CENTER FOR Science IN THE Public Interest
Your Food and Health Watchdog

December 18, 2025

Russell Vought
Director of the Office of Management and Budget
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Vought:

We are writing to applaud 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 disclosure.[1] For decades, the Center for Science in the Public Interest (CSPI), an independent consumer advocacy organization, has advocated for the closure of the loophole, and we are pleased to see a reform proposal currently under review at the Office of Management and Budget (OMB).[2]

The administration should seize this opportunity to comprehensively reform the GRAS process. However, based on the FDA's description of the proposed rulemaking, we are concerned that the proposal falls short of delivering meaningful reform. In particular, the proposal refers primarily to mandatory notice and listing procedures (i.e., listing GRAS notices in a database) instead of establishing a robust framework for rigorous FDA premarket review and a post-market assessment system for GRAS chemicals.[3]

The Department of Health and Human Services' (HHS) March 2025 press release announced plans to explore GRAS reform, stating that "Eliminating the self-affirmation process would require companies seeking to introduce new ingredients in foods to publicly notify the FDA of their intended use of such ingredients, along with underlying safety data, before they are introduced in the food supply."[4] The announcement makes no reference to any rigorous premarket review that we believe GRAS substances must undergo if the system is to be truly

[1] Center for Science in the Public Interest (CSPI). *How food companies sneak new ingredients past the FDA*. March 4, 2024. https://www.cspi.org/cspi-news/how-food-companies-sneak-new-ingredients-past-fda.
[2] US Office of Management and Budget (OMB). *List of Regulatory Actions Currently Under Review*. https://www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp.
[3] OMB. *Substances Generally Recognized as Safe* (RIN: 0910-AJ02). https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0910-AJ02.
[4] US Department of Health and Human Servies (HHS). *HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe*. March 10, 2025. https://www.hhs.gov/press-room/revising-gras-pathway.html.

credible and consumer-protective, nor does it reference making underlying data publicly available. 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.[5] The Regulatory Agenda does not reference requiring premarket review of any substances.[6]

It is critical that any GRAS reform includes a process for prioritizing and addressing concerns with GRAS substances that are both currently on the market as well as those that will be introduced in the future.

We urge the Administration to ensure that the FDA's proposed rule incorporates the following essential elements:

1. Require notices for all GRAS substances and uses—both those currently on the market and those introduced after the rule is finalized.
A mandatory notification system is necessary to ensure FDA knows the universe of substances added to the food supply.

2. Require complete reporting of all investigations related to safety, 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.

3. Require rigorous FDA premarket review for all future GRAS notices.
Independent, rigorous, and transparent GRAS determinations by FDA scientists is the only reliable safeguard against conflicts of interest (industry can currently self-certify a GRAS substance as safe) and scientifically inadequate self-assessments.

4. Publish GRAS notices—including unredacted data needed to establish safety—and provide a meaningful opportunity for public comment before final determinations.
Transparency is essential to public trust and scientific rigor.

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[5] 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.
[6] OMB. *Substances Generally Recognized as Safe* (RIN: 0910-AJ02). https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202504&RIN=0910-AJ02.

5. For GRAS substances already on the market, 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.

6. 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]

7. Request adequate funding from Congress to support these strengthened oversight responsibilities.
FDA must have the resources necessary to conduct timely and thorough reviews.

These reforms are both reasonable and urgently needed. They will help ensure that substances added to food are truly safe, and they will build a more transparent, science-driven system worthy of public confidence. We urge you to ensure that these elements are included in the proposed regulation that leaves OMB.

Thank you for your attention to this critical matter for public health. We stand ready to assist in any way that would support FDA's efforts to modernize and strengthen the GRAS system.

Sincerely,

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[7] 21 U.S.C. § 348(c)(3)(A).