Let's Mow Down the GRAS Myths

Generally Recognized as Safe (GRAS) is a science-based framework that helps ensure the safety of the ingredients used in the affordable and convenient foods and beverages that Americans rely on every day. Today, there is enhanced interest in the GRAS process and the U.S. Food and Drug Administration (FDA) recently published a proposed rule that would require mandatory GRAS notifications for human and animal food substances purported to be GRAS. The CPG industry has consistently supported greater transparency and welcomes GRAS reform as part of a national uniform standard for ingredient safety and transparency, including updated FDA regulations that require mandatory notification.

MYTH

GRAS Isn't Clearly Defined

FACT

GRAS status is defined in the Federal Food, Drug and Cosmetic Act under section 201(s) as, "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." GRAS substances are excluded from the definition of food additives, although the safety standard is the same.

MYTH

GRAS Ingredients Aren't Properly Evaluated for Safety

FACT

GRAS status requires safety evidence that is publicly available and widely accepted by qualified experts, with key data published (typically in peer-reviewed journals) and a consensus that the substance is safe for its intended use.

MYTH

GRAS Is Just a Loophole

FACT

GRAS is not a loophole; it's a science-based regulatory pathway established by Congress and overseen by the FDA. GRAS ingredients must meet the same "reasonable certainty of no harm" safety standard as approved food additives. GRAS substances are subject to FDA oversight and post-market review enforcement. Indeed, FDA recently proposed a rule that if finalized, would make FDA's oversight more robust and provide more detailed ingredient information to the public.

MYTH

Nothing Happens if New Safety Concerns Emerge

FACT

GRAS safety determinations are made case-by-case using current scientific evidence, must be conducted by qualified experts, and can change over time as new evidence emerges. Companies and FDA are expected to reevaluate their GRAS determinations as new safety data or concerns emerge. FDA is able to act if a substance is no longer considered safe and has issued a proposed rule that would enhance its ability to efficiently respond to new safety concerns.

MYTH

The Food Industry Opposes GRAS Reform

FACT

The CPG industry supports greater transparency and welcomes GRAS reform as part of a national uniform standard for ingredient safety and transparency, including updated FDA regulations that require mandatory notifications.