Packaged Food Industry Willing To Work With FDA On GRAS Process

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The packaged food industry presented itself at a conference this week as a cooperative partner in the Trump administration's push to reform the food additive review process, emphasizing its commitment to a safe and transparent food supply despite concerns by other food industry groups about a potential overhaul of the current regulatory paradigm. HHS Secretary Robert F. Kennedy Jr. on Monday (March 10) asked FDA to revisit its years-long policy of relying on the food industry to voluntarily attest that its food ingredients are "generally recognized as safe."

Kennedy specifically instructed the acting FDA commissioner to explore revising the agency's food additive standard to eliminate companies' ability to designate ingredients as GRAS without FDA review of the underlying evidence.

"FDA's Generally Recognized as Safe (GRAS) process plays an important role in enabling companies to innovate to meet consumer demand," Sarah Gallo, senior vice president of product policy at the Consumer Brands Association (CBA), told *Inside Health Policy*. "As the administration looks to revise GRAS, we stand ready to work with agency experts on continued analysis of safe ingredients and increased consumer transparency."

Kennedy met with top industry leaders on Monday, and CBA described the discussion to *IHP* as "constructive."

"It was a constructive conversation, and we look forward to continued engagement with the secretary and the qualified experts within HHS to support public health, build consumer trust and promote consumer choice," Melissa Hockstad, CBA president and CEO, said in a statement.

At the National Food Policy conference Tuesday (March 11), food industry insiders also recognized that regulatory changes are imminent -- whether at the federal level or through state legislation.

"I think there was maybe a little bit of angst before that meeting among some of the food company CEOs, but they recognized they really need to think through where is the place that they can land, that they will be able to implement to meet some of these goals that RFK and others have put out," one food industry expert said at the conference.

The expert also said that the companies acknowledge a pressing need to reformulate products in response to mounting public and regulatory pressure around nutritional health.

At the same time, around 300 food and agriculture organizations are pushing back against what they call "unfounded criticisms" of the U.S. food system, urging the Trump administration to rely on "sound, quality science and data" in regulatory decisions.

In a March 7 letter to top officials including Kennedy, Agriculture Secretary Brooke Rollins and Environmental Protection Agency Administrator Lee Zeldin, the organizations emphasized the importance of risk-based oversight and warned against policy changes driven by "misleading or outlier studies." Signers include the American Farm Bureau Federation, the International Food Additives Council, the National Seasoning Manufacturers Association and dozens of others.

The organizations cautioned that restricting GRAS ingredients based on questionable studies could lead to food shortages, higher prices, and increased reliance on imports. The letter also underscored the stringent federal regulatory processes already in place, calling the U.S. system the "global gold standard" for food safety.

"Limiting GRAS ingredients and additives due to dubious studies that do not meet appropriate data quality standards could lead to food shortages, limited options for consumers with dietary or religious food restrictions, intensified food waste, and increased imported food ingredients that would both spike costs and decrease food safety certainty," the groups wrote.

While the organizations expressed a willingness to work with the administration, they stressed the need for scientific integrity in policy decisions.

"Our organizations support and share in the goal of improving health outcomes for Americans, but it is vital that any review efforts of the Commission or individual participant agencies are based on quality data and accept the strong scientific consensus on these topics," they wrote. "Further, any assessments must acknowledge the robust science- and risk-based processes our regulatory agencies already have in place and the extensive history of safe use that has resulted therefrom."

A legal expert tells *IHP* that requiring the submission of GRAS notifications to FDA for review and approval, and potentially eliminating the "Self-GRAS" pathway, would likely require congressional action. FDA currently lacks the statutory authority to mandate such notifications.

According to the FDA's final rule establishing the GRAS notification process, Congress explicitly excluded substances that are "generally recognized as safe" from the definition of food additives in the 1958 Food Additives Amendment to the Food, Drug, and

Cosmetic Act (FD&C Act). This exclusion was made on the premise that certain substances added to food do not require premarket approval, either because they have a long history of safe use or because qualified experts have determined their safety based on available data.

Despite calls from some parties to require companies to notify FDA of their GRAS conclusions, FDA has confirmed that it does not have express statutory authority to impose such a requirement. The 1997 Food and Drug Administration Modernization Act (FDAMA) amended section 409 of the FD&C Act to create a mandatory notification program for food contact substances, but Congress has not amended the same section to establish a mandatory GRAS notification procedure. As a result, FDA has limited authority to require companies to submit notices regarding GRAS status conclusions.

In response to public comments suggesting that FDA may have implied legal authority to require such notifications, FDA during the Biden administration clarified that any move to mandate GRAS notifications would require new rulemaking. This would include a separate notice and comment process to ensure adequate public input and compliance with legal procedures. FDA also stated that while it is not currently proposing to mandate GRAS notifications, it will continue to evaluate the effectiveness of its voluntary notification system and consider whether further action is needed to protect the safety of the food supply. -- *Maaisha Osman*(mosman@iwpnews.com), *Luke Zarzecki*