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U.S. Department of Health and Human Services Moves to Eliminate Self-Affirmed GRAS Pathway for Food Ingredients

Samuel D. Jockel and Angela M. Spivey*

In this article, the authors examine the potential impact on ingredient suppliers, manufacturers, regulatory professionals, and legal teams of the U.S. Department of Health and Human Services' effort seeking to "promote radical transparency" and upend the decades-old generally recognized as safe (GRAS) pathway for food ingredients.

The U.S. Department of Health and Human Services (HHS) has directed[1] the Food and Drug Administration (FDA) to explore rulemaking that would eliminate the self-affirmed generally recognized as safe (GRAS) pathway—a pathway that has been used by ingredient suppliers and food manufacturers for decades. This move aims to increase "radical transparency" and regulatory oversight for the food industry. Given GRAS's long-standing role in the nation's food system, understanding this change—and its potential impact—is critical for ingredient suppliers, manufacturers, regulatory professionals, and legal teams.

Self-Affirmed GRAS Pathway

The 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FDCA) established a premarket review and approval system for food additives, effectively placing the burden of proof on industry to demonstrate the safety of a substance intentionally added to food. The FDCA defines a "food additive" 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 . . . , if such substance is not generally recognized . . . to be safe under the conditions of its intended use." Importantly,

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the definition excludes substances that are generally recognized, "among experts qualified by scientific training and experience to evaluate its safety," to be safe under the conditions of its use. This is also known as the GRAS exemption. GRAS status may exist based on a level of scientific agreement about a substance's safety, or for a substance used in food before January 1, 1958, on scientific procedures or common use in food.

Making a conclusion that a particular ingredient is GRAS, and therefore not subject to FDA premarket review and approval, requires a factual determination based on the date of introduction into food in the United States or the safety of the use of the ingredient at the levels anticipated. There are two pathways for reaching a GRAS conclusion: (1) submitting a GRAS notification to the FDA for review, or (2) making an independent (self-affirmed) GRAS conclusion without notifying the FDA. The self-affirmed GRAS pathway has existed since the FDA proposed a notification procedure in 1997,[2] which was later finalized in 2016 as the GRAS Final Rule.[3]

In 2021, the U.S. District Court for the Southern District of New York[4] upheld the FDA's GRAS Final Rule. The court ruled the FDA did not unlawfully delegate any duty to manufacturers since it retains authority over self-affirmed GRAS conclusions and can intervene if an ingredient is unsafe.

The court also noted the FDCA can be reasonably interpreted to allow a voluntary notification system and agreed with the government's position for its decision to not require a mandatory GRAS notification system.

Finally, the court noted that it found no conflicts between the GRAS Final Rule and the FDCA, noting that Congress—not the courts—must decide on any changes to the GRAS process.

HHS Press Release on Eliminating Self-Affirmed GRAS Pathway

Now, under HHS Secretary Robert F. Kennedy Jr.'s direction, the FDA has been directed to explore eliminating the self-affirmed GRAS pathway as part of the Secretary's commitment to "promoting radical transparency to make sure all Americans know what is in their food." In the press release, Kennedy called the self-affirmed GRAS pathway process a "loophole" that "has allowed

new ingredients and chemicals, often with unknown safety data, to be introduced into the U.S. food supply without notification to the FDA or the public."

By eliminating the self-affirmed GRAS pathway, the FDA would require companies to publicly notify the FDA of new food ingredients and submit supporting safety data before those ingredients enter the market. The press release concludes by stating that HHS plans to collaborate with Congress on legislation to "completely close the GRAS loophole," alongside potential future rulemaking efforts.

What Industry Should Do Next

Considering these developments, marketers of food and beverages and companies that supply ingredients should proactively ensure compliance and mitigate risk. This includes:

- Taking an inventory of and assessing current ingredients to understand their regulatory status. This could include working with suppliers to better understand assurances provided to legally market food ingredients.
- Monitor FDA rulemaking and participate in public comment periods to provide industry perspectives.
- Continue to monitor state-level developments on ingredient restrictions and bans.

As the FDA evaluates rulemaking options, industry stakeholders should stay ahead of potential regulatory shifts and prepare for a more transparent and structured GRAS review process.

In Summary

- The GRAS exemption has been in use since 1958, and the self-affirmed GRAS pathway has existed since 1997.
- A federal court previously ruled that Congress must decide on any changes to the GRAS process.
- Companies affected by the potential change should take an inventory of and assess their current ingredients to check their regulatory status.

Notes

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1. https://www.hhs.gov/press-room/revising-gras-pathway.html.
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