Policy Alert: Revising the GRAS Designation for Food

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Action: Department of Health and Human Services (HHS) Secretary Robert F. Kennedy, Jr. directed the Commissioner of the Food and Drug Administration to take steps to explore potential rulemaking to revise the Substances Generally Recognized as Safe (GRAS) Final Rule (last revised in 2016) and related guidance used by companies to self-affirm food ingredients as safe.

Key Insights

- Since 1958, the FDA has been responsible for evaluating the safety of new chemicals and substances in food before they reach the market. Any ingredient considered a "food additive" (any substance that is intentionally added to food) must be reviewed and approved by the FDA before use in foods, "unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use."
- Under relevant sections of the Food, Drug & Cosmetic Act and regulations, GRAS designation is achieved either though "experience based on common use in food" for substances used in food before 1958 (including common additives such as salt) or "[g]eneral recognition of safety through scientific procedures [using] generally available and accepted scientific data, information, or methods, which ordinarily are published" which "may be corroborated by the application of unpublished" material.
- In practice, the GRAS exemption has been somewhat wide. Research published last

year in the *American Journal of Public Health* suggests that the exemption may allow unsafe ingredients to enter the food supply. According to Jennifer Pomeranz, associate professor of public health policy and management at the NYU School of Global Public Health, from 1990 to 2010, an estimated 1,000 substances were labeled GRAS by manufacturers and used without notifying FDA.

- A potential change to the current Final Rule and related guidelines would likely require companies to notify FDA and submit related safety data before adding new ingredients to their food products.
- Kennedy's directive won praise from some food safety advocates as well as President Biden's FDA Commissioner Robert Califf. Califf added that the effort would require FDA to increase staff "to assess the data that would determine whether an ingredient is safe . . . the budget impact would be significant."
- In a related development, Kennedy reportedly expressed a "'strong desire'" to remove synthetic color additives from the food supply" during a meeting with industry leaders and suggested he would act if industry were not proactive in doing so.