



A Regulatory Mirage:

Why the Proposed GRAS Rule Fails to Protect Public Health

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I. Introduction:

The Food and Drug Administration's proposed rule that would transition from a voluntary GRAS (Generally Recognized As Safe) Notification Program to a mandatory one ostensibly signals a commitment to greater transparency and oversight in the food supply. However, a thorough analysis of the proposed rule reveals that it represents a regulatory mirage. While the shift toward a mandatory notification process appears to be a step forward, the proposal fails to address the fundamental regulatory gaps that have long plagued the GRAS framework.

Our analysis shows that the proposed rule is insufficient to protect public health because it preserves the core deficiencies of the existing system. By failing to require premarket safety evaluations and neglecting evidence of safety for the approximately 1,000 "secret" GRAS substances already in commerce, the proposal falls short of necessary reform.

Furthermore, the rule's weak enforcement mechanisms—treating non-compliance merely as a factor for future review rather than a trigger for immediate action—threaten to solidify a system that prioritizes industry convenience over consumer safety. This analysis details these critical shortcomings and outlines the essential steps required to establish a robust, science-based safety assessment process.

Independent of the rule's substantive failings, internal warnings from agency staff—through recent [media reports](#)—suggest a lack of resources necessary for implementation. These reports indicate that, without an increase in staffing, the additional burden of the proposed rule would likely exceed the agency's current operational capacity.

II. The Transition to Mandatory GRAS Falls Short

While appearing to be a positive step forward, the proposed rule is actually more of a mirage, with a number of the following caveats.

- **The mandatory safety data determination part of the GRAS Notification Program only covers new substances (or new uses of existing substances).** This would not adequately address the safety assessment for all the secret GRAS substances (thought to be roughly 1,000) that may already be on the market.
- **Does not require notification completed before the substance is allowed on the market.** In fact, there is no clear timeline for when the notification is required to be submitted. Would it be acceptable for a company to put a new substance on the market six months before a GRAS notice is submitted? As the proposed rule notes:

“Thus, a company may continue marketing a purported GRAS substance before submitting a GRAS notice or after submitting a GRAS notice before it is filed by FDA. Similarly, a company may reach a GRAS conclusion about a new use of a substance and introduce the substance into interstate commerce before submitting a GRAS notice.”
- **FDA makes clear that this proposed rule does not require premarket evaluation.** This is a significant problem, given that a legal analysis demonstrates that the FDA could require premarket review of GRAS substances.
- **Weak enforcement.** If a GRAS Notice is not submitted, food is not considered adulterated and can remain on the market. Rather, FDA would only “consider such noncompliance as a factor in its prioritization of food substances for post-market review.”

III. The Streamlined Submission Loophole Undermines Safety and Oversight

The introduction of a 'streamlined submission' process for trying to retrieve data on secret GRAS substances that might currently be on the market creates significant regulatory loopholes that prioritize administrative efficiency over the rigorous safety assessment of food ingredients. This may inadvertently encourage companies to rush new substances onto the market without any safety data. This approach not only leaves safety rationales undisclosed but also encourages practices that weaken proactive oversight, as detailed below.

- **Under this "streamlined submission," companies would not be required to provide the safety data supporting their GRAS determinations.** Instead, filings would only need to include basic information: i) the submitter's name and address, ii) the substance's name using descriptive terms, and iii) the intended use conditions—such as target foods, use levels, and intended functions. Consequently, while secret GRAS substances would be identified, the safety rationale behind them would remain undisclosed.
- **Because enforcement of mandatory notification remains weak, companies may simply choose not to file streamlined submissions for their secret GRAS ingredients.** This makes the disclosure of secret GRAS substances essentially voluntary, leaving FDA with no clear way to identify non-reported uses. Although receiving basic identity and use details is a small step forward, it remains insufficient without safety data. The lack of data places the burden of proof entirely on the FDA to demonstrate a substance is unsafe before taking enforcement action. This legal dynamic reverts regulatory oversight back to the Pure Food and Drug Act of 1906, which required the FDA to prove harm, rather than the framework established by the 1938 Federal Food, Drug, and Cosmetic Act, which mandated that companies demonstrate safety prior to market entry.
- **The "time-limited period" creates a significant regulatory loophole by allowing the introduction of various new ingredients or applications without mandatory safety data.** Companies would essentially be incentivized to rush substances into commerce before one year following the rule's enactment to avoid disclosure requirements, thereby shifting the burden of proof to the FDA. This framework is particularly alarming for substances with limited existing or no toxicity data, as it effectively presumes safety until the agency can prove harm—a dynamic that fundamentally undermines proactive public health protection.

IV. The Proposed FOIA Exemption Obscures Safety Data

The proposed rule introduces a regressive policy regarding data transparency by permitting companies to exempt safety-related information from disclosure under the Freedom of Information Act (FOIA). Specifically, the changes to § 170.250(e) allow notifiers to withhold non-public safety data while claiming a basis for GRAS status. This provision is deeply concerning, as it fundamentally undermines the possibility of independent scientific review—a prerequisite for ensuring true food safety.

Since the history of the voluntary GRAS program demonstrates that inadequate safety analyses have historically led to unapproved food additive uses, shielding the supporting data from public scrutiny represents a significant step backward.

Ensuring the safety of the food supply requires transparent, verifiable scientific evidence; by permitting the concealment of safety data under the guise of proprietary exemption, the FDA risks prioritizing corporate secrecy over the public's ability to independently verify the safety of substances introduced into the marketplace. Health and safety data should never be designated as confidential business information (CBI).

V. The Risks of Expanding Threshold of Regulation (TOR) Exemptions

The proposed revisions to § 170.39 represent a dangerous expansion of the Threshold of Regulation (TOR) exemption, extending its scope beyond food contact substances (FCS) to include direct food additives. This expansion rests on the scientifically unsupported assumption that substances present in food at dietary concentrations below 0.5 parts per billion (ppb)—or 500 parts per trillion (ppt)—cannot pose a health risk. Current scientific data contradicts this threshold, as substances such as PFOA and PFOS are known to cause adverse health effects at levels significantly lower than 500 ppt.

Furthermore, the TOR proposal fails to account for the critical issue of cumulative effects. It neglects to consider that multiple direct and indirect food additives—each individually below the 500 ppt limit—could act on the same safety endpoint, potentially resulting in aggregate exposures that cause adverse health effects. Because the TOR framework operates without requiring comprehensive safety data or even ingredient identification, the FDA would be virtually unable to identify these substances, rendering any evaluation of cumulative risk almost impossible.

VI. Failure to Address Omissions in Science and Emerging Technologies

The proposed rule fails to reconcile the GRAS framework with contemporary scientific advancements, remaining anchored in 1958 paradigms while neglecting modern safety concerns. While the proposal correctly excludes carcinogens, it stops short of addressing other critical categories of substances—specifically endocrine-disruptive chemicals, genetically engineered chemicals, and engineered nanoparticles. Furthermore, the reliance on "expert" determinations for general recognition of safety often lacks the rigorous scientific scrutiny required for food additives, a deficiency particularly evident in the current handling of genetically engineered ingredients.

Most critically, the proposal overlooks the distinct safety profiles of emerging technologies, particularly intentionally engineered nanoparticles. These substances possess unique physical characteristics—such as increased surface area and altered bioavailability—that distinguish them from their traditional, macroscale counterparts. Consequently, safety assessments based on macroscale models are fundamentally inadequate.

Although the FDA's 2014 guidance acknowledged these risks, it remains non-binding and insufficient to protect consumers. To establish a robust, science-based safety assessment process, the FDA must explicitly prohibit the use of GRAS determinations for engineered nanoparticles, endocrine disruptors, and GE chemicals. Instead, the agency should require that these substances undergo formal safety assessments prior to market entry.

VII. The Inadequacy of Exempting Biotech and Animal Cell Consultations from GRAS Review

The proposed rule's inclusion of § 170.205(b)(4) establishes a problematic exception by waiving the GRAS notice submission requirement for substances that have undergone existing "voluntary consultations," such as those for biotech plants and animal cell culture products. This exemption is inherently flawed because these voluntary consultations are fundamentally not equivalent to a rigorous premarket safety assessment. In these processes, the FDA does not independently verify safety; rather, the agency merely acknowledges a company's self-determined conclusion that their product does not raise issues requiring further FDA review—a practice that falls far short of the necessary due diligence required for public health protection.

The historical practice of permitting ingredients derived from genetically engineered plants, animals, or microorganisms to utilize the GRAS framework is fundamentally flawed. We maintain that any substance or processing aid produced through modern biotechnology must be explicitly prohibited from the GRAS process and instead be subjected to a premarket safety assessment.

Furthermore, this approach places the United States significantly out of step with established international scientific standards. The Codex Alimentarius—the authoritative food standards agency jointly run by the World Health Organization (WHO) and the Food and Agriculture Organization (FAO)—has clearly stated that foods derived from modern biotechnology are sufficiently distinct from those produced via conventional breeding to necessitate mandatory premarket safety evaluations.

By favoring voluntary consultations over rigorous premarket approval for these complex and emerging technologies, the FDA fails to meet these recognized global benchmarks. Permitting these ingredients to bypass mandatory oversight based on weaker, non-binding consultations ignores their unique risk profiles and creates a dangerous regulatory void. To ensure the integrity of the food supply, all ingredients derived from modern biotechnology or animal cell culture must be subjected to a robust, transparent, and mandatory premarket safety assessment, rather than being permitted to circumvent oversight via existing, insufficient consultation processes.

VIII. Historical Context of Voluntary GRAS Oversight

One strong feature of the proposed rule is its compelling account of the background and limitations of voluntary GRAS oversight. The proposal effectively details three major systemic shortcomings caused by the voluntary framework:

- **Deficient Safety Analyses:** Inadequate or incomplete safety evaluations supporting self-determined GRAS claims can result in unapproved food additives reaching consumers.
- **Unchecked Commercial Entry:** Substances regularly enter the market even after a notifier requests to withdraw a GRAS notice and the FDA halts its review.
- **Administrative and Enforcement Impediments:** A lack of comprehensive data severely restricts the FDA's ability to efficiently administer and enforce the FD&C Act.

Although this thorough historical perspective outlines a persuasive case for transitioning to mandatory notification to protect public health, the substance of the proposed rule ultimately fails to establish those necessary protections.

IX. Conclusion

Ultimately, the FDA's proposed rule fails to deliver the comprehensive reform necessary to safeguard the American food supply from potentially harmful chemicals and additives. The rule functions more as a regulatory mirage than a substantive improvement to the current GRAS framework. By prioritizing administrative expediency over rigorous, science-based safety assessments, the proposal perpetuates the very systemic weaknesses it purports to fix.

The continued reliance on voluntary compliance, combined with loopholes that allow for proprietary data concealment and the unchecked entry of substances into commerce, renders the proposed rule insufficient for adequately protecting public health.

To ensure true protection, the FDA must abandon this incremental approach and implement a framework that demands transparency, accountability, and proactive safety validation. This requires mandating premarket safety evaluations for all new food additives, addressing the backlog of existing "secret" GRAS substances, and establishing stringent oversight for emerging technologies like nanotechnology. Without these fundamental shifts, the current proposal will do little more than codify a flawed system, leaving consumers at risk while prioritizing the commercial convenience of industry over public health concerns.

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