

HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Self-Affirmed GRAS Pathway

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- On March 10, 2025, the Department of Health & Human Services (HHS) Secretary Robert F. Kennedy Jr. [announced](#) that he is directing the U.S. Food & Drug Administration (FDA) “to explore potential rulemaking to revise its Substances Generally Recognized as Safe (GRAS) Final Rule and related guidance to eliminate the self-affirmed GRAS pathway.”
- This self-affirmation process is built into the [1958 Food Additive Amendments](#), which amended the definition of a “food additive” and allows certain substances to be exempt from premarket review if they are GRAS based on scientific procedures or history of use in food as determined by qualified experts. Notably, the announcement also specifically references “substances that come into contact with food.”
- The announcement is made to promote oversight and transparency. The announcement expresses a commitment to working with Congress to close the GRAS self-affirmation pathway and acknowledges that legislation will be pursued in tandem with potential future rulemaking.
- Importantly, there is no immediate effect on ingredients currently marketed, allowing companies to continue their operations without disruption while FDA explores potential rulemaking. Keller and Heckman will continue to monitor developments related to the GRAS program.

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