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**Consumer Protection and FDA & Health Care Update** March 12, 2025

# Kennedy Directs FDA to Revamp Food Ingredient Safety Process

While the proposal is in its early stages, companies in the food industry should consider efforts to engage in any forthcoming notice-and-comment regulatory process, including by submitting comments on any proposed regulation and participating in related public meetings.

On March 10, 2025, Robert F. Kennedy, Jr., Secretary of the Department of Health and Human Services (HHS), directed the Food and Drug Administration (FDA) to explore rulemaking to require manufacturers to submit for FDA review notifications demonstrating that new food ingredients are generally recognized as safe (GRAS).[1] Such a change, if finalized, would have a significant impact on the food industry, which has relied in substantial part on manufacturers' self-affirmations, in some cases based on review of available data by expert panels, that their ingredients are GRAS without FDA notification or review. While this proposal is in its early stages, companies in the food industry should consider efforts to engage in any forthcoming notice-and-comment regulatory process, including by submitting comments on any proposed regulation and participating in related public meetings.

**The Current Framework**

- A food ingredient is considered a "food additive," unless it is generally recognized to be safe for its intended use by qualified experts based on generally available and accepted scientific data, information, or methods.[2]
- A food additive is "unsafe" unless its use is consistent with a food additive regulation.[3] In order to obtain a food additive regulation for a new food additive, a manufacturer must submit a food additive petition to FDA containing scientific data and information on the

conditions for its safe use.[4] If FDA grants the petition, it publishes a final rule prescribing the conditions under which the food additive may be used in food.[5]

- At present, manufacturers can, but are not required to, notify FDA of new food ingredients they believe to be GRAS by submitting a GRAS notice, which contains, among other things, data on the ingredient's chemical composition, manufacturing process, specifications, dietary exposure, and supporting data.[6] FDA then responds with one of three type of letters: a "no questions letter" stating that it has no questions at this time relating to the basis for the notifier's GRAS conclusions, an "insufficient basis letter" stating that the notice does not provide a sufficient basis for a GRAS determination, or a "cease to evaluate letter" noting that FDA has ceased to evaluate the GRAS notice at the submitter's request.[7]
- When it formally adopted the GRAS notification process in 2016, FDA stated explicitly that submission of GRAS notifications is voluntary in nature. The agency noted that the Federal Food, Drug, and Cosmetic Act (FDCA) expressly requires FDA review of food additives, but is silent on any required review for GRAS substances, which fall outside the definition of "food additive."[8] Accordingly, manufacturers have largely "self affirmed" the GRAS status of food ingredients, maintaining scientific substantiation to support their conclusions without submitting that data and information to FDA.

**How the Regulatory Landscape Could Change**

- Efforts to reshape the GRAS notification process are part of Secretary Kennedy's position on "radical transparency" regarding food ingredients.[9] President Trump's nominee for FDA Commissioner, Dr. Marty Makary, has also expressed concerns about health risks with food ingredients and additives.[10]
- Submission of a GRAS notice entails substantial time, effort, and resources for manufacturers, as well as uncertainty with respect to FDA's evaluation of the notice. Accordingly, a shift from voluntary to mandatory GRAS notices likely will have a significant impact on the food industry.
- It is unclear how FDA would phase in mandatory GRAS notification requirements, if adopted. For example, the HHS directive does not address whether and how FDA would grandfather in currently marketed ingredients for which manufacturers have self-affirmed GRAS status.
- It is also unclear whether any forthcoming FDA regulation would provide a grace period for GRAS notice submissions, and how a potential deluge of notices might impact FDA review timelines or other FDA activities in the foods space. The agency has faced criticism in other areas where it has been slow to act on premarket submissions following a change in the agency's policy for submissions, such as for new tobacco products.[11] Long review timelines may delay companies' innovations in food ingredients given the potential enforcement risk if FDA disagrees and determines that an ingredient is not GRAS, and therefore requires food additive review.[12]
- Enforcement risk likely also will increase if FDA mandates submission of GRAS notices. GRAS notices provide more touchpoints between FDA and food industry that could result in enforcement action if FDA calls into question the safety or lawful marketing status of an ingredient.

**How Companies Should Prepare**

- Companies that have used the self-affirmation process for food ingredients should ensure that they continue to maintain appropriate documentation of the scientific review conducted to support their conclusions that the ingredients are GRAS.
- FDA actions to mandate GRAS notices will require notice-and-comment rulemaking and may include public meetings and other opportunities for engagement before and after the publication of a proposed rule. Companies should consider submitting comments to agency notices and participating in public hearings to both shape the regulatory process and stake their positions in anticipation of potential litigation.
- Companies should also be aware that Congress could pursue legislative changes to the regulatory construct for food ingredients if it takes issue with any proposed rulemaking, or if it believes a statutory fix is ideal or required.

Gibson Dunn is closely monitoring developments within the food regulatory landscape and is prepared to help companies consider and address the implications of potential regulatory changes, including through regulatory counseling, agency and legislative engagement, and litigation.

[1] HHS, Press Release, "HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe" (Mar. 10, 2025) ("HHS Press Release").

[2] A food ingredient used in food prior to September 6, 1958, is considered a "food additive" unless it is generally recognized to be safe based on common use in food. Food additives do not include color additives. 21 U.S.C. § 321(s); 21 CFR 170.30, 570.30.

[3] 21 U.S.C. §§ 342(a)(1), (2)(C)(i), 348(a).

[4] *See id.* § 348(b); 21 CFR 170.39.

[5] *See* 21 U.S.C. § 348(c); 21 CFR Parts 172-186.

[6] *See* 21 CFR 170.220-170.255. When a GRAS notice is filed for review, FDA discloses the name and address of the notifier, the name of the notified substance, the intended conditions of use, and the statutory basis of the conclusion of GRAS status on its public GRAS notice database. 81 Fed. Reg. at 55022-23; 21 CFR 170.275(b); *see* FDA, "GRAS Notices" (last visited Mar. 12, 2025). FDA also publishes its response to a GRAS notification. *See, e.g.*, FDA, Guidance for Industry: Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act (Nov. 2017), at 6; 81 Fed. Reg. at 55014-15.

[7] 81 Fed. Reg. at 55015.

[8] *Id*. at 54970-71.

[9] HHS Press Release.

[10] *See, e.g.*, "Trump's FDA Pick Made His Name by Bashing the Medical Establishment. Soon He May Be Leading It," *U.S. News & World Report* (Mar. 4, 2025).

[11] *See, e.g.*, HHS Office of Inspector General, Rep. No. A-06-22-01002, The Food and Drug Administration Needs to Improve the Premarket Tobacco Application Review Process for Electronic Nicotine Delivery Systems to Protect Public Health (Nov. 2023).

[12] 21 CFR 170.38.

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Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding the issues discussed in this update. 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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