

# FDA's Proposed GRAS Rule: Mandatory Notifications, Expanded Scope, and Open Questions

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Following through with long-stated intentions, FDA yesterday [published](#) a proposed rule that could fundamentally reshape how food substances reach the U.S. market under the Generally Recognized as Safe (GRAS) framework. Under the proposed rule, what has historically been a voluntary notification system would become mandatory, requiring companies to disclose their GRAS conclusions to FDA before—or shortly after—introducing substances into interstate commerce. The rule would also establish a streamlined version of the submission process for certain intended uses of substances already on the market.

The rule raises several questions that are likely to be debated extensively in the public comment period that runs through December 9, 2026, including those related to FDA's legal authority to require GRAS notifications, the agency's capacity to administer and oversee the program, and the practical impact on industry. As part of the announcement of the GRAS Rule, HHS also announced that it has submitted for final review, along with the USDA, a long-awaited proposed definition of ultra-processed foods (UPFs) and, presumably, related requirements and restrictions on UPFs.

## What the Proposed Rule Would Do

At its core, the proposed rule would require any person introducing a substance into interstate commerce based on a GRAS conclusion under Section 201(s) of the FD&C Act to notify FDA of that conclusion. Companies that choose not to do so would not be prohibited from marketing the substance, but they could face increased post-market scrutiny. Key aspects of the proposal include:

- Companies would no longer be able to rely solely on self-affirmed GRAS determinations without any disclosure to FDA. In this regard, the longstanding practice of independently concluding that a substance is GRAS and marketing it without notifying the agency would effectively come to an end.
- Importantly, however, the proposal would not convert GRAS determinations into a premarket approval system. Companies could continue to market substances without any FDA review or approval. However, failure to submit a required notification would become a factor in FDA's risk-based prioritization for post-market review and enforcement of food and pet food products.
- Not every substance would require a new GRAS notice. The proposal exempts, among other things, substances that have already received an FDA "no questions" letter, are affirmatively listed in FDA regulations as GRAS, are covered by an effective Food Contact Notification, or

have been reviewed through certain existing FDA programs, such as biotechnology consultations.

- Recognizing that many substances have been marketed for years based on independent GRAS conclusions, the proposal provides a one-year transition period during which companies may submit abbreviated information rather than a full GRAS notice. FDA estimates that more than 1,000 substances currently on the market may fall into this category.
- The proposal would extend and modify the Threshold of Regulation (TOR) process, historically limited to food contact substances, to a broader range of food substances that meet updated safety criteria. FDA would also revise exposure calculations to better account for differences among subpopulations.
- To accommodate the anticipated increase in submissions, FDA proposes extending its review period from 180 days to as much as 360 days, including up to two 90-day extensions.

## The Catalyst and the Proposed Rule's Expanded Scope

- The political momentum for the proposed rule stems both from the Make America Healthy Again or "MAHA" movement and a series of high-profile safety concerns involving substances that entered the food supply without FDA review. In the preamble, FDA points to several examples of recalls, import alerts, or warning letters involving certain ingredients, including tara flour, which was associated with hundreds of adverse event reports and hospitalizations in 2022; Delta-8 THC products, which raised neurodevelopmental and cardiopulmonary concerns; caffeinated alcoholic beverages that prompted FDA warning letters; ashwagandha, which FDA placed on import alert after concluding it was an unsafe food additive; and stevia leaf crude extracts, which remained on the market for decades despite longstanding FDA concerns.
- These examples helped fuel calls for greater transparency, culminating in Secretary Kennedy's March 2025 directive to explore rulemaking and the Administration's broader "Make America Healthy Again" initiative. Although much of the public discussion has focused on food ingredients that consumers intentionally ingest, FDA framed the proposal more broadly. The rule would apply not only to ingredients added directly to food, but also to substances that enter food indirectly through packaging, processing equipment, containers, and other food-contact applications.

If finalized, companies would have 18 months from the rule's effective date to comply with what would be one of the most significant changes to the GRAS framework in decades. Mandatory GRAS reporting would create additional compliance burdens for industry stakeholders, despite FDA's apparent intention to preserve the industry's ability to make independent GRAS conclusions.

## Questions Worth Asking

### ***Does FDA Have the Legal Authority?***

FDA states that it is issuing the proposed rule "consistent with our authority in sections 201, 402, 409, and 701 of the FD&C Act," arguing that mandatory notifications help the agency fulfill its post-market review authority under § 409(a) and (d) to determine whether substances constitute unapproved food additive uses.

But this argument has potential vulnerabilities. Congress in 1958 specifically exempted GRAS

substances from premarket approval requirements. The GRAS provision was designed to allow the food supply to function without FDA having to pre-clear every safe substance. Does a mandatory notification requirement conflict with that Congressional intent? The rule carefully insists it is “not a premarket review program,” but the practical effect of heightened enforcement priority for non-notifiers blurs that line. Whether FDA can impose a notification requirement without congressional action remains an open question and is likely to be a central issue in any legal challenge to the rule.

### ***Can FDA Actually Handle the Volume?***

FDA acknowledges that the rule will significantly increase submissions. As of January 2011, an estimated 1,000+ substances were on the market under independent GRAS conclusions, and the streamlined submission window alone could produce 155 filings in a single year (by FDA’s own estimate). Add ongoing mandatory notices for new substances, and the pipeline could grow substantially.

The two additional 90-day extension periods (potentially stretching review to 360 days) are a tacit acknowledgment that resources may not keep pace. If FDA cannot timely evaluate notices, the practical effect may be a growing backlog of filed-but-unreviewed GRAS notices—technically satisfying the “notification requirement” while providing little actual safety oversight. This raises the question of whether mandatory notification without corresponding review capacity actually achieves the stated safety goals, or merely creates an administrative burden for industry without corresponding benefits to the public.

## **What Companies Should Do Now**

Companies that rely on self-GRAS determinations should consider the requirements of the Rule and consider submitting comments on particular requirements or issues with particular relevance. Additionally, in evaluating potential compliance burdens of the rule, companies should:

- Identify products containing substances that rely on self-GRAS conclusions.
- Evaluate the strength and completeness of existing GRAS documentation and request any documentation from suppliers where applicable.
- Identify any gaps between the initial self-GRAS conclusion and current uses.
- Determine which affected products were introduced into interstate commerce before the effective date of any final rule and assess potential eligibility for the proposed streamlined notification pathway.
- Evaluate how the proposed rule will impact business operations and consider whether alternative regulatory pathways or reformulation strategies could reduce future compliance burdens.

The proposed rule raises hard questions about statutory authority and administrative capacity. Comments are due December 9, 2026, and stakeholders in both the ingredient and food contact spaces should be paying close attention.

## **FDA’s Highly Anticipated UPF Definition Remains Under Wraps**

Separately, FDA Acting Commissioner Kyle Diamantas announced that a white paper outlining the agency’s proposed definition of ultra-processed foods (UPFs) is currently under White House review.

Additional details are expected in the near future. We will continue to follow this issue.