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FDA Proposes Mandatory GRAS Notification for Food Substances, with a Time-Limited Streamlined Path

FDA has proposed converting its voluntary notification program for substances in food that are generally recognized as safe (GRAS) into a mandatory one, with a one-year window for streamlined submissions for food substances already on the market. If the GRAS notification requirement is not met, FDA intends to consider noncompliance as a factor in its prioritization of food substances for post-market review.

On August 10, 2026, HHS announced FDA's widely anticipated proposed rule requiring submission of GRAS notifications (the GRAS rule). HHS also announced "final review" of a proposed definition of "ultra-processed foods," referring to an HHS/FDA/USDA white paper currently under review with the Office of Management and Budget.[1]

The GRAS rule proposes to amend FDA regulations (21 CFR parts 170 and 570) to require notices for uses of human and animal food substances purported to be GRAS under section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2] This proposed rule follows Secretary Kennedy's March 10, 2025 direction that FDA eliminate the pathway by which GRAS substances are marketed without notification to FDA.[3] Acting FDA Commissioner Kyle Diamantas described the GRAS rule as closing a decades-old information gap while "respecting the limitation to our authority," referring to commentary that FDA lacks the statutory authority to mandate GRAS reporting.[4] The comment period for the proposed rule closes on December 9, 2026.

GRAS notification requirement, with seven exceptions. Under the proposed rule, any person introducing a substance into interstate commerce under the GRAS provision would be required to notify FDA of the basis for its GRAS conclusion, unless one of seven exceptions applies:

1. The substances are subject to an existing "no questions" letter that covers the conditions of its intended use. A letter may not extend to a use where identity, manufacturing process, or conditions of use differ significantly from the underlying notice.
2. The substances are listed or affirmed as GRAS in 21 CFR Parts 182, 184, or 186, which hinge on particular conditions of use.
3. The substances are considered GRAS as (a) pre-1958 ingredients of natural biological origin widely consumed for their nutrient properties and without known detrimental effects or (b) substances affirmed as GRAS under its intended use in Part 184 or 186, with no limitation other than good manufacturing practice, so long as its conditions of use do not differ significantly from those in the regulation.
4. The substances' intended use has been considered by FDA through established FDA processes (i.e., Voluntary Premarket Consultations and Meetings, or Animal Cell Culture Consultations), and public FDA documentation does not identify a need for a GRAS notice. Informal technical assistance and the Early Food Safety Evaluation Program do not qualify.
5. The substances' intended use is subject of a threshold of regulation (TOR) exemption.
6. The substances are subject to an effective food contact substance notification (FCN), for the manufacturer or supplier listed in the FCN.[5]
7. Substances where information about the intended conditions of use has been submitted in a streamlined submission, discussed further below, and the submission is included on a public list, unless FDA has determined a GRAS notice or food additive petition must be submitted.[6]

Review timelines remain the same, with additional extension. The notification obligation is met only when FDA files the submission. FDA proposes a 45-day pre-filing evaluation period and intends to issue filing decision letters within two business days. In terms of review timelines, existing regulations provide for an 180-day review period after filing, followed by one 90-day extension, if needed. The proposed rule would add the option for a second 90-day extension. The addition of a second 90-day extension suggests an anticipated strain on review timelines, but FDA does not estimate the staffing or other resources required to absorb the increase in GRAS notices.

Time-limited streamlined submission option. For a period of one year after a final rule goes into effect, a streamlined submission will be able to substitute for a full GRAS notice for certain intended uses of substances that were introduced into interstate commerce before the effective date. This streamlined submission need not include underlying data or information pertaining to a conclusion of GRAS status but would need to include the file number of any prior GRAS notice on which FDA issued a cease to evaluate letter. A streamlined submission would not be available, however, for conditions of use that are the subject of an insufficient basis letter or of an FDA determination that the substance is not GRAS. FDA notes that it intends to use the information gathered through these streamlined submissions to evaluate whether the use of substances

should be re-evaluated, including whether a GRAS notice must be submitted for the intended use of the substance that is the subject of a streamlined submission.

No premarket review? FDA asserts that a mandatory GRAS notification program would not, unlike with food additives, constitute a premarket review and approval requirement. Rather, the proposed rule would facilitate FDA's efficient administration and enforcement of provisions of the FD&C Act that task FDA with identifying food substances that have not been the subject of a safety review. FDA also submits that a company can introduce a substance into interstate commerce before submitting a GRAS notice, or continue to market purported GRAS substances before submitting a GRAS notice or after submitting a GRAS notice before it is filed with FDA. FDA states that failure to comply with the GRAS notification requirements would factor into the agency's prioritization of food substances for post-market review.

Other key aspects of the proposed rule include:

- **Implications of ceased evaluations**: Currently, a notifier can ask FDA to cease evaluating a GRAS notice with no regulatory implications. Of 1,215 filed GRAS notices that have been resolved, 231 have ended in a cease-to-evaluate letter, with roughly 17% for human foods, and 37% for animal foods.[7] Under the proposed rule, if FDA ceases evaluation, even of its own accord, it means the notification requirement is not met.
- **Expanded threshold of regulation (TOR) exemption**. Current FDA regulations allow for an exemption from regulation for substances used in food contact articles if such substance meets certain criteria that demonstrate safe use due to very low dietary exposure. The proposed rule would exempt food substances more broadly from the GRAS notification requirement if it meets these TOR criteria.
- **No-questions letters can be updated or rescinded.** The proposed rule provides that FDA can question a notifier after issuing a no-questions letter, and may update or rescind it.
- **Public disclosure.** FDA currently makes data and information in GRAS notices publicly available in a searchable inventory. FDA further puts the onus on submitters of GRAS notices to identify specific data and information viewed as exempt from public disclosure under the Freedom of Information Act. Under the proposed rule, if submitters fail to do so, FDA will consider the data and information not to be exempt from disclosure or that the submitter has waived any claim of confidentiality.
- **Application to animal food.** FDA proposes parallel revisions to FDA's animal food regulations that largely track the human food provisions, with certain key differences. FDA proposes two exceptions to the GRAS notice requirement with no human food counterpart: one for substances whose intended use has been the subject of an established animal-ingredient consultation with FDA (e.g., the Animal Food Ingredient Consultation) and a summary document made publicly available by FDA through that process indicates FDA has no questions or concerns about its safety; and one for ingredients listed in and used in accordance with Chapter 6 of the 2024 edition of the Official Publication of the Association of American Feed Control Officials (AAFCO), unless FDA has publicly expressed concerns about the ingredient's GRAS status or the use of the ingredient. Streamlined submissions for animal food ingredients must identify the target species and, for food-producing animals, the residue quantities to which humans may be exposed in edible animal tissues.

- **Rule compliance dates**: FDA proposes a final rule effective date of 60 days after its publication, and a compliance date of 18 months after the effective date. The window for streamlined submissions would close one year after the effective date.

Looking ahead

Preparation. Companies relying on independent GRAS conclusions should start preparing now. In particular, they should: (1) inventory self-affirmed determinations and supporting documentation, including those inherited through acquisitions or held by suppliers; (2) determine which uses are already covered by a no questions letter, a GRAS affirmation or listing, or an effective FCN, and confirm conditions of use have not evolved; (3) evaluate whether particular uses are suited for a TOR request or FCN (neither is available for animal food); and (4) decide which legacy food substances go through a streamlined submission versus a full notice.

Legislation. GRAS notification rulemaking could turn into GRAS notification legislation. HHS has urged Congress to legislate, and Acting Commissioner Diamantas has described bipartisan discussions on legislative options for GRAS and nutrition reform. However, no introduced GRAS legislation on the Hill is bipartisan at this time, and obstacles to such legislation include likely sticking points on the scope of GRAS reporting, enforcement authorities, state preemption, and FDA funding amounts and mechanisms (e.g., appropriated funds versus user fees). Public reception to the proposed rule could influence bipartisan talks and momentum for legislation, as could the results of the midterm elections this fall.

Gibson Dunn lawyers are prepared to help companies consider and address the implications of these changes, if finalized, and submit comments to FDA on the proposed rule.

[1] U.S. Department of Health and Human Services, Secretary Kennedy Announces Landmark Food Policy Reforms to Advance President Trump's MAHA Agenda (Aug. 10, 2026), https://www.hhs.gov/press-room/hhs-announces-ultra-processed-foods-gras-reforms.html. Office of Information and Regulatory Affairs, Pending EO 12866 Regulatory Review: White Paper: Proposed Definition of Ultra-Processed Food, RIN 0910-ZD60 (HHS/FDA), received Aug. 3, 2026, https://www.reginfo.gov/public/do/eoDetails?rrid=1495413.

[2] Food and Drug Administration, HHS, Substances Generally Recognized as Safe, Proposed rule, 91 Fed. Reg. 51834 (Aug. 11, 2026), Docket No. FDA-2025-N-3262, RIN 0910-AJ02; FDA, Substances Generally Recognized as Safe: Preliminary Regulatory Impact Analysis (PRIA), Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, Docket No. FDA-2025-N-3262, https://www.fda.gov/media/194138/download.

[3] U.S. Department of Health and Human Services, HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe (Mar. 10, 2025), https://www.hhs.gov/press-room/revising-gras-pathway.html; see also The MAHA Report (May 2025), available at https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf.

[4] Remarks of Acting FDA Commissioner Kyle Diamantas, press event (Aug. 10, 2026)

https://www.youtube.com/watch?v=PQWnhvLsvBk.

[5] The TOR and FCN exceptions do not apply to animal food.

[6] Certain uses cannot be the subject of a GRAS notice because they fall outside the statutory definition of a food additive: pesticide chemicals and pesticide chemical residues, color additives, substances used under a sanction or approval granted before September 6, 1958, new animal drugs, and ingredients described in section 201(ff) of the FD&C Act in, or intended for use, in a dietary supplement.

[7] See PRIA at 12.

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Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any leader or member of the firm's Consumer Protection or FDA & Health Care practice groups:

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