



Comments submitted for 12866 meeting regarding HHS/FDA RIN 0910-AJ02: Substances Generally Recognized as Safe

January 16, 2026

We are happy to see the administration's commitment to reforming the "Generally Recognized as Safe" (GRAS) loophole, which allows companies to introduce new food chemicals without US Food and Drug Administration (FDA) review or public disclosure. And we thank you for this opportunity to discuss the proposed FDA rule to address this loophole.¹

Background

The Food Additives Amendment, adopted by Congress in 1958, sought to ensure that any new chemicals introduced into the food supply are safe.² This law required FDA to conduct pre-market safety evaluations for all additives. However, familiar and widely used ingredients (e.g. baking soda, flour, vinegar, standard spices) were exempted as being "Generally Recognized as Safe (GRAS)" as a practical consideration. An ingredient is considered GRAS if scientists with expertise about the safety of substances added to food deem its use to be safe.³ FDA has interpreted this provision to allow companies introducing new chemicals to use in-house or contracted experts to determine if the chemical is safe. A company does not need to notify FDA that it made such a safety determination before using the chemical. They can voluntarily notify FDA, which usually indicates it has "no questions" about the determination. However, these self-certifications have often been affected by conflicts of interest.⁴

This practice has led to the introduction of many chemicals that have not been adequately assessed for safety. Food companies have self-certified as safe as many as 1000 food ingredients without notifying the FDA.⁵ The Environmental Working Group states that 99% of new chemicals have been introduced into the food supply via the GRAS process, rather than via pre-market approval petition to the FDA. New ingredients can be introduced and listed generically on package ingredient lists as "natural flavors" or "artificial flavor" or "spices" or other additive classes rather than specifically naming the ingredient.

Thus, this self-affirmation process is seriously flawed. It allows food manufacturers to use ingredients that have not undergone a formal safety review by FDA or by credible, unconflicted experts. It leaves FDA and the public in the dark about what chemicals are in the food supply and if they are safe.

FDA proposed rule

As described in the posting on [Reginfo.gov](https://www.reginfo.gov), FDA has stated its intent to develop a rule that addresses:

Mandatory GRAS Notices:

Companies would **be** required to submit a GRAS notice to FDA **for any** substance they intend to

market as GRAS for human or animal food use—closing the longstanding “self-affirmed” GRAS loophole where firms could claim safety without notifying FDA.

Exemptions:

Substances already listed or affirmed as GRAS by regulation **or those with an FDA “no questions” letter in the GRAS Notice Inventory would be exempt from** the new mandatory notice requirement.

Public GRAS Inventory:

FDA would be required to maintain and update a publicly accessible inventory of GRAS notices and their conditions of intended use.

Clarified Non-GRAS Process:

The rule would formalize how FDA determines when a substance does *not* qualify as GRAS, including transparency around FDA decisions.

Extension to Indirect Substances:

The proposed requirements would apply not only to food ingredients but also indirect additives (e.g., substances that migrate from packaging into food)

Concerns with proposed rule

Based on the FDA’s description of the proposed rulemaking, we are concerned that the proposal falls short of needed reform. In particular, the proposal focuses on mandatory notice and listing procedures (i.e., listing GRAS notices in a database), which are important. However, while necessary, this is insufficient. **What is needed is a strong and rigorous approach to FDA premarket review of chemicals proposed for use in foods and a greatly enhanced approach to post-market assessment of current and future GRAS chemicals.**

The Center for Science in the Public Interest has noted that in a recent podcast, Kyle Diamantas—FDA’s Deputy Commissioner for Human Food—stated that GRAS reform would only require notices for new GRAS substances moving forward, in effect grandfathering in hundreds of chemicals that FDA has never reviewed.⁶ The proposed rule does not reference requiring premarket review of any substances.

Suggestions for effective GRAS reform

We suggest the following for consideration in the design of effective GRAS reform and urge the Administration to work with FDA to include them in the FDA final rule:

Require food companies submit notices for all GRAS substances introduced into the US food supply — both those currently on the market and those introduced after the rule is finalized.

A mandatory notification system is necessary to ensure FDA and the public know the universe of substances added to the food supply. The FDA is unable to appropriately regulate chemicals in food if the universe of chemicals added to food is unknown. The public needs to know what is in its food. Making GRAS notices mandatory is an important and necessary first, although not sufficient, step.

Require complete reporting of all investigations related to safety in GRAS notifications submitted to FDA, including:

- Detailed descriptions of study methods;
- Evidence on hazard, exposure, and risk, including any dose-response assessments;
- Information on cumulative effects of chemically and pharmacologically related substances;

- Application of adequately protective safety factors that reflect scientific uncertainties and population sensitivities; and
- Evidence demonstrating that the substance is not carcinogenic and does not cause reproductive or developmental toxicity in humans or animals, including via endocrine disruption mechanisms.

The FDA should publicly share these investigations and any documents related to its own assessment of the safety and toxicity of chemicals that form the basis of its response to requests for GRAS status.

To the extent possible, the FDA should include evidence related to medium and long-term health effects on humans, based on well-designed prospective cohort studies as well as clinical studies that assess short-term health effects or effects on biomarkers for chronic diseases or other validated metabolic, genetic and physiologic intermediate measures and outcomes.

Require rigorous FDA premarket review for all future GRAS notices

Independent, rigorous, and transparent GRAS determinations by FDA scientists, rather than conflicted food industry employees or contractors is the best way to assure that chemicals added to food are objectively and rigorously evaluated. Scientifically inadequate or conflicted self-assessments are not acceptable. A company should not be able to introduce a new chemical until the FDA has reviewed a GRAS application and issued a “no questions” letter.

Publish GRAS notices and allow for public comments prior to awarding GRAS status

All materials related to GRAS determinations should be made public. This includes unredacted data from applicants and FDA scientists used to determine safety. After being made public, there should be a meaningful opportunity for public comment before final determinations. Transparency is essential for public trust and scientific rigor.

For GRAS substances already on the market (listed GRAS, self-affirmed GRAS, subjects of a “no questions” letter), implement a systematic post-market assessment program to identify, prioritize, and assess GRAS substances in need of safety reviews.

This should prioritize post-market assessments of substances with emerging or significant safety concerns based on current scientific evidence. FDA should develop a process for public participation in prioritizing substances for review, determining key questions for the review to address, and commenting on the review findings.

Ensure all GRAS substances comply with the Delaney Clause.

No substance shown to cause cancer in humans or animals should ever be considered safe for use in food in accordance with federal statute.⁷

Request adequate funding from Congress to support these expanded set of FDA activities

FDA must have the resources necessary to conduct timely and thorough reviews. We encourage the FDA to ask Congress for sufficient funding to review future GRAS notices and applications and to reassess current GRAS chemicals of concern.

These reforms are needed, without delay, to assure that chemical in the foods supply are healthy for Americans. They will help ensure that substances added to food are truly safe. They will build a more transparent, science-driven system, one that Americans can trust. We urge you to ensure that these suggestions are included in the proposed regulation vetted by OMB.

Thank you for receiving our suggestions on this matter important to healthy eating, real food and

health.

Sincerely,

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¹ <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0910-AJ02>

² 21 U.S.C. § 321(s)

³ Neltner, T. G., Kulkarni, N. R., Alger, H. M., Maffini, M. V., Bongard, E. D., Fortin, N. D., & Olson, E. D. (2011). Navigating the U.S. Food Additive Regulatory Program. *Comprehensive Reviews in Food Science and Food Safety*, 10(6), 342–368. <https://doi.org/10.1111/j.1541-4337.2011.00166.x>

⁴ Neltner, T. G., Alger, H. M., O'Reilly, J. T., Krimsky, S., Bero, L. A., & Maffini, M. V. (2013). Conflicts of interest in approvals of additives to food determined to be generally recognized as safe: Out of balance. *JAMA Internal Medicine*, 173(22), 2032–2036. <https://doi.org/10.1001/jamainternmed.2013.10559>

⁵ Thomas G. Neltner et al., “Navigating the U.S. Food Additive regulatory Program,” *Comprehensive Reviews in Food Science and Food Safety* 10 (2011), p. 342.

⁶ US Food and Drug Administration (FDA). *FDA Direct: Citrus Regs, Natural Dye Pledges, and Hidden Opioids*. Aug 18, 2025. <https://www.youtube.com/watch?v=2iOTi4WFJJs&t=1263s>.

⁷ 21 U.S.C. § 348(c)(3)(A).