

HHS Directive Could Overhaul Food Ingredient Safety Rules

By **Natalie Rainer and Pete Coneski** (April 2, 2025)

In an announcement on March 10, U.S. Department of Health and Human Services Secretary Robert F. Kennedy Jr. directed the U.S. Food and Drug Administration to "explore potential rulemaking to ... eliminate the self-affirmed [Generally Recognized As Safe] pathway."^[1]

The so-called GRAS pathway refers to a formal exemption from the definition of "food additive" under Section 201(s) of the Federal Food, Drug and Cosmetic Act, that allows a food ingredient to be used without premarket approval from the FDA when there is adequate scientific data to support the general recognition by qualified experts that the intended use of a substance in food is safe.

Under the existing regulatory framework, the food industry relies on self-GRAS positions for everything from the use of flavors to caffeine — in any application other than cola-type beverages — to novel ingredients popular in health foods — like ashwagandha and maca. Self-GRAS determinations are also a uniquely helpful tool for food-contact substances used in food packaging and processing equipment, as food-contact substances are viewed as potential food additives under the Federal Food, Drug and Cosmetic Act.

HHS has suggested that rather than eliminating self-GRAS positions entirely, the FDA would modify through rulemaking the current framework to require manufacturers to notify the FDA of a GRAS position prior to marketing it. It is not clear whether the FDA would require the manufacturer to wait for the FDA to respond before marketing the product containing the given ingredient.

If so, it would subject GRAS substances to premarket approval. We provide a brief background on the GRAS exemption below, followed by comments on legal and pragmatic challenges these changes may pose to the food industry.

Brief Background on the GRAS Exemption

The GRAS exemption from the definition of "food additive" is unique from an international food regulatory perspective and has facilitated innovation in the American food supply, but it has been mired in controversy for many years, since consumer groups like the Center for Food Safety called into question the ability of the food industry to police itself in this regard.

Why the controversy? The GRAS exemption allows food companies to go to market without FDA premarket review if there are sufficient safety data — e.g., chemistry, characterization and toxicology — to support the conclusion that the intended use is safe. Detractors are of the opinion that the food industry cannot be trusted to make its own safety determinations.

There are a relatively limited number of substances that are the subject of GRAS regulations in Parts 182 and 184 of the FDA's food additive regulation, and these regulations formally recognize the GRAS status of certain natural flavors, nutrients, preservatives and other substances. It is far from a comprehensive set of regulations.



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Somewhat confusingly, the FDA administers a program to evaluate GRAS assessments on behalf of the food industry through the GRAS notification program. After informally administering the program for 20 years, the FDA formalized regulations on the GRAS notification program in 2016 at Title 21 of the Code of Federal Regulations, Part 170, Subpart E, in part in response to a 2014 lawsuit filed by the Center for Food Safety.[2]

As of March, approximately 1,200 notifications have been submitted to the FDA through this program, which has largely replaced the more administratively burdensome and theoretically slower Food Additive Petition process that results in the promulgation of a food additive regulation codified in Title 21 of the Code of Federal Regulations.

Under the GRAS notification process, the best-case outcome is to receive a "no questions" letter in which the FDA does not object to the submitter's GRAS conclusion. The FDA does not approve the product or even affirm the GRAS conclusion — the agency simply does not object to the submitter's position.

There is a notice-and-comment rulemaking process whereby companies can file a petition to seek the FDA's affirmation that a substance's intended use is GRAS under Title 21 of the Code of Federal Regulations, Part 170.35. Successful petitions result in a regulation being issued to amend Title 21 of the Code of Federal Regulations, Part 184, for substances added to food, and Part 186 for food-contact substances.

However, since the FDA started accepting GRAS notifications, the notification program has replaced the GRAS affirmation petition process because it is faster and does not require notice-and-comment rulemaking.

Can the FDA Eliminate the GRAS Self-Affirmation Pathway?

The FDA has been in the position of defending the GRAS self-affirmation process in relatively recent litigation, and has raised the defense that it does not have the authority to eliminate self-GRAS determinations.

Specifically, in *Center for Food Safety v. Becerra*, the nonprofit Center for Food Safety sought to challenge the FDA's GRAS notice regulations and in part sought to require the FDA to review all GRAS determinations — effectively seeking to end GRAS self-determinations.[3] The Center for Food Safety argued that the FDA's tolerance of self-GRAS determinations violated the Administrative Procedure Act and amounted to an unlawful delegation of its authority to regulate food additives, among other arguments.

The U.S. District Court for the Southern District of New York in finding for the FDA and upholding the GRAS notification program, in 2021, held:

[I]t remains unclear under the statute whether FDA even has the authority to make GRAS notifications mandatory. I decline Plaintiffs' invitation to rewrite the statute. The remedy Plaintiffs seek lies with Congress, not me, and Congress has chosen not to act despite the increase in the number of food additives over the last five decades.[4]

The outcome of the case illustrates a potential statutory challenge to rulemaking to end GRAS self-determinations. In addition, with the end of *Chevron* deference under *Loper Bright Enterprises v. Raimondo* and *Relentless Inc. v. Department of Commerce*, in the U.S. Supreme Court in June 2024,[5] the FDA is not entitled to the level of deference it once enjoyed, and a move to close off GRAS self-determinations would presumably require

strong statutory support to survive a legal challenge from the food industry. Reading the *Center for Food Safety v. Becerra* arguments and in light of the end of Chevron deference,[6] modification of the statute itself by Congress may be needed to limit the scope of the GRAS exemption, and this is clearly understood by HHS as well, which states in the directive that it is "committed to working with Congress to explore ways legislation can completely close the GRAS loophole." [7]

Practical Implications of HHS Directive

The GRAS exemption is a well-established in American food regulation and has saved years of administrative review of substances in the food supply for ingredients we regard as fairly common and ubiquitous, like natural flavors that are not otherwise cleared by regulation. If the HHS directive were to come to fruition, we note the following factors that would affect the food industry.

- GRAS notices cover one ingredient per filing. Thus, a single product — e.g., an energy drink with added amino acids and caffeine — could require the preparation of multiple GRAS notices to comply with FDA requirements in the new landscape.
- GRAS notices are manufacturing process-specific and take into account the unique safety considerations that are implicated in a single manufacturing process. This issue is reflected in the number of steviol glycoside GRAS notices that are described on the current inventory. Many of these filings apply to the same target compound but describe different manufacturing processes.
- The FDA may receive many GRAS notices for the same compound — e.g., caffeine — for different end uses. While some of the uses will overlap, e.g., carbonated beverages, companies may not be privy to competitors' GRAS filings and may submit duplicative requests. The FDA will also be faced with the challenge of accumulating estimated exposures from different applications submitted by different submitters. There may be an advantage to be being the first to file a GRAS notice, as later filers may find that the current safety data do not support additions to the cumulative exposure.
- The current wait time for GRAS notices, prior to staffing cuts, was typically in excess of a year. If GRAS notices were to become mandatory, it is possible that a user-fee program could develop similar to what is seen in other FDA-regulated sectors to support reviewers and shorten review times.
- Smaller businesses, which are likely to have smaller budgets for food regulatory compliance, would be faced with a more limited palette of ingredients to choose from

when crafting food products — e.g., substances cleared in the food additive regulations or a GRAS notice for their intended use.

- For food-contact materials, manufacturers would likely choose to file food contact notifications to support the FDA status of those substances. Since those filings are proprietary to the notifier, the FDA would potentially receive several notifications for the same substance as a result.

The end of the GRAS self-affirmation pathway would be a sea change for the food industry and the food-contact material industry. While some companies have deep familiarity with GRAS notices and many existing GRAS self-determinations on file that could be readily submitted to the FDA, others would face a steep regulatory compliance burden.

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[1] HHS, HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe (March 10, 2025), available at <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>.

[2] Ctr. for Food Safety v. Burwell, Case No. 1:14-cv-267-RC, Consent Decree, ECF No. 14-1 (Oct. 20, 2014).

[3] Ctr. for Food Safety v. Becerra, 565 F. Supp. 3d. 519 (S.D.N.Y. 2021).

[4] Id. at 539.

[5] Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412–13 (2024).

[6] The Chevron doctrine was the legal doctrine dictating that courts should defer to agencies' reasonable interpretations of ambiguous statutes. Chevron U.S.A. Inc. v. Nat. Res. Def. Council Inc., 467 U.S. 837 (1984).

[7] Supra note 1.