

FDA's Proposed GRAS Rule - Mandatory Notifications, Expanded Scope, and Open Questions

[Donnelly L. McDowell](#), [Katie Rogers](#), [Cristina Ferretti](#)

September 1, 2026

What could a major change to the GRAS framework mean for food companies? In this episode, we unpack the FDA's proposed rule that would transform the long-standing voluntary GRAS notification system into a mandatory one, while also expanding the scope of the program and creating a streamlined pathway for certain substances already on the market. We explore what the proposal could mean for companies relying on self-affirmed GRAS determinations, including new notification requirements, transition periods, potential post-market scrutiny, and longer FDA review timelines. The proposal also raises significant questions about FDA's legal authority and whether the agency has the resources to manage a substantial increase in submissions. For food and ingredient companies, the rule could represent one of the most significant changes to the GRAS framework in decades, making it important to assess current GRAS determinations and prepare for what comes next.

Hosted by Simone Roach. Based on a blog post by [Donnelly L. McDowell](#), [Katie Rogers](#), and [Cristina Ferretti](#).