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MEMORANDUM

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BY ELECTRONIC MAIL

FROM: Olsson Frank Weeda Terman Matz PC

RE: Proposed Rule; Substances Generally Recognized as Safe

On August 10, 2026, during the U.S. Health and Human Services ("HHS") Food Policy Celebration ("Event"), the U.S. Food and Drug Administration ("FDA" or the "agency") released its much-anticipated proposed rule, "Substances Generally Recognized as Safe" ("Proposed Rule"), which was published in the *Federal Register* today. The Proposed Rule, if finalized, would change the longstanding process around substances Generally Recognized as Safe ("GRAS") by replacing the current voluntary process for notifying the agency of a company's use of a self-determined GRAS substance with a mandatory notification and submission for human and animal (including pets) food (hereafter "food" as defined under Section 201(f)) substances[1] that purport to be GRAS.

Substances subject to mandatory notification include direct food ingredients and indirect food substances (such as chemicals that migrate from packaging or other food-contact materials) in both human and animal food. The Proposed Rule, if finalized, would apply to both new uses and substances already marketed or used in the food supply. For ingredients already on the market, FDA is proposing a time-limited, streamlined submission pathway. The Proposed Rule is intended to provide FDA with clearer pre-market visibility and oversight of food substances for both humans and animals.

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[1] The Proposed Rule would revise 21 C.F.R. part 170 governing human food and establish parallel proposed provisions in 21 C.F.R. part 570 governing animal food. The principal distinction in the Proposed Rule's application to human versus animal food does not arise from different GRAS-notification obligations; rather, it reflects the distinct regulatory and scientific considerations applicable to animal food. Animal-food GRAS submissions must be tailored to the relevant target species and, for food-producing animals, must also address potential human exposure through foods derived from those animals. ***Note – this memorandum focuses on human food. Please let us know if you have specific animal food questions.***

Although FDA's intent and goal appear reasonable, in our view, the agency lacks the statutory authority to require GRAS notification. We believe this rulemaking is at odds with legal precedent and the agency's own, and long-repeated, statements.

We provide additional information on FDA's legal authority below, but first start with background, requirements, exceptions proposed by FDA, procedural changes, and other notable revisions in the Proposed Rule. There are a number of areas where industry comments appear to be warranted. **Comments on the Proposed Rule are due by December 9, 2026 (120 days after publication).**

Background

In 1958, Congress amended the Federal Food Drug & Cosmetic Act (FD&C Act) by enacting the Food Additives Amendments.[2] The 1958 Amendments added Section 409 to the FD&C Act which requires premarket review and approval[3] for "***food additives,***" which are defined as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[4]

Congress, however, expressly ***excluded*** from this definition any ***substance that is GRAS***, that is, ***generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.***[5]

Under the 1958 Amendment, a substance that is GRAS under the conditions of its intended use is not a "food additive" and is therefore not subject to mandatory premarket review and approval. For a substance to be "GRAS" under the conditions of its intended use, publicly available data and information must show it meets the same safety standards of a food additive, i.e., for a substance to be GRAS, there must be common knowledge throughout the expert scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use. Manufacturers have used this alternative to the food additive process to self-affirm that a food substance is GRAS. This process currently occurs without any FDA input or review. However, FDA's GRAS regulations[6] (finalized in August 2016 – "GRAS Final Rule") include a *voluntary procedure* through which a manufacturer may choose to notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use in human food.[7]

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[2] Pub. L. No. 85-929, 72 Stat. 1784.
[3] Congress specified that the petitioner must include, among other things, "all relevant data bearing on the physical or other technical effect of such additive" and "full reports of investigations." FD&C Act, § 409 (b)-(g), 21 U.S.C. § 348 (b)-(g).
[4] FD&C Act, § 201(s), 21 U.S.C. § 321(s).
[5] *Id.*
[6] 21 C.F.R. Parts 170 and 570; *See also*, GRAS Final Rule.
[7] Any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the FD&C Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use. A submission containing this view (a GRAS notice) must contain seven parts, including an explanation of how the generally available data and information relied on to establish safety provide a basis for the

This voluntary, rather than mandated, notification to FDA of self-affirmed GRAS status has been criticized as a "loophole." Consumer groups, some members of Congress, and Secretary of HHS Robert F. Kennedy have all urged closing the "GRAS loophole." GRAS reform has also been a priority for the "Make America Health Again" ("MAHA") movement.

I. Proposed Rule Requirements And Exemptions

a. What are the major[8] changes under the Proposed Rule?

(1) Convert the current GRAS notification program (under 21 C.F.R. Parts 170 and 570) from voluntary to mandatory;
(2) Identify a time-limited option to make a streamlined submission to FDA for certain substances already in use in interstate commerce;
(3) Identify exceptions from the requirement to submit a GRAS notice; and
(4) Identify uses of substances that are not eligible to be the subject of a GRAS notice.

Below we breakdown the main aspects and changes proposed under the Proposed Rule.

b. What "Food Substances" Would The Proposed Rule Apply To?

The Proposed Rule would apply to:

- Direct food ingredients in both FDA- and U.S. Department of Agriculture (USDA)-regulated foods, such as additives used in the food itself;
- Indirect food substances, such as chemicals that enter food from packaging or other food-contact materials;
- Both human food and animal food; and
- Both new uses and substances already being sold or used in the food supply.

This proposed rule ***does not*** apply to uses of substances that are excepted from the FD&C Act definition of a "food additive,"[9] which include:

- Ingredients in or intended for use in dietary supplements.[10]
- Substances approved prior to September 6, 1958,
- Pesticide chemical residues in or on raw agricultural commodities and processed foods,
- Pesticide chemicals,
- Color additives, and
- New animal drugs.

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proponent's conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use. 21 C.F.R. § 170.250(b).

[8] In addition to substantive changes, FDA is also proposing to: make conforming edits throughout part 170 to reflect the change to a mandatory program; change procedural regulations for a Threshold of Regulation (TOR) exemption to reflect updated scientific guidance and to expand the scope of this exemption to cover uses of substances in food and Food Contact Substances (FCSs) generally, in addition to FCSs used in food contact articles; and make other non-substantive edits.

[9] FD&C Act, § 201(s)(1)-(6), 21 U.S.C. § 321(s)(1)–(6).

[10] FD&C Act, § 201(ff), 21 U.S.C. § 321(ff).

c. How Does The Proposed Rule Address Substances Already Self-Affirmed As GRAS For Intended Use In Food?

For substances already on the market before any final rule becomes effective, a person or company could use a ***one-year*** (i.e., one-year after the final rule takes effect), streamlined submission alternative. This alternative would not require the notifier to provide all the underlying safety data supporting its GRAS conclusion but, instead, it would give FDA basic information about what is already being used in food.

This one-year alternative ***would be available*** to companies whose substances:

- Were introduced into interstate commerce before the final rule's effective date;
- Were already marketed based on a conclusion that it is GRAS for its intended use; and
- The intended use is one that could properly be the subject of a GRAS notice.

A submission in this manner ***would not*** be permissible if:

- FDA previously sent an "insufficient basis letter" for the same substance and intended conditions of use. In that case, the person or company must submit a new GRAS notice so FDA can reevaluate the use; potentially, FDA would expect the company to submit a food additive petition.
- FDA previously determined that the substance is not GRAS for those same conditions of use. In that case, FDA would generally expect submission of a food additive petition; if someone believes the use is GRAS anyway, they must submit a GRAS notice.
- The use falls within one of the statutory exclusions from the definition of "food additive" or "color additive" in FD&C Act, § 201(s)(1)–(6), because those uses cannot be the subject of a GRAS notice.

The submission would have to include: (1) The submitter's name and address; (2) A descriptive name for the substance; (3) The intended conditions of use, including the foods in which it is used or contacts, use levels, and purpose of use; (4) Evidence that the substance was in interstate commerce for that use before the final rule's effective date; and (5) The GRAS notice file number, if FDA previously issued a letter agreeing to stop evaluating a GRAS notice for the same use (discussed further below). Optionally, the person or company may also explain whether its GRAS conclusion is based on scientific procedures or common use in food.

d. How Does The Proposed Rule Address GRAS Substances In Food Which Already Have A No Questions Letter ("NQL")?

The Proposed Rule would, if finalized, establish a regulatory definition for the NQL. Under the Proposed Rule, an NQL:

> "[M]eans a letter from FDA, sent in response to a GRAS notice, which states that, based on the information you provided, as well as other information available to FDA, [FDA has]…. no questions ***at this time*** regarding your conclusion that the notified substance is GRAS under the conditions of its intended use. A no questions letter is neither an affirmation by FDA that the notified substance is GRAS for its intended conditions of use

under § 570.35, nor a published finding under section 721(b)(4) of the Act declaring the use of such substance exempt from the term "food additive" because of its being GRAS."

FDA is proposing an exception from mandatory GRAS Notice Submission when an existing NQL covers the substance under the conditions of its intended use. The Proposed Rule preamble indicates that the FD&C Act does not provide a notifier "exclusivity for the use of a substance on the basis that it is GRAS under the conditions of its intended use." Therefore, if a NQL exists for a substance, then FDA would not need to evaluate again the GRAS status of a substance where the conditions of use are the same. However, if the identity of, manufacturing process for, or the conditions of use for a substance differ significantly from conditions in the GRAS notice covered by the NQL, then this exception would not apply. Similarly, FDA would require a GRAS notice if the agency later rescinded the NQL pertaining to conditions of use of the substance.

e. Are There Additional Proposed Exceptions To The Mandatory GRAS Notice?

In addition to exceptions covered by NQLs, the Proposed Rule identifies circumstances where the mandatory GRAS notice would be "unnecessary or unwarranted," including:

- Substances listed or affirmed as GRAS under conditions of intended use in 21 C.F.R. Parts 182, 184, or 186 or, for animal food/feed, in Parts 582 or 584 (unless otherwise later repealed).
- Substances considered GRAS under conditions of intended use because the substance is a food ingredient of natural biological origin, conventionally processed, and widely consumed in the United States since before January 1, 1958, without known detrimental effects (see 21 C.F.R. § 170.30(d) and 21 C.F.R. § 570.30(d)).
- Substances evaluated via an established FDA process and publicly documented as not needing to submit a GRAS notice, such as via Voluntary Premarket Consultations, Voluntary Premarket Meetings, and Animal Cell Culture Consultations.
- Substances subject to an established animal food ingredient consultation process with FDA with a publicly available summary document, such as the Animal Food Ingredient Consultation (AFIC) process.
- Animal food ingredients listed in and used in accordance with Chapter 6 "Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions" of the Official Publication of the Association of Animal Feed Control Officials, Inc. (AAFCO), 2024 ed., and are not subject of a public FDA statement of concern.
- Substances subject to the Threshold of Regulation (TOR) exemption for human food (see 21 C.F.R. § 170.39).
- Substances covered by an effective Food Contact Substance (FCS) premarket notification (i.e., food contact notification or FCN).
- Substances introduced into interstate commerce before the effective date of the final rule based on an independent conclusion of GRAS (i.e., self-GRAS) (see Section II above regarding proposed Subpart F).

II. GRAS Notice Submission Procedure, Freedom of Information Act ("FOIA"), and Other Changes Under the Proposed Rule

a. *What Content is Required in a Notice?*

The Proposed Rule does not change the substance of the content that is currently required under the voluntary program, i.e., Parts 1-7 of a GRAS Notice under 21 C.F.R. §§ 170.225-170.255, with the exception of important clarification surrounding FOIA exemptions (discussed further below).

b. How are Notices Submitted?

FDA has revised the current rule to require, as the default, an electronic submission. The notifier would submit the notice electronically through the Centralized Online Submission Module (COSM), unless FDA grants a waiver for paper submission. In addition, any foreign-language material submitted in or referenced by the notice must include a complete and accurate English translation.

c. What Happens Following A Mandatory GRAS Notice Submission To FDA? Does A Person Or Company Need To Wait To Hear From FDA Before Including GRAS Ingredients In Food?

Currently, when FDA receives a voluntary GRAS determination, if FDA responds, it responds by issuing:

1. A NQL,
2. An *insufficient basis* letter, or
3. A *Cease to Evaluate* letter (as requested by notifier).

Under the Proposed Rule, FDA must respond to the notice and will conduct an initial evaluation of the submission to determine whether to file it as a GRAS notice. The proposed timeline for this initial pre-filing evaluation is forty-five (45) days. Upon evaluation, FDA will inform the notifier in writing of either the date of filing or reasons for not filing the submission as a GRAS notice. ***If FDA files the submission as a GRAS notice, then the notification requirement would be met.*** FDA would then have 180 days from the filing date plus two (2) ninety (90)-day extensions, if needed, to complete the evaluation. ***This process does not require notifiers to wait to hear from FDA before marketing the ingredient purported to be GRAS—a person or company can introduce into interstate commerce or continue marketing the substance before submitting or after submitting to FDA the required GRAS notice.***

d. What Are A Company's Options For Preserving Confidentiality In Mandatory GRAS Notices?

FOIA exemptions must be identified at the time the notice is submitted to FDA. FDA has revised the regulation to require the notifier to identify at the time of submission the information claimed to be exempt from disclosure. If information is not identified as exempt, it would be treated as nonconfidential or as subject to a waived confidentiality claim. In addition, if the notifier claims safety-related information is nonpublic, the notifier must explain how there can still be a basis for a GRAS conclusion when qualified experts do not have access to that information.

e. Under The Proposed Rule, What Are The Requirements For "Continued Public Disclosure"?

While not addressed specifically, the background section of the Proposed Rule provides that "a mandatory program that includes the continued public disclosure of information about GRAS uses of substances would substantially increase the public's access to information concerning the substances being added to human and animal food."

This implies that FDA may require, under a final rule, continuous information updates to substances even after initial mandatory notice has been provided to FDA and/or the substance has been posted on the public listing of GRAS substances.

f. What Is The Impact Of FDA's Revisions On The "Threshold of Regulation" Exemption In 21 C.F.R. § 170.39?

There does not seem to be any significant impact. TOR is an exemption from the Food Additive Approval and GRAS notification process. FDA has proposed revising the TOR exemption pathway in two ways.

First, the Proposed Rule would extend application of the TOR to substances used in food (in addition to the current regulation, which only includes FCS). Although this change might seem significant, the TOR is not often used because it is only available for substances that are expected to result in dietary concentrations at or below 0.5 parts per billion (or 1.5 micrograms/person/day).

Second, FDA is also proposing to amend the TOR exemption in 21 C.F.R. § 170.39 to reflect updated scientific guidance, including updated approaches to account for assessment of cancer risk. The Proposed Rule would prohibit any carcinogenic impurity with a lifetime cancer risk greater than one in one million, when calculated using a TD_{50}[11] value or another approach based on chronic feeding studies reported in the scientific literature or otherwise available to FDA, when present in the diet at 0.025 micrograms per kilogram bodyweight per day. FDA clarifies that this value results in an equivalent level of safety to the current limit of 6.25 milligrams per kilogram bodyweight per day.

Although FDA already maintains a TOR database, FDA proposes maintaining a publicly available list of substances and their uses subject to the TOR exemption.

III. Enforcement and Effect on State Law

a. When is the Compliance Deadline?

The proposed compliance date for mandatory GRAS notice in 21 C.F.R. §§ 170.205 and 570.205, if finalized, would be eighteen (18) months after the effective date of the final rule.[12] FDA opines

[11] TD_{50} is the specific dose of a substance that causes a defined toxic effect in 50% of a test population.
[12] Any final rule resulting from this Proposed Rule would become effective sixty (60) days after the date of publication in the *Federal Register*.

that this compliance period would provide industry with sufficient time to comply and for FDA to make available the public listing of GRAS substance information submitted during the time-limited, streamlined submission period.

b. What Are The Consequences If A Person Or Company Does Not File A Mandatory Notification?

While enforcement is not addressed in any detail, the Proposed Rule does indicate that FDA would take action against any impermissible ingredients in food. Enforcement may include the issuance of warning letters and seizure of adulterated foods. Similarly, FDA might prioritize the substance for post-market review for safety. ***However, without significant funding and personnel, we anticipate that FDA action will be limited to consumer complaints and Plaintiff's attorneys could play a heavier role in enforcement.***

Consequences for the failure to submit a GRAS notification appear to undermine the agency's own contention that this is not a process involving pre-market review and approval.

c. Under The Proposed Rule, Is There Any Preemption From Any Inconsistent Or Different State Law?

Recently, several states[13] have introduced legislation aimed at expanding ingredient disclosure and transparency requirements for food manufacturers, including the submission of safety, usage, and other product and ingredient-related information to state agencies and creation of public databases. While none have been signed into law, the prospect of a state GRAS patchwork adds another layer of complexity.

FDA does not offer a solution to conflicting state laws or suggest that the Proposed Rule would preempt state GRAS-related requirements. In fact, FDA states that the Proposed Rule does not contain policies with "substantial direct effects" on states, the federal–state relationship, or the allocation of governmental power and responsibilities. Thus, the agency does not intend for the Proposed Rule to impede any state legislative efforts to impose new and additional requirements around food ingredients and the GRAS process.

IV. The Proposed Rule May Be Vulnerable To Legal Challenge

The agency sets forth several bases for its authority to issue the Proposed Rule. FDA asserts repeatedly that the mandated GRAS notification is not a pre-market review and avoids characterizing a GRAS notice as any form of review. Rather, it is a notification requirement coupled with a "preliminary assessment to determine whether the submission is adequate to file," and FDA will only evaluate whether the GRAS conditions are satisfied after it has accepted the GRAS filing. This careful and repeated characterization is likely an attempt to avoid a legal

[13] See, for example, NJ S 3277 (https://legiscan.com/NJ/drafts/S3277/2026), NJ A 3069 (https://legiscan.com/NJ/drafts/A3069/2026), NY S 01239 (https://www.nysenate.gov/legislation/bills/2025/S1239), PA SB 820 (https://legiscan.com/PA/bill/SB820/2025), PA HB 1130 (https://legiscan.com/PA/text/HB1130/2025).

challenge to the agency's authority over GRAS substances by distinguishing the new, mandatory GRAS notification process from the pre-market review and FDA approval of food additives.

Further, FDA claims that:

- **Section 701(a)** gives FDA the "authority to promulgate regulations for the efficient enforcement" of the FD&C Act.
- **Section 409(d)** provides that FDA may "at any time," upon its "own initiative," issue a food additive regulation.
- The mandated notification would, if finalized, allow the agency to "more efficiently determine if the use of a substance constitutes a food additive use that is subject to FDA review and approval under the FD&C Act." (See page 7 and elsewhere in the Proposed Rule).

We are skeptical of these asserted bases. The agency's own repeated statements and court decisions do not support these claims and characterizations. We believe there are strong arguments that the agency would exceed its statutory authority in finalizing the Proposed Rule as proposed.

First, it is long-established, *and has been reiterated by FDA*, that the agency ***does not have the statutory authority to subject GRAS substances to either pre-review submissions or notifications.*** Even if the proposed mandated GRAS notification process involved no "review" – and the agency *does* review the notification and decide whether to file the notification or reject it – it has long been clear that the agency's authority over GRAS substances does not permit mandated GRAS notifications either. "Congress laid out an elaborate regime for FDA's premarket approval of 'food additives' in Section 348, but expressly carved out GRAS substances from this regime… Had Congress wished to *require* FDA to conduct similar premarket review of GRAS substances, or even to require a subset of those procedures, it would have said so." *Ctr. for Food Safety v. Becerra*, No. 17-CV-3833 (S.D.N.Y. Sept. 30, 2021) (emphasis in original). "FDA's own brief in the *Becerra* litigation states: "Congress expressly carved GRAS substances out of the premarket FDA notice and approval regime that applies to 'food additives.'" Indeed, the 2010 Government Accounting Office report cited to frequently in the Proposed Rule states, "FDA officials stated that the agency would have to seek authority from Congress in order to require all companies to inform it of their GRAS determinations."

For over 50 years, FDA and courts have *never* interpreted the FD&C Act as conferring on the agency the authority to require GRAS submissions or notifications. Even during yesterday's Event, FDA noted limitations upon its GRAS authority. Specifically, FDA Acting Commissioner Kyle Diamantas was careful in describing the Proposed Rule, emphasizing that it was not intended to be a "pre-market approval," but rather is a notification statute intended to advance FDA's oversight of food safety "while respecting the limitations of [FDA's] authority under the statute." Mr. Diamantas stated that FDA will continue working with Congress to "further address and advance GRAS reform." If the agency had the authority to require GRAS notifications or submissions, the many pending bills to amend the FD&C Act to specifically confer these authorities upon the

agency would not be necessary.[14] To subject GRAS substances to the requirements of the Proposed Rule would, in our view, first require an amendment to the FD&C Act.

Regardless of this repeated insistence that the Proposed Rule would only establish a permissible GRAS ***notification*** program, and not ***an extra-statutory premarket review program***, we believe this distinction to be largely illusory. As discussed above, the agency will "review" the notification for sufficiency before filing it and can reject notifications. Further, though the agency states a person or company would not need to submit the GRAS notification pre-market, the submission would be mandatory and, as discussed above, there may be legal and regulatory consequences for failing to submit the GRAS notification. ***In sum, despite the semantic effort and careful phrasing, the Proposed Rule's notification program appears to establish a mandatory, pre-market review of GRAS substances.***

FDA does not rely solely upon this strained distinction between "notification" and "pre-market review." It also asserts authority to issue the Proposed Rule under a combination of section 409(d) and section 701(a) of the FD&C Act. Section 409(d), 21 U.S.C. § 348(d), states (emphasis supplied) that FDA "*may* at any time… propose the issuance of a regulation prescribing, with respect to any particular use of a food additive…" Section 701(a), 21 U.S.C. 371(a), is a general housekeeping provision that confers upon FDA the "authority to promulgate regulations for the efficient enforcement" of the FD&C Act. FDA asserts repeatedly in the Proposed Rule that mandating GRAS notifications will promote "efficient" implementation of its wholly discretionary authority to issue a food additive regulation where warranted.

In our view, the combination of Sections 409(d) and 701(a) cannot make up for the lack of authority in the first instance to require GRAS notifications or other submissions. Section 409(d) is optional for the agency, not mandated. Section 701(a) is not an independent grant of authority that permits FDA to issue *any* regulation the agency determines would advance the public health mission. It is well-established in case law[15] that FDA regulations, such as the Proposed Rule, issued under § 701(a) must be pursuant to authority conferred by Congress elsewhere in the FD&C Act, which, as discussed above, does not exist as to mandatory GRAS submissions.

These legal arguments are complex and nuanced. We will continue to refine these points and welcome further discussion with you and your legal teams.

V. Other Considerations and Related Issues

Outside of the legal challenges, if the Proposed Rule were finalized and mandatory reporting was introduced, it would require significant resources and personnel for FDA to review and file GRAS notices. An expansive pre-review requirement would seemingly be antithetical to the avowed goals and actions of the Administration as they work to shrink the federal workforce and decrease regulatory burden. We understand that FDA has committed to using artificial intelligence (AI),

[14] *See, e.g.*, S. 2341 - Ensuring Safe and Toxic-Free Foods Act of 2025; S. 3122 - Better FDA Act of 2025; HR 4958 – GRAS Act; HR 7291 - GRAS Oversight and Transparency Act.

[15] *See, e.g.*, *Nat'l Confectioners Ass'n v. Califano,* 569 F.2d 690, 695 (D.C. Cir. 1978); *Pharm Ass'n of Am., Physicians & Surgeons, Inc. v. United States FDA,* 226 F. Supp. 2d 204 (D.D.C. 2002).

such as the Warp Intelligent Learning EnginE (WILEE),[16] to review post-market submissions for food safety. This raises concerns regarding legitimacy, fairness, and accountability, as well as privacy, data integrity, and security risks.

Finally, even if FDA has authority under FD&C Act § 701(a) to require mandatory GRAS notification, the agency has failed to take or consider the less burdensome approaches. FDA mentions the term "transparency" twenty-two times in the Proposed Rule. If transparency is the primary objective of a new GRAS rule, less burdensome alternatives may be more closely aligned with this objective, such as requiring public disclosure or listing of self-determined GRAS uses via a publicly accessible link. FDA could then use its existing post-market assessment tools to target certain substances and the conditions of use and assess safety.

VI. Next Steps and Comments

In the Proposed Rule preamble, FDA broadly requests comments and stakeholder feedback on any related topic, including but not limited to:

- The overall approach of converting GRAS from a voluntary notification system to a mandatory notice requirement for both human and animal food.
- The scope and applicable criteria, including which substances and uses are subject to notification, and which fall within proposed exceptions (e.g., previously NQLs, listed/affirmed GRAS, or uses already evaluated through other FDA processes).
- The streamlined submission pathway for substances already in the food supply based on prior independent GRAS conclusions, including what information must be provided.
- The time frames and effective dates, including the proposed period for bringing existing GRAS substances into the notification inventory, and the final rule effective date.
- Administrative and economic impacts, such as recordkeeping and submission burdens, effects on supply chains, and any suggested alternative approaches that could achieve FDA's public-health objectives with less burden.
- FDA's authority, or lack of authority, to issue a final rule regarding mandatory GRAS.

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Hope this proves useful. Please contact us if you would like assistance with comments on the Proposed Rule and/or with any of your public policy, scientific, and regulatory questions or needs.

[16] See page 6 of *The Enhanced Systematic Process for FDA's Post-Market Assessment of Chemicals in Food* (May 2026), available at: https://www.fda.gov/media/192046/download.