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HHS Directs FDA to Explore Rulemaking to Increase Oversight of Food Ingredients

Food product manufacturers should prepare for shifts in the regulatory landscape.

Key Points:

- FDA may seek to modify the self-affirmed GRAS pathway for marketing a new food ingredient by requiring notice of the manufacturer's self-affirmation to FDA prior to marketing.
- FDA may lack the statutory authority to remove the self-affirmed GRAS pathway altogether without a legislative fix.
- For now, self-affirming a new ingredient as GRAS without notifying FDA and marketing it on that basis remains the most commercially viable option for food product manufacturers to introduce a new ingredient into the food supply — but manufacturers should prepare for changes to this pathway.

On March 10, 2025, Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. announced in a press release that he has directed the Food and Drug Administration (FDA) to explore rulemaking to implement a seismic shift in how most companies introduce ingredients into the nation's food supply. The shift would eliminate the option for companies to self-affirm — without notifying FDA or seeking the agency's feedback — that an ingredient is "Generally Recognized as Safe" (GRAS) for its intended use and marketing it on that basis.

In the press release, HHS describes the self-affirmed GRAS pathway for marketing a new food ingredient as a loophole that "has allowed new ingredients and chemicals, often with unknown safety data, to be introduced into the U.S. food supply without notice to the FDA or the public. Eliminating this pathway, according to the press release, would "provide transparency to consumers, help get our nation's food supply back on track by ensuring that ingredients being introduced into foods are safe, and ultimately Make America Healthy Again."

Rather than remove the self-affirmed GRAS pathway altogether, however, HHS suggests that a final rule may simply modify it to require manufacturers to notify FDA when they have self-affirmed that an ingredient is GRAS before marketing.[1] Under current law, such notices are voluntary.[2] Presumably, this regulatory reform would make submission of such notices a premarket requirement.

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In practice, removing the GRAS pathway altogether would likely require legislation to withstand a legal challenge under the Administrative Procedure Act (APA). HHS seems to acknowledge this practical obstacle, stating that it is "committed to working with Congress to explore ways legislation can completely close the GRAS loophole." But as we discuss below, FDA may lack sufficient statutory authority to remove the GRAS pathway without such a legislative fix.

We expect industry will obtain clarity on just how extensive regulatory reforms to the self-affirmed GRAS pathway will be when the administration begins the rulemaking. Until FDA finalizes such a rule or Congress passes legislation to reform the pathway, self-affirming a new ingredient as GRAS and marketing it on that basis remains the most commercially viable option for food product manufacturers to introduce a new ingredient into the food supply.

This Client Alert identifies the Trump administration's recent commitments to revolutionizing food policy and contextualizes these initiatives within the existing statutory and regulatory framework for the self-affirmed GRAS pathway, the primary mechanism by which new food ingredients enter the US food supply.

Overview

Secretary Kennedy has been a vocal proponent of reforming how FDA regulates the nation's food supply.[3] He has consistently expressed concern that many of the ingredients and additives in the food supply are contributing to worse health outcomes for Americans. Echoing Secretary Kennedy's remarks, President Trump has made reforming food policy a priority of his administration, stating in his recent address to a joint session of Congress that his goal is to "get the poisons out of our food supply, and keep our children healthy and strong."[4]

Most recently, Marty Makary, President Trump's nominee for FDA Commissioner, affirmed that he would prioritize this initiative, stating during his confirmation hearing that he intends to "build off the new momentum and enthusiasm from Secretary Kennedy and President Trump" to tackle the issues they have raised regarding food policy reform.[5]

The Self-Affirmed GRAS Pathway

The Food Additives Amendment of 1958

In 1958, Congress enacted the Food Additives Amendment of 1958 (the 1958 Amendment) in response to public concern about the increased use of chemicals in the food supply.[6] The 1958 Amendment set forth three categories of ingredients added to food: (1) prior-sanctioned ingredients, or those FDA or the Department of Agriculture approved for use in food during 1938-1958; (2) ingredients that are GRAS for their intended use based on a consensus of qualified experts; and (3) food additives, which Congress defined as ingredients that are neither GRAS nor prior-sanctioned and are intended to become a component of food or otherwise affect the characteristics of any food.[7]

For an ingredient to be GRAS, the expert scientific community knowledgeable about the safety of ingredients added to food must be reasonably certain that the ingredient is safe under the conditions of its intended use.[8] To reach this consensus, qualified scientific experts must generally agree that the ingredient's overall impact on the diet is not harmful, and that the way in which people will likely consume it — and the likelihood that other ingredients will form in or on food because of its presence — does not raise safety concerns.[9] FDA has stressed that this consensus on the GRAS ingredient's safety is what distinguishes it from a food additive.[10]

The 1958 Amendment established the premarket approval pathway for food additives.[11] Under this pathway, manufacturers seeking to introduce a new food additive into the food supply must petition FDA to issue a regulation specifying the conditions under which the food additive may be safely used.[12] Food additive petitions are typically burdensome, requiring comprehensive scientific data and rigorous documentation to demonstrate the safety of the food ingredient.[13]

The Voluntary Notice Process

Notably, the 1958 Amendment did not require premarket approval of GRAS ingredients.[14] Nor did it preclude manufacturers from self-affirming that an ingredient is GRAS for its intended use and marketing it on the basis of that self-affirmation.[15] FDA has since taken the position that the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) does not provide it with premarket review authority over GRAS ingredients, stating that manufacturers can add an ingredient to human food if the manufacturer self-affirms that the ingredient is GRAS under the conditions of its intended use.[16] In 2016, FDA finalized regulations setting forth a process for manufacturers to voluntarily notify FDA of a GRAS self-affirmation.[17]

Under the voluntary notice process, manufacturers who want some agency imprimatur for their conclusions may voluntarily notify FDA that they have self-affirmed that an ingredient is safe for its intended use and seek FDA's feedback.[18] In response, FDA will send the notifier a "No Questions Letter" or an "Insufficient Basis Letter" or, at the manufacturer's request, a letter that FDA has ceased to evaluate the GRAS notice.[19]

A "No Questions Letter" informs the notifier that, based on the information it has provided, as well as other information available to the agency, FDA has no questions regarding the notifier's conclusion that the ingredient in question is GRAS under its intended conditions of use.[20] An "Insufficient Basis Letter," by contrast, informs the notifier that FDA has evaluated the information that the notifier discusses in its GRAS notice and determined that it *does not* provide a sufficient basis for a determination that the ingredient is GRAS for its intended use.[21]

Notably, FDA does not affirm in a "No Questions Letter" that an ingredient is GRAS for its intended use; FDA simply states that it has no questions regarding the notifier's conclusion.[22] Indeed, to formally affirm that an ingredient is GRAS, FDA can follow the GRAS affirmation process set forth in 21 C.F.R. § 170.35, which resembles the regulatory process it can follow for announcing that an ingredient is *not* GRAS.[23]

Self-affirming that an ingredient is GRAS and immediately introducing it into food requires no interaction with FDA — and no potential for regulatory delay. But beginning research on a new food ingredient, preparing a food additive petition, and navigating FDA's burdensome administrative process for approval requires substantial resources. Even voluntarily submitting a GRAS notice requires manufacturers to comply with a complex regulatory framework.[24] While there are indeed commercial benefits to voluntarily submitting a GRAS notice — manufacturers may want to advertise that FDA has determined that the ingredients in their products are safe, or simply avoid the prospect of enforcement action — immediately marketing a product without regulatory delay is a substantial commercial benefit that often outweighs the benefits of submitting a GRAS notice.

Proposed Regulatory Reform

As noted above, the HHS press release suggests that regulatory reform would modify the framework to make submission of a GRAS notice mandatory prior to marketing rather than removing the self-affirmed GRAS pathway altogether. It states that "[e]liminating the self-affirmation process would require companies seeking to introduce new ingredients in foods to publicly notify the FDA of their intended use of such ingredients, along with underlying safety data, before they are introduced in the food supply."[25]

If FDA amends its regulations accordingly, manufacturers would still self-affirm new ingredients as GRAS; they would just be required to notify FDA of their conclusions prior to marketing the ingredient and provide what we expect would be the same quantum of evidence and safety data required under the existing framework for GRAS notices. The significance of this change on industry remains to be seen, but such regulatory reform could affect industry while FDA seeks removal of the self-affirmed GRAS pathway altogether from Congress.

FDA's Statutory Authority

Modifying the self-affirmed GRAS pathway through rulemaking as contemplated in the press release suggests that FDA plans to depart from its prior position on the self-affirmed GRAS pathway. As discussed earlier, FDA finalized its regulations setting forth the process and criteria for voluntary GRAS notices less than a decade ago.[26] Despite numerous comments on the proposed rule and a recommendation from the Government Accountability Office, FDA declined at that time to require manufacturers to provide the agency with basic information about their GRAS determinations, such as the ingredient's identity and intended uses.[27] According to FDA, it lacked express statutory authority to require companies to provide even such limited information,[28] a position FDA has consistently taken over the years.[29]

In fact, FDA recently raised this limitation on its statutory authority to prevail in a lawsuit asserting that it had abdicated its statutory responsibility to "protect the public health by ensuring that ... foods are safe" by making GRAS notices voluntary.[30] FDA invoked *Chevron* to defend its interpretation, arguing that the "general, broadly worded statutory sections plaintiffs identify do not 'directly [speak] to the precise question at issue' and demand the procedures Plaintiffs seek."[31] The court agreed with FDA, noting that the statute is not only silent on whether GRAS notices must be mandatory, but also specifically exempts GRAS ingredients from the premarket review regime for food additives.[32] The court found FDA's interpretation reasonable "given that GRAS substances are specifically exempted from the rigorous review applicable to food additives ... and in more than sixty years Congress has never required mandatory GRAS submissions."[33]

Since any final rule would significantly reverse course on a position FDA has consistently taken over the years, the rule will need to comply with well-established principles of administrative law for an agency change in position. Following the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo* and *Relentless Inc. v. Department of Commerce*, which overruled the *Chevron* doctrine and requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, FDA will also need to identify the statutory basis for implementing such a change.[34]

Other Potential Legal Obstacles

President Trump's recent executive orders may also pose obstacles for any rulemaking. Executive Order 14192, titled "Unleashing Prosperity Through Deregulation," requires agencies to eliminate 10 regulations for every new regulation they issue.[35] And Executive Order 14219, titled "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," requires agencies to identify and rescind regulations that "are based on anything other than the best reading of the underlying statutory authority or prohibition."[36] These executive orders and others further complicate the pathway for FDA to increase its oversight of food ingredients through regulations.

Perhaps recognizing some of the legal obstacles described above, HHS states in the press release that it is also "committed to working with Congress to explore ways legislation can completely close the GRAS loophole."[37] While legislative efforts to reform the self-affirmed GRAS pathway have historically struggled to gain traction,[38] recent support from President Trump and Secretary Kennedy, as well as the

newly formed Make America Healthy Again Caucus, may provide a legislative amendment with the congressional momentum it needs.

Potential Next Steps

Legislation could potentially resemble the Toxic Free Food Act of 2024, which was referred to the House Energy and Commerce Committee but failed to advance beyond that stage. If enacted, the Act would have made sweeping changes to the self-affirmed GRAS pathway. First, it would have prohibited manufacturers from introducing a new GRAS ingredient into the food supply without first notifying FDA of the GRAS self-affirmation, during which time the manufacturer could not market the ingredient.[39] Second, it would have required FDA to provide the public with at least 90 days to review each GRAS self-affirmation.[40] Third, it would have prohibited FDA from relying on the determination of qualified scientific experts with conflicts of interest.[41] Finally — and perhaps most significantly — it would have required FDA to create a process for systematically reassessing any ingredient that was previously self-affirmed as GRAS if it no longer met the revised standards for self-affirmation.[42]

In the meantime, Secretary Kennedy and Dr. Makary, if confirmed, could begin taking several steps to achieve their food policy goals without rulemaking or legislation. They could, for example, direct FDA to increase its oversight of the food supply to re-evaluate self-affirmed GRAS ingredients in food and identify which ones are not, in the agency's view, GRAS for their intended use. After identifying such an ingredient, FDA could publish a scientific memorandum explaining the basis for its determination and begin taking case-by-case enforcement action against manufacturers for products that contain the ingredient at issue.[43] FDA could also simply send warning letters to manufacturers asserting that the use of a particular ingredient in food is not GRAS for its intended use and therefore requires approval through a food additive petition.[44] Or FDA could heighten the standard it applies in its review of voluntary GRAS notices, more frequently requesting additional data before issuing a "No Questions Letter." FDA could also decline to issue such a response altogether, instead using its other responses to GRAS notices to instruct industry to seek FDA feedback through the more stringent food additive petition process.

Conclusion

Despite the obstacles to legal reform, manufacturers should prepare for shifts in the regulatory landscape, particularly if legislative efforts like the Toxic Free Food Act gain traction. Manufacturers will also benefit from an increased understanding of FDA's post-market process for assessing ingredients identified in food and the implications of recent changes in administrative law.

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Endnotes

[1] HHS Press Office, *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/about/news/2025/03/10/hhs-secretary-kennedy-directs-fda-explore-rulemaking-eliminate-pathway-companies-self-affirm-food-ingredients-safe.html (HHS Press Release).

[2] 21 C.F.R. § 170.205.

[3] Robert F. Kennedy Jr., *Enough is Enough*, YouTube (Sept. 24, 2025), https://www.youtube.com/watch?v=0_OjKe4BuDE&t=4s.

[4] Remarks by President Trump in Joint Address to Congress (Mar. 4, 2025), https://www.whitehouse.gov/remarks/2025/03/remarks-by-president-trump-in-joint-address-to-congress/.

[5] CSPAN, *FDA Commissioner Nominee Testifies at Confirmation Hearing* (Mar. 6, 2025), https://www.c-span.org/program/senate-committee/fda-commissioner-nominee-testifies-at-confirmation-hearing/656394, at 1:15:22.

[6] Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified as amended at 21 U.S.C. § 321(s)).

[7] *Id.*

[8] Substances Generally Recognized as Safe, 62 Fed. Reg. 18938, 18941 (Apr. 17, 1997) ("In proposing these changes, FDA is: (1) Emphasizing that a GRAS substance is distinguished from a food additive by the common knowledge about the safety of the substance for its intended use rather than by what the substance is, or on the basis of the types of data and information that are necessary to establish its safety"); *see also* FDA, *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: Guidance for Industry* 6-7 (Nov. 2017), https://www.fda.gov/media/109117/download (GRAS Guidance).

[9] 21 C.F.R. § 170.3(i).

[10] 62 Fed. Reg. 18941.

[11] Food Additives Amendment of 1958 at 72 Stat. 1785-1786 (codified at 21 U.S.C. § 348(b)).

[12] 21 U.S.C. § 348(b)(2).

[13] *See Id.*

[14] *See, e.g.,* Food Additives Amendment of 1958 at 72 Stat. 1784.

[15] *See id.*

[16] *See, e.g.,* GRAS and Food Additive Status, Proposed Procedures for Affirmation and Determination, 37 Fed. Reg. 6207, 6208 (Mar. 25, 1972) (establishing procedures for a manufacturer to seek FDA affirmation, not approval, of a GRAS determination);

Substances Generally Recognized as Safe, 81 Fed. Reg. 54960, 54961 (Aug. 17, 2016) (stating that a "food manufacturer can intentionally add a substance to human food or animal food without [FDA] premarket review or approval If the substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use (GRAS)"; Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67169, 67170 (Nov. 8, 2013) ("[A] substance that is GRAS for a particular in food is not a food additive, and may lawfully be utilized for that use without Agency review and approval."); 81 Fed. Reg. 54981, 54982 ("The creation of this GRAS provision reflected Congress' determination that many substances intentionally added to food for a specific use do not need premarket review by FDA to ensure their safety").

[17] Substances Generally Recognized as Safe, 81 Fed. Reg. 54960 (codified as amended at 21 C.F.R. Part 170, Subpart E).

[18] 21 C.F.R. §§ 170.205, 170.220.

[19] Substances Generally Recognized as Safe, 81 Fed. Reg. 54900, 54967 (Aug. 17, 2016). If a manufacturer requests that FDA cease to evaluate its GRAS Notice, FDA can also issue a "Cease to evaluate letter."

[20] *Id.*

[21] *Id.*

[22] *See, e.g.,* FDA Letter to Synlait Milk Limited, GRAS Notice No. GRN 001172 (Feb. 22, 2024), https://www.fda.gov/media/183695/download ("This letter is not an affirmation that liquid milk blend is GRAS under 21 CFR 170.45.").

[23] *See* 21 C.F.R. § 170.38(b)(3).

[24] *See* 21 C.F.R. Subpart E – Generally Recognized as Safe (GRAS) Notice (setting forth the general requirements applicable to a GRAS notice).

[25] *See* HHS Press Release.

[26] Substances Generally Recognized as Safe, 81 Fed. Reg. 54960 (codified as amended at 21 C.F.R. Part 170).

[27] GAO-10-246 Food Safety at 36, https://www.gao.gov/assets/gao-10-246.pdf; *see also* 81 Fed. Reg. 54981-82.

[28] 81 Fed. Reg. 54981-82.

[29] Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Information, 78 Fed. Reg. 67169, 67170 (Nov. 8, 2013) ("As noted previously, under section 201(s) of the FD&C Act, a substance that is GRAS for a particular use in food is not a food additive, and may lawfully be utilized for that use without Agency review and approval.").

[30] *Ctr. for Food Safety v. Becerra*, 565 F.Supp. 3d. 519, 523–524 (S.D.N.Y. 2021) (citing 21 U.S.C. § 393(b)(2)).

[31] Defendants' Reply Memorandum of Law in Further Support of Their Cross-Motion for Summary Judgment at 2-3 No. 1:17-cv-03833-VSB, *Ctr. for Food Safety v. Becerra*, ECF No. 90 ("First, the statute setting forth FDA's basic mission does not establish an unambiguous requirement of mandatory notification and recordkeeping.").

[32] *Ctr. for Food Safety v. Becerra*, 565 F.Supp. 3d. at 536.

[33] *Id.* at 538.

[34] *Loper Bright Enterprises v. Raimondo,* 603 U.S. 369, 412–413 (2024).

[35] Executive Order 14192, Unleashing Prosperity Through Deregulation, 90 Fed. Reg. 9065, 9065 (Feb. 6, 2025).

[36] Executive Order 14219, Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative, 90 Fed. Reg. 10583, 10583 (Feb. 25, 2025).

[37] HHS Press Release.

[38] Toxic Free Food Act of 2024, H.R. 9817, 118th Cong. (2024).

[39] Toxic Free Food Act of 2024, H.R. 9817, 118th Cong. (2024).

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] *See, e.g., Post-market Determinations that the Use of a Substance is not GRAS*, FDA (Dec. 18, 2024), https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=Postmarket.

[44] *See, e.g.,* Warning Letter to Lithia Mineral Water, Inc. (July 20, 2012) (on file with author) (requesting that Lithia Mineral Water provide FDA with its basis for concluding that "actively charged ionic colloidal silver" is GRAS for use in mineral water).