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FDA proposes mandatory GRAS notification requirement

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The U.S. Food and Drug Administration (FDA) has issued a proposed rule that would require the submission of a Generally Recognized as Safe (GRAS) notice for the use of a human or animal food substance that is the subject of a GRAS conclusion under 21 U.S.C. § 321(s).[1] Specifically, the "Substances Generally Recognized as Safe" proposed rule (GRAS proposed rule) would convert the current voluntary GRAS notification program into a mandatory program. The GRAS proposed rule also would establish several exceptions to the mandatory notification requirement, including a time-limited opportunity to submit streamlined information regarding substances already in interstate commerce that have been marketed on the basis of a self-determination of GRAS status. If finalized as proposed, the rule would significantly change how food substances are brought to market and would require companies to review and assess which substances in their portfolios must be notified to FDA. Comments on the proposed rule are due by December 9, 2026.

Background

In 1958, Congress created a framework for FDA's oversight of substances added to food that adopted a very broad definition for "food additive" that encompasses all substances the intended use of which would reasonably be expected to result, directly or indirectly, in the substance becoming a component of, or otherwise affecting, the characteristics of food. A food that contains a food additive is deemed adulterated unless FDA has issued a food additive regulation covering the intended use of the substance in food or food contact substances.[2] Congress specifically exempted GRAS substances from the definition of "food additive" and recognized that a substance could be GRAS on the basis of either scientific procedures or common use in foods prior to 1958. Since 1958, GRAS ingredients have been exempt from the premarket approval requirements for food additives.

Under the statute, FDA has the authority, on its own initiative, to issue a regulation that establishes the safe conditions of use for food additives. In 1997, the current voluntary GRAS notification framework was proposed, which allowed, but did not require, companies to share

[1] 91 Fed. Reg. 51834 (Aug. 11, 2026), available at https://www.govinfo.gov/content/pkg/FR-2026-08-11/pdf/2026-16296.pdf.
[2] Pub. L. 85–929, 72 Stat. 1784.

with the agency the underlying data used to support their conclusion that a food substance is GRAS.[3] This program was finalized in 2016.[4]

On March 10, 2025, Secretary of Health and Human Services Robert F. Kennedy Jr. directed FDA to explore rulemaking that would require entities to inform the agency of their GRAS conclusions as part of the Administration's Make America Healthy Again initiative. The GRAS proposed rule is the result of this instruction. FDA notes a mandatory GRAS notification would increase transparency and give FDA greater visibility into substances entering the food supply.

Legal Authority

The preamble states that the proposed rule would assist FDA in carrying out its responsibilities under Sections 409(a) and (d) of the FFDCA (21 U.S.C. § 348(a), (d)), which grant FDA the authority to propose and establish food additive regulations.[5] FDA explains that Sections 409(a) and (d) together task the agency with identifying substances that have not been part of a Food Additive Petition (FAP) or a Food Contact Notification (FCN) and "with initiating review of the safety of such substances for particular uses." The preamble asserts these sections of the FFDCA authorize the agency to review new and existing substances (including those marketed based on a GRAS determination) to assess whether their uses render them food additives that would require a food additive regulation to be lawfully marketed.

The agency further explains that the proposed rule is intended to promote transparency regarding the substances used in food that have not undergone premarket approval and would facilitate efficient administration of Sections 409(a) and (d) by informing the agency of substances on the market it would not otherwise know exist. FDA claims that the rule would also allow the agency to review the available safety data for all new or already-marketed substances. FDA also cites to section 701(a) (21 U.S.C. § 371(a)) and the authority it confers on the agency to implement regulations for the efficient enforcement of the FFDCA. FDA asserts the increased transparency from the available safety data on marketed substances would support the agency's compliance and enforcement activities related to unapproved food additives and would support the agency's mission to "prohibit the use in food of additives which have not been adequately tested to establish their safety."[6] Further review and analysis of the agency's stated basis for the statutory authority is warranted to assess whether the agency's position could withstand the scrutiny of the courts.

Proposed Amendments in the GRAS Proposed Rule

The proposed rule contains largely similar regulations for human and animal food substances.[7] This memorandum focuses on the human food provisions of the proposed rule.

The proposed rule would make the following changes to the GRAS framework.

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[3] 62 Fed. Reg. 18938 (Apr. 17, 1997), available at https://www.govinfo.gov/content/pkg/FR-1997-04-17/pdf/97-9706.pdf.
[4] 81 Fed. Reg. 54960 (Aug. 17, 2016), available at https://www.govinfo.gov/content/pkg/FR-2016-08-17/pdf/2016-19164.pdf.
[5] 91 Fed. Reg. 51834, at 51846.
[6] 91 Fed. Reg. 51834, at 51846.
[7] For animal food substances, FDA proposes to convert the current voluntary GRAS notification program into a mandatory notification regime, subject to exceptions including certain animal food ingredient consultations and ingredients listed and used in accordance with Chapter 6 of the 2024 AAFCO Official Publication.

1. Mandatory GRAS Notification Requirement

If finalized, the proposed rule would require any company introducing a food substance into interstate commerce under the GRAS provisions of FFDCA Section 201(s) (21 U.S.C. § 321(s)) to submit to FDA a GRAS notice explaining the basis for their conclusion that the substance is GRAS.[8] The rule would apply to substances already in the market and those that will be marketed in the future, although it would establish a time-limited streamlined notification program for self-GRAS ingredients in the marketplace prior to the effective date. The preamble to the proposed rule clarifies that companies would still have the option to make their own GRAS conclusion, but they would be required to submit those conclusions to the agency for review. Alternatively, the proposed rule would allow entities to file an FCN for uses that meet the definition of a food contact substance. The proposed rule clarifies that substances excepted from the definition of a food additive under FFDCA Section 201(s)(1)-(6) (21 U.S.C. § 321(s)(1)-(6)) could not be the subject of a GRAS notice. These substances are a pesticide chemical residue, pesticide chemicals, color additives, substances that are prior sanctioned, new animal drugs, and dietary supplements.

The information required to be included in the GRAS notice for GRAS substances, other than those marketed by industry on the basis of a self-determination of GRAS status prior to the effective date, would remain the same as under the current voluntary notification framework, except that for any safety-related data and similar information designated as exempt from disclosure under the Freedom of Information Act (FOIA) or otherwise not public, the notifier would be required to explain how a GRAS conclusion can be reached despite the fact that qualified experts do not have access to the data.

The proposed rule states that simply submitting materials for a GRAS notice would be insufficient to meet the notification requirement. Instead, the requirement would be met only when FDA files the submission as a GRAS notice.[9] The GRAS proposed rule provides that, within 45 days of receiving a GRAS submission, the agency would determine as a preliminary matter whether the submission meets the notification requirement. The agency would then inform the submitter of its decision within two business days. The preamble clarifies that this preliminary determination would *not* be a determination of GRAS status, but would determine whether the submission meets the mandatory notification requirements, subject to the restrictions discussed below.

After conducting the preliminary review of the GRAS notice, the proposed rule states that the agency would have 180 days plus up to two 90-day extensions to evaluate the substance of the notice. The agency would then be required to issue a response explaining its conclusion. If FDA ceases to evaluate the GRAS notice, the proposed rule states the mandatory notification requirements would not be met. The text of the proposed rule does not specifically address the consequences of an agency letter concluding insufficient information exists to support the notifier's GRAS position. The preamble to the proposed rule clarifies that a negative response to a GRAS notice (e.g., a finding that the notice does not provide sufficient information to support a GRAS conclusion) would *not* mean the notifier failed to meet their reporting obligation. It would, however, factor into FDA's analysis of whether a food substance is considered an unapproved food additive. All portions of GRAS notices not identified as exempt from disclosure under FOIA as

[8] 91 Fed. Reg. 51834, at 51850.
[9] 91 Fed. Reg. 51834, at 51851

well as all agency responses would then be made publicly available on a database maintained by FDA.

The preamble provides that a company would be permitted to continue marketing a substance determined to be GRAS before submitting a GRAS notice and could reach a GRAS conclusion and begin marketing a new substance prior to submitting a GRAS notice.[10] Accordingly, while the proposal would impose a mandatory post-market notification obligation, FDA asserts it would not require the agency to affirmatively approve a GRAS conclusion before the substance may be marketed.

If finalized, the mandatory notification requirement would have a compliance date of 18 months after the final rule's effective date. The proposal is silent on the legal status of substances that are marketed without filing a mandatory GRAS notification. It does not, for example, deem it a prohibited act to market a substance without filing the mandatory GRAS notification or deem the substance adulterated as an unapproved food additive. Further analysis of the legal status of substances that are not the subject of a mandatory GRAS notification is warranted.

2. Time-limited Streamlined Submissions for Substances Introduced into Interstate Commerce Prior to the Final Rule Effective Date

The proposed rule also would create a separate Subpart F covering substances introduced into interstate commerce under the GRAS provisions of 201(s) prior to the effective date of the final rule.[11] Under this provision, an entity could submit information regarding the substance and its conditions of use instead of submitting a GRAS notice. Submissions under Subpart F would not be allowed for conditions of use that are the subject of an agency letter finding an insufficient basis to support a GRAS conclusion or a determination by the agency that the substance is not GRAS. Submissions under this Subpart would be required to include the following information:

- The name and address of the submitter;
- The name of the substance;
- "The intended conditions of use of the substance, including the foods in which the substance is used or is in contact with, the levels of use, and the purposes for which the substance is used;"
- Evidence that the substance was present in interstate commerce prior to the effective date of the final rule; and
- If applicable, a GRAS Notice number (GRN No.) in instances when FDA ceased reviewing a GRAS notification for the substance.

The submission may also contain a description of the statutory basis for the GRAS conclusion (e.g., through scientific procedures). However, this is not necessary. The preamble to the proposed rule clarifies that Subpart F submissions would not need to include the underlying data

[10] 91 Fed. Reg. 51834, at 51851.
[11] 91 Fed. Reg. 51834, at 51880.

or information explaining the GRAS conclusion. The submissions could only be filed for up to one year after the effective date of the final rule.

The proposal would identify three actions that could result after FDA receives the submission. First, FDA would post the information contained in a submission in a publicly available list. However, the proposed rule states that posting this information would not mean the agency has reviewed the substance's GRAS status. Second, the agency could ask the submitter questions about their submission. Third, the agency could issue a determination that a GRAS notice or FAP is required. Such a determination would also be publicly available. The proposed rule is silent on the criteria that FDA would apply in situations when it makes a determination that the substance must be reviewed under a mandatory GRAS notice or a FAP. In the preamble, FDA explains it would use the information it gathers "to evaluate through post-market activities whether the use of substances should be re-evaluated, including whether a GRAS notice regarding the conditions of use of a substance must be submitted."

3. Exceptions to the Mandatory GRAS Notification Requirement

The proposed rule contains seven exceptions to the mandatory notification requirement. A GRAS notice would not be required under the following conditions:

- The food substance is the subject of a "No Questions" letter covering the substance's intended conditions of use;

- The substance is listed or affirmed as GRAS under the intended conditions of use in 21 CFR Parts 182, 184, or 186;

- The substance is considered GRAS under the intended conditions of use in accordance with 21 CFR 170.30(d) (a food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States before January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced before January 1, 1958, and for which no known safety hazards exists) or proposed 21 CFR 170.30(i)(1) (food ingredients affirmed as GRAS with no conditions of use other than current good manufacturing practices if the conditions of use do not differ significantly from those in the regulation);

- The intended use of the substance has been considered by FDA through an established FDA process to evaluate the potential presence of unapproved food additives, and FDA has made public its recommendation that the substance does not require a GRAS notice (e.g., for foods from new plant varieties developed through biotechnology: Animal Cell Culture Consultations and Voluntary Premarket Consultations; for foods developed from cultured animal cells: Voluntary Premarket Meetings; however this exception would not apply to informal written statements, such as technical assistance, or substances that are part of the Early Food Safety Evaluation Program for non-pesticidal proteins produced by new plant varieties not intended to enter the food supply);

- The intended use is the subject of a Threshold of Regulation (TOR) exemption;

- An effective FCN covers the substance under its intended conditions of use and the substance is used by the entity listed on the effective FCN; or

- Information regarding the intended conditions of use of the substance was submitted under the new Subpart F and is included on a public list maintained by FDA, unless the agency determined that a GRAS notice or FAP was required.

Notably, the above exemption for common use in foods would be limited to those food ingredients of natural biological origin commonly used in foods in the United States. An ingredient that falls outside of this narrow exemption would trigger the mandatory notification requirement (e.g., synthetic ingredients commonly used in the US prior to 1958 and ingredients primarily used outside of the United States prior to 1958). Furthermore, the proposed rule does not expressly exempt from the mandatory notification requirement those substances which the Flavor and Extract Manufacturers Association (FEMA) concluded are GRAS.

4. Threshold of Regulation (TOR)

The proposal would make several changes to the TOR. For example, it would expand the regulation to cover substances used in foods in addition to food contact substances. It also would change the threshold from 0.5 ppb in the diet to 0.025 micrograms per kilogram body weight. In addition, the regulation would clarify the threshold for substances with carcinogenic impurities would equate to a lifetime cancer risk of less than one in one million. Substances reviewed favorably through this regulatory program would be exempt from the mandatory notification requirements.

5. Enforcement

If a substance is subject to the mandatory notification requirement, the preamble explains that FDA would consider failure to submit a notification when determining which food substances to prioritize as part of its post-market review. Furthermore, the preamble to the proposed rule states that the mandatory GRAS notice requirement would support FDA's enforcement activities related to unapproved food additives, such as the issuance of warning letters and seizure of adulterated foods. For example, the agency would consider a finding that there was an insufficient basis for a GRAS conclusion in its determination of whether a food substance is an unapproved additive, which could inform enforcement action taken against the substance.[12]

Additional Information

In addition to the changes outlined above, the proposed GRAS rule would also make several additional modifications, including:

- Clarifying that FDA may update or rescind "No Questions Letters" issued previously or in the future if FDA later determines that the substance is no longer GRAS under its intended conditions of use;

[12] 91 Fed. Reg. 51834, at 51854.

- Clarifying that substances affirmed as GRAS under 21 CFR Parts 184 or 186 with no limitations other than current good manufacturing practices will be regarded as GRAS if its conditions of use are not significantly different than those outlined in the regulation;

- Clarifying the procedure for removing a substance from 21 CFR Parts 182, 184, or 186;

- Modifying definitions to conform to the mandatory reporting requirement.

Furthermore, the proposed rule would not expressly preempt states from regulating ingredients through bans or through their own GRAS notification programs. In the preamble, FDA states the agency has "determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government." The proposed rule contains an economic impact analysis. Further analysis of the costs and benefits associated with the mandatory program should be conducted.

Next Steps

Industry should evaluate the proposed rule carefully and consider providing comments. All comments must be submitted by December 9, 2026. Companies should also consider evaluating their portfolios to determine which of their ingredients would be subject to the GRAS rule, if finalized.

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