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Is Self-Affirming GRAS Off the Menu?

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United States Department of Health and Human Services (HHS) Secretary Kennedy recently directed the U.S. Food and Drug Administration (FDA) to consider rulemaking to revise its longstanding regulations and guidance governing the oversight of food ingredients to eliminate the ability of individuals and companies to self-affirm that their ingredients are Generally Recognized as Safe (GRAS). This would mark a massive shift in how new food ingredients are introduced to the market.

In 1958, Congress enacted the Food Additives Amendment to the Food, Drug and Cosmetic Act (FDCA). These amendments required that "food additives" receive premarket approval from FDA, unless they were "substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety as having been adequately shown... to be safe under the conditions of their intended use." Such substances are considered to be "generally recognized as safe".[1]

The agency's approach to GRAS determinations has evolved over the intervening decades, with the last major change coming in 2016 with the publication of what is referred to as the final GRAS rule. Under this rule, "any person may notify FDA of a view that a substance is not subject to the premarket approval requirements...." 21 C.F.R. § 170.205. This provision establishes a voluntary pathway for industry to submit a GRAS notification to FDA—in other words, a person or company may make an "independent conclusion of GRAS status" without also making a submission to FDA (though FDA strongly encourages submitting notice to the agency for review).[2]This process, otherwise known as "self-affirming," is the subject of Secretary Kennedy's order.

In his order, Secretary Kennedy states that "[f]or far too long, ingredient manufacturers and sponsors have exploited 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... Eliminating this loophole will provide transparency to consumers, [and] help get our nation's food supply back on track...." Further still, the order notes that HHS is "committed to working with Congress to explore ways legislation can completely close the GRAS loophole."

While details are sparse, removal of the self-affirming pathway would presumably require rulemaking or legislation. In the interim, FDA could start exercising greater scrutiny of self-affirming GRAS determinations. An end to the self-affirmation process would also create significantly more work for the agency in evaluating proposed new ingredients, at a time when the administration is attempting to drastically shrink the FDA work force.

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[1] Note that substances used in food before 1958 may also be considered GRAS based on a determination made through experience based on common use in food. 21 C.F. R. § 170.30.

[2] 81 Fed. Reg. 54,960, 54,966 (Aug. 17, 2016).

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