use in food or qualified experts agreed that the ingredient is safe. This was originally intended for ingredients like salt, pepper, baking powder, and vinegar.

Over time, this pathway became the default way for new ingredients to enter the U.S. food supply, including ingredients that the public would say do not meet the spirit of the GRAS pathway and far beyond its original purpose. One example is potassium bromate, a dough conditioner used in U.S. commercial bread production that has since been banned in the EU, UK, and Canada due to its known link to cancer. The exploitation of the GRAS pathway has factored into the chronic disease crisis; in fact, researchers have identified food additives as a contributing factor to Americans' worsening health.

The existing regulatory language creates a voluntary notification system for food companies to self-attest that their product can be safely consumed.

- Existing regulatory language at 21 CFR §170.205 states that "any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use."
    - The voluntary notification requirement lets a company conduct its own review and self-affirm that an ingredient is safe, without submitting its findings to the FDA.
    - A March 2026 analysis of ingredients revealed that over 100 food chemicals have been secretly added to the U.S. food supply, without the FDA or the public being alerted.
    - One of these ingredients, tara flour, made 393 people ill, and another 133 were hospitalized. The food company, Daily Harvest, used the GRAS pathway to bring this ingredient to market without even submitting a voluntary notification. The FDA has since done a full safety review and concluded this ingredient did not meet the GRAS safety standards.

Depending on the substance and its intended use, ingredients do not all follow the same regulatory pathway before entering the U.S. food supply, creating a confusing web of approvals.

- An ingredient may require formal FDA premarket approval, qualify under existing GRAS regulation or historic review, or be introduced based on a manufacturer's own GRAS determination.
    - Direct Food Additive Petition: A manufacturer submits a petition for FDA review when a substance does not qualify for GRAS status or another exemption. FDA must review the safety evidence and issue a regulation authorizing the intended use before the additive may be marketed for food use.

- FDA-affirmed GRAS substances: FDA historically affirmed the GRAS status of certain substances through rulemaking. These ingredients are listed in 21 CFR Parts 182, 184, or 186.
- SCOGS Review: In the 1970s, FDA's Select Committee on GRAS Substances (SCOGS) reviewed the available scientific literature for many ingredients already considered GRAS. SCOGS conclusions are an important part of the historical record, but a favorable SCOGS review does not itself operate as a current, stand-alone FDA approval for every possible use of a substance.
- Voluntarily Self-Affirmed GRAS: A manufacturer may independently conclude that a substance is GRAS for a specific intended use and voluntarily notify FDA under 21 CFR §170.205.
- Self-Affirmed GRAS: A company may also make its own GRAS determination and market the ingredient without submitting a GRAS notice to FDA. The company remains responsible for having sufficient publicly available evidence and expert consensus to support the determination, but FDA may have no advance notice or opportunity for premarket review. This pathway is commonly referred to as "the loophole."

MODERNIZING THE GRAS PATHWAY

On August 10, 2026, the U.S. Department of Health and Human Services (HHS), led by Secretary Robert F. Kennedy, Jr., announced the department's plan to take major steps toward closing the GRAS loophole and provide greater transparency into American food quality, in line with recommendations that the America First Policy Institute (AFPI) has championed previously.

The new proposed rule requires manufacturers to notify FDA when a substance added to food is GRAS, instituting mandatory GRAS notification rather than voluntary GRAS notification.

★ The proposed rule amends 21 CFR Parts 170 and 570 to require mandatory GRAS notifications, with exemptions for substances already listed under 21 CFR Parts 182, 184, or 186. It requires:
- Public Transparency. The FDA will be required to maintain and update a public inventory of all GRAS notices, in accordance with 21 C.F.R. Part 20.
- Review of Existing GRAS Ingredients. For companies already using self-affirmed GRAS ingredients on the market, FDA is proposing a practical, time-limited, streamlined pathway that provides a predictable regulatory route.
- Penalties for Noncompliance. The FDA will review new GRAS submissions within 180 days, remaining with the current standard practice for voluntary notices. If a company doesn't submit the required notice at all, FDA will treat that noncompliance as a factor in deciding which substances to prioritize for post-market safety review, meaning those products will have a higher chance of being flagged in the future.

HHS and the U.S. Department of Agriculture (USDA) proposed the federal government's first definition of ultra-processed foods (UPFs). Without a standardized definition, research for UPFs has lacked consistency across government agencies, and Americans have lacked information.

MAKING AMERICANS HEALTHY AGAIN

Since the 1958 Food Additives Amendment created the GRAS pathway, Americans' health has changed significantly. Today, more than 70% of Americans are overweight or obese, and 75% of American adults report at least one chronic condition. The proposed reforms to the American food supply will modernize our food system and support American education on nutrient dense food.