# Your Review and Input is Needed: FDA's Proposed Rule to Mandate GRAS Notices

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The Food and Drug Administration (FDA) has proposed its long-awaited rule to eliminate the pathway for the food industry to introduce generally recognized as safe (GRAS) substances into the U.S. food supply without first notifying the FDA. The FDA's proposal aligns with the administration's Make America Healthy Again (MAHA) initiative while doing less than MAHA supporters would like and leaving questions for the food industry regarding whether the FDA will be provided with sufficient resources to meet the proposed timelines and avoid significant delays and bottlenecks for industry. The FDA will accept comments on the proposed rule through early December 2026 and seeks comments on potential alternatives that would help the FDA achieve its objectives while reducing the burden on industry. Therefore, the proposed rule merits careful review and input from interested stakeholders.

## What is the FDA's Proposed Rule on Substances Generally Recognized as Safe?

Food companies currently have the flexibility to introduce innovative and novel food substances if they affirm that such substances are GRAS for a specific intended use. If a substance is GRAS, it is excluded from the definition of a "food additive" that would require the FDA's prior approval before introducing the substance into interstate commerce. When introducing a GRAS substance, a food company currently may, but is not required to, notify the FDA of its conclusion that the substance is GRAS for the specific intended use. On August 11, 2026, the FDA issued a proposed rule that would convert FDA's currently voluntary GRAS notification system into a mandatory notice requirement and that would obligate companies that market food substances under the GRAS exemption to notify FDA of their GRAS determinations.[1]

The proposed rule, if finalized in its current form, would implement several significant new requirements:

- Mandatory Submission: GRAS notices would no longer be voluntary. Proposed § 170.205(a) would require submission for any substance marketed under the GRAS exemption, unless another exemption applies.[2] A GRAS notice has seven required parts, as detailed in current 21 CFR §§ 170.225 to 170.255, which are largely unchanged by the proposed rule and require all data and information relied on to support the GRAS conclusion to be included.
- Mandatory Electronic Submission: All notices must be submitted electronically through FDA's Centralized Online Submission Module (COSM). Waivers would be available for entities unable to submit electronically.[3]
- English Translation Requirement: All foreign-language materials included in a GRAS notice must be accompanied by an English translation.[4]
- FOIA Disclosure Requirements: Under proposed § 170.250(d), if a notifier does not affirmatively and specifically identify data or information as exempt from disclosure under the

Freedom of Information Act (FOIA) at the time of submission, FDA will consider the exemption waived. Additionally, notifiers relying on non-public safety data and seeking a FOIA exemption must explain how a GRAS basis can exist given the data's non-public nature.[5]

- Streamlined Submission Pathway for Existing GRAS Substances: Proposed §§ 170.303 and 170.305 would establish a time-limited streamlined submission pathway for substances already in interstate commerce before the rule's effective date. This submission would need to include:

    1. Name and address of submitter
    2. Name of the substance
    3. Conditions of intended use (foods, levels, and purposes)
    4. Evidence of presence in interstate commerce before the effective date
    5. If FDA sent a cease to evaluate letter in response to a submitter's previous GRAS notice, the file number (GRN No)

  This streamlined submission *may* inform FDA of the basis for the conclusion that use of the substance is GRAS, but **a streamlined submission does not require underlying safety data or a full safety narrative.**[6] This option will only be available for one year after the effective date of the final rule, and it is not available for any conditions of intended use of a substance for which FDA has sent an insufficient basis letter or FDA has determined is not GRAS.[7]

Importantly, the notification requirement is met upon FDA's *filing* of the GRAS notice, not mere submission.[8] This distinction means that a submission that does not meet the criteria for filing will not satisfy the notification obligation. However, companies may continue marketing their products while a notice is pending, as the proposed rule is *not* a premarket approval requirement.[9]

The GRAS notice pathway cannot be used for a pesticide chemical or its residue, a color additive, any substance used in accordance with a sanction or approval granted prior to September 6, 1958, a new animal drug, or a dietary supplement or dietary supplement ingredient.

## Why is the FDA Mandating GRAS Notices?

The MAHA movement has sought to close the so-called GRAS loophole by eliminating the pathway for firms to introduce self-affirmed GRAS substances into the food supply without notifying FDA. The U.S. Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. said in a 2025 directive to FDA that eliminating the self-affirmed GRAS pathway would "enhance the FDA's oversight of ingredients considered to be GRAS and bring transparency to American consumers."[10] In the press conference announcing the proposed rule, Secretary Kennedy noted that due to the current voluntary GRAS notice system the FDA does not know the full universe of substances currently in the American food supply, which hinders FDA's ability to carry out its post-market safety evaluations of such substances.[11]

By mandating GRAS notices, the FDA believes that it will:

- Obtain a fuller picture of substances already in use in the U.S. food supply

- Be better able to determine if the use of a substance is not GRAS, but instead, a food additive that is subject to FDA's premarket review and approval
- Increase the information made available to the FDA and the public regarding substances used in human and animal foods

The FDA seeks to resolve issues that have arisen from the voluntary GRAS notification system, including:

- Potentially inadequate analyses to support independent conclusions of GRAS status, resulting in unapproved food additive uses (e.g., continued use of stevia leaves as opposed to FDA-evaluated high-purity steviol glycosides)
- Substances that may have been introduced into the food supply as self-affirmed GRAS after the FDA has ceased to evaluate a GRAS notice at the notifier's request (a step often taken when the FDA is not going to issue a "no questions" letter in response to a GRAS notice)
- Insufficient information about substances in the U.S. food supply

## If the Proposed Rule is Finalized in its Current Form, Who Must Comply?

Proposed § 170.205(a) would require "any person introducing a substance into interstate commerce under the GRAS provision of section 201(s) of the FD&C Act" to submit a GRAS notice to FDA.[12] This requirement would apply to:

- Food manufacturers and processors using GRAS substances in their products
- Ingredient suppliers marketing substances under the GRAS exemption
- Food contact substance manufacturers (who may alternatively submit a Food Contact Notification (FCN) under § 170.100)
- Animal food companies (under parallel requirements in proposed Part 570)
- Any other entity marketing substances under the GRAS exemption in interstate commerce

Critically, the proposed rule applies not only to substances being introduced to the food supply for the first time, but also to substances *already in interstate commerce*.[13] An abbreviated pathway would be temporarily available for substances already in interstate commerce. Additionally, the term "food substances" encompasses both direct ingredients and substances added indirectly, such as those migrating from food packaging.[14]

The proposed rule covers human food and animal food. Therefore, pet food marketers and others should also review the proposed rule and consider commenting on the proposed rule.

## If the Proposed Rule is Finalized in its Current Form, When Would Compliance Be Required?

The proposed rule establishes several important dates and timelines:

- **Effective Date:** 60 days after publication of the final rule in the Federal Register[15]
- **Compliance Date:** 18 months after the effective date of the final rule[16]
- **Streamlined Submission Window:** One year from the effective date of the final rule for substances already in interstate commerce before the effective date[17]

The proposed rule also establishes the following FDA review timelines:

- **Initial Evaluation Period:** 45 days for FDA to determine whether a submission is sufficiently complete for filing[18]
- **Initial Evaluation Filing Decision:** Within two business days of making a filing decision, FDA will send the notifier a letter informing them of the decision and reasoning if the decision is not to file the notice in its current form[19]
- **FDA Response Time:** Within 180 days of filing, extendable by 90 days up to two times (for a potential total of 360 days)[20]

## If the Proposed Rule is Finalized in its Current Form, Are Exemptions Available?

A substance would not require a GRAS notice if any of the following conditions apply:[21]

- **No Questions Letter:** FDA has already issued (and has not rescinded) a no questions letter covering the substance under its conditions of intended use.
- **Listed or Affirmed GRAS:** The substance is listed or affirmed as GRAS for its intended use in 21 CFR Parts 182, 184, or 186 (human food) or Parts 582 or 584 (animal food).
- **Pre-1958 Natural Substances:** The substance qualifies as GRAS under § 170.30(d) (natural biological origin, widely consumed before 1958) or proposed § 170.30(i)(1) (affirmed GRAS under conditions not significantly different from those already evaluated).
- **Prior FDA Consideration:** FDA has considered the substance through an established process (*e.g.*, Voluntary Premarket Consultations, Animal Cell Culture Consultations) and did not recommend submission of a GRAS notice for the intended use.
- **Threshold of Regulation (TOR):** The substance and intended use has been granted a threshold of regulation exemption under the proposed expanded § 170.39. Under current regulations, a substance used in a food-contact article that migrates into food is exempt from regulation as a food additive if certain criteria are met. The proposal would expand the scope of the TOR exemption to substances used directly in food as well as food-contact substances generally.
- **Food Contact Notification (FCN):** An effective food contact notification covers the substance and its intended use (human food only), and the substance *originates from the manufacturer or supplier listed in the effective FCN*.
- **Streamlined Submission:** The substance has been submitted for its intended use through the time-limited streamlined pathway under proposed Subpart F (for pre-existing substances only) and is listed on FDA's public database. A streamlined submission is not permitted if: (i) the use of a substance was the subject of an FDA insufficient basis letter, or (ii) FDA has previously determined the substance is not GRAS under those conditions.
- **Additional Exemption for Animal Food:** For animal food specifically, proposed § 570.205(b)(6) would provide an additional exemption for ingredients listed in, and used in accordance with, Chapter 6 of AAFCO's 2024 Official Publication, provided that FDA has not publicly expressed concern about the ingredient's GRAS status.[22]

## If the Proposed Rule is Finalized in its Current Form, Can Compliance Be Delegated to a Third Party?

Companies may continue to engage third-party consultants, toxicologists, attorneys, and qualified experts to prepare and submit GRAS notices. Still, the legal responsibility for compliance cannot be transferred or delegated to a third party. The entity introducing the substance into interstate

commerce bears the ultimate obligation. As a practical matter, industry stakeholders that rely upon a broad network of contract manufacturers, ingredient suppliers, and other third parties should evaluate their portfolio of products to ensure that all substances — including both direct ingredients and packaging materials — are subject to an existing FDA approval or notification or if a GRAS notice or abbreviated submission will be needed if the proposed rule is finalized.

## If the Proposed Rule is Finalized in its Current Form, Will GRAS Notices Become Exclusive to the Submitter?

As is often the situation currently, if an existing GRAS notice and FDA no questions letter covers the substance and intended use, third parties (other than the submitter) may continue to rely on the GRAS notice and FDA no questions letter. Also unchanged, however, is the need to carefully examine such GRAS notices, the manufacturing of the specific substance at-issue, and the intended use(s) to ensure that changes do not necessitate a new notification.

## What Should Industry Do Now?

The FDA will accept comments on the proposed rule through December 9, 2026. All food industry stakeholders should carefully examine the proposed rule and consider submitting comments or proposing alternatives to FDA. The Agency is working within a statutory framework that does not provide it with the authority to mandate premarket approval of GRAS substances and therefore, has instead crafted a narrow pathway to obtain more information from industry to support the Agency's postmarket reviews of substances in the U.S. food supply. There are likely to be practical alternatives that allow industry to provide the information that the FDA seeks while avoiding the burden of GRAS notices for all substances and all intended uses in the future. The Agency is encouraging the submission of alternative proposals during the comment period. Even if an industry participant has not submitted GRAS notices in the past and has relied on third parties' GRAS conclusions and notices, because the proposed rule would broadly apply to all parties who introduce a substance into interstate commerce, the rule is likely to impact future product portfolio decisions.

While any compliance date for a final rule is still years away, if resources allow, additional next steps might include:

- **Conduct a Food Additive and GRAS Substance Inventory:** Examine the legal pathway relied upon for all substances in the company's current product portfolio and identify those for which the company relies on a GRAS determination (whether reached independently or through a formal evaluation). Identify reliance on existing no questions letters and whether intended uses are adequately covered. This inventory should include both direct food ingredients and food contact substances, such as packaging and food contact substances in the production environment.
- **Map Substances Against Existing Food Additive Regulations and Proposed Exemption Categories:** Determine which substances may fall within one of the seven enumerated exemptions under proposed § 170.205(b). Substances covered by existing no questions letters, listed in 21 CFR Parts 182, 184, or 186 (or Parts 582 or 584 for animal food), or subject to effective FCNs may not require new notifications.
- **Prepare for Streamlined Submissions:** For substances already in interstate commerce, the streamlined pathway under proposed Subpart F (§§ 170.303, 170.305) provides a simplified submission process, but the window is limited to one year from the effective date. Therefore, companies may want to consider identifying substances that could be the subject of a

streamlined submission and assembling the required information now: name and address of submitter, name of substance, conditions of intended use, and evidence of prior presence in interstate commerce.
- **Review and Strengthen GRAS Documentation:** Ensure that existing GRAS evaluations are supported by adequate data. Evaluate whether current safety assessments meet the scientific standard for GRAS determinations, including general recognition among qualified experts.
- **Establish Electronic Submission Capability:** Register for and familiarize personnel with FDA's Centralized Online Submission Module (COSM) to ensure readiness for mandatory electronic submission.
- **Monitor Rulemaking Progress and Databases:** Track the status of the FDA's rulemaking, including any changes between the proposed and final rule that may affect compliance obligations. If planning to rely on no questions letters, monitor the database to ensure FDA has not rescinded such letters.

## What Are the Proposed Penalties for Noncompliance?

The proposed rule does not create new direct penalties specifically for failure to submit a GRAS notice. However, FDA advises that failure to comply with the notification requirement would be a factor in FDA's prioritization of substances for post-market review, meaning noncompliant products may face heightened regulatory scrutiny.[23]

Additionally, under the existing statutory framework, a food bearing or containing an "unsafe food additive" is deemed adulterated.[24] A food additive is deemed "unsafe" unless its use conforms with a food additive regulation or an applicable exemption applies (*e.g.*, it is established as GRAS).[25] Accordingly, failure to satisfy the mandatory GRAS notice requirement, if finalized as proposed, may result in FDA determining the substance is not GRAS, which may render the food product adulterated. Available enforcement tools include warning letters, import alerts, seizure of adulterated foods, and injunctions.[26]

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[1] Proposed § 170.205, 91 Fed. Reg. at 51850.
[2] *Id.*
[3] Proposed § 170.210, 91 Fed. Reg. at 51853.
[4] Proposed § 170.220(c), 91 Fed. Reg. at 51853.
[5] Proposed § 170.250, 91 Fed. Reg. at 51853-54.
[6] Proposed §§ 170.303 and 170.305, 91 Fed. Reg. at 51855-57.
[7] *Id.*
[8] Proposed § 170.265(a)(2), 91 Fed. Reg. at 51854.
[9] *Id.*
[10] HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients are Safe (Mar. 10, 2025) (available at: https://www.hhs.gov/press-room/revising-gras-pathway.html).
[11] *See* Secretary Kennedy Announces Landmark Food Policy Reforms to Advance President Trump's MAHA Agenda (Aug. 10, 2026) (available at: https://www.hhs.gov/press-room/hhs-announces-ultra-processed-foods-gras-reforms.html).

[12] Proposed § 170.205, 91 Fed. Reg. at 51850.
[13] 91 Fed. Reg. at 51836.
[14] Proposed § 170.3(m), 91 Fed. Reg. at 51846.
[15] 91 Fed. Reg. at 51867.
[16] *Id.*
[17] Proposed §§ 170.303 and 170.305, 91 Fed. Reg. at 51855-57.
[18] Proposed § 170.265, 91 Fed. Reg. at 51854.
[19] *Id.*
[20] *Id.*
[21] Proposed §§ 170.205, 91 Fed. Reg. at 51851-53.
[22] Proposed § 570.205(b)(6), 91 Fed. Reg. at 51866.
[23] 91 Fed. Reg. at 51835.
[24] Section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 USC § 342(a)(2)(C)(i)).
[25] FDCA § 409(a), (21 USC § 348(a)).
[26] FDCA § § 302, 304 (21 U.S.C. §§ 332, 334).