Environmental Defense Fund

BROKEN GRAS

HOW A COMMON-SENSE LEGAL DESIGNATION WAS CO-OPTED TO LET UNSAFE INGREDIENTS INTO OUR FOOD.

At least 1,000 ingredients in food products on our grocery store shelves have never been checked for safety by FDA. The reason for this lies in the misuse of a little-known legal designation called GRAS–or Generally Recognized as Safe.

WHAT IS GRAS AND WHAT DOES IT DO?

Generally Recognized as Safe (GRAS) is a designation Congress created for a small number of commonly used food ingredients which would not need pre-market safety approval by the Food and Drug Administration (FDA). These substances had been routinely used for a long time and were found to be safe through their history of common use in food. Examples include oils, vinegar, baking soda and common spices.

Unfortunately, the universe of substances designated as GRAS has grown far beyond what Congress originally intended. Today, almost all new food substances that enter the market are designated as GRAS.

Current law requires manufacturers to demonstrate that a new food ingredient meets FDA's safety standard of "reasonable certainty of no harm" before it can be released on the market. However, FDA interprets the law in a way that allows companies to independently—and often secretly—determine the safety of substances.

THE GRAS DESIGNATION PROCESS IS RIDDLED WITH CONFLICTS OF INTEREST

A substance is eligible for GRAS classification if there is "common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use." In other words, the substance must be widely recognized by experts as safe to use in food—essentially, commonly accepted as safe.

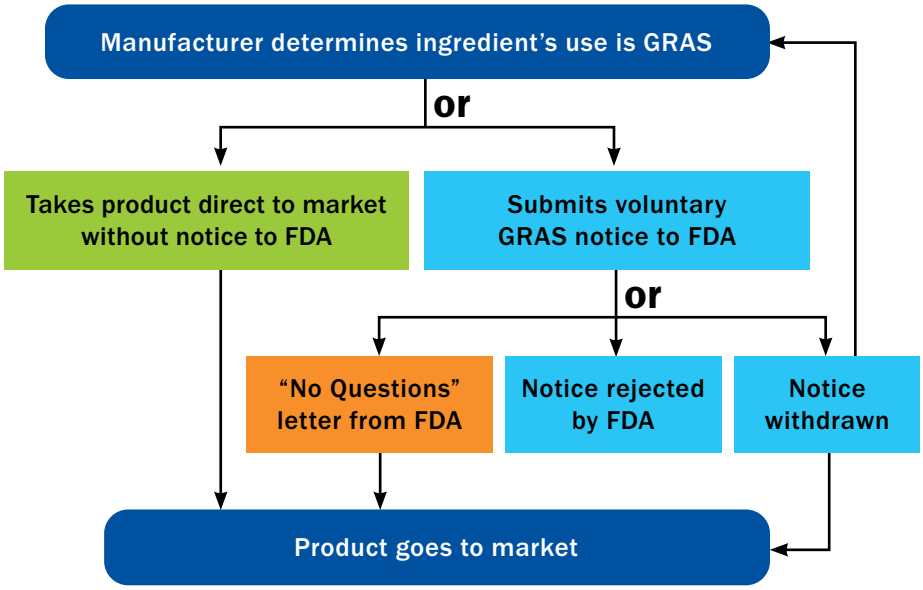
Companies often rely on their own employees, a panel of hired experts or advice from hired consultants to help them classify a substance as GRAS. Given their financial ties to the company, these reviewers are hardly independent. This results in a process plagued with bias and conflicts of interest. To make matters worse, manufacturers are not even required to notify FDA when they deem an ingredient as GRAS before taking it to market.

The Legal Definition of GRAS:

"generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use" (21 CFR 170.30).[1]

[1] https://uscode.house.gov/view.xhtml?req=(title:21%20section:321%20edition:prelim)

A GRAS SUBSTANCE'S PATH TO MARKET



THE CURRENT GRAS SYSTEM PUTS AMERICANS' HEALTH AT RISK

The current GRAS designation process allows companies to avoid FDA review, with real-life impacts on Americans' health. Harmful substances that have been falsely declared GRAS, such as tara flour, have caused illness and even death.

The voluntary GRAS notification system provides poor or often no visibility into the chemicals in our food, making it ineffective at protecting our health. Records indicate that manufacturers have notified FDA of fewer than half of the chemicals that they market as GRAS. Even if a company notifies FDA of a GRAS determination and FDA later raises questions about whether the determination complies with regulations, the manufacturer can withdraw its request for review and still claim the product is GRAS.

REFORMING GRAS

A comprehensive fix to GRAS will require legislation from Congress. In the meantime, FDA has options to ensure a more rigorous GRAS determination process that better protects Americans' health.

WHAT FDA CAN DO NOW

- **Use existing authority to remove GRAS designations from ingredients it deems unsafe** and take them off the market. FDA can also notify manufacturers, importers, distributors and retailers that the substance is no longer GRAS.
- **Enforce the requirement that companies base GRAS designations on publicly available data.** Although this won't curtail companies' ability to self-declare substances as GRAS, it will require those who do to be transparent in citing their evidence.
- **Enforce the requirement that GRAS safety assessments consider vital health information** such as a substance's dietary sources, potential cancer risks and the cumulative health effects of similar substances.
- **Prevent companies from withdrawing GRAS notices by notifying them when they fail to comply with GRAS criteria** and requiring them to revise and resubmit their data for review.

A COMPREHENSIVE FIX: WHAT CONGRESS CAN DO

- Congress can make GRAS more health protective by updating the law to require all GRAS determinations to be independently reviewed and approved by FDA before an ingredient is allowed on the market.
- Congress can also improve transparency by revising the law to require public disclosure of all safety data supporting GRAS determinations.