Kennedy’s Crusade Against Food Safety Rule Threatens Supplement Industry

By going after an obscure regulatory designation he describes as a “loophole,” Mr. Kennedy has put an industry he champions on the defensive.

Robert F. Kennedy Jr. has said he hopes to eliminate a “loophole” that allows companies to easily introduce new ingredients or chemicals into the American food supply.Credit...Tierney L. Cross/The New York Times

By Jane Black

Aug. 6, 2025

In his first weeks as health secretary, Robert F. Kennedy Jr. declared war on an obscure regulatory process that many argue has been exploited by the food industry for decades.

The pathway allows companies to introduce new ingredients or chemicals into food products without a Food and Drug Administration review, as long as they self-certify them as “generally recognized as safe,” or GRAS for short.

The designation has allowed new chemicals to be viewed as “innocent until proven guilty,” leading to thousands of ingredients flooding the American food system, Mr. Kennedy said at his confirmation hearing in January. “It needs to end, and I believe I’m the one person who’s able to end it,” he added.

In March, Mr. Kennedy directed the Food and Drug Administration to revisit the GRAS rule, describing it as a "loophole" that needed to be eliminated.

Food companies and ultraprocessed snacks may be the target of Mr. Kennedy's ire. But the elimination of GRAS would also be a significant setback for the growing multibillion dollar supplement industry, which has regularly used the pathway to quickly bring new ingredients to market with little oversight.

Mr. Kennedy's announcement has rattled the industry, prompting concerned calls from supplement makers and intense lobbying in Washington by the trade associations that represent them. Since March, leaders of four dietary supplement trade associations have met multiple times with F.D.A. officials to lobby the agency on the designation's benefits.

Supplement makers are worried they could become collateral damage in a campaign targeting unhealthy foods. Kennedy and his team "may not have fully appreciated how it could end up limiting consumer choice in supplements, something that runs counter to their broader platform," said Duffy MacKay, a senior vice president of dietary supplements at the Consumer Healthcare Products Association, a trade group.

And Mr. Kennedy has indeed been an avid supporter of supplements. In the lead up to the 2024 presidential election, he promised to end what he called the "aggressive suppression" of vitamins and dietary supplements, among other wellness products.

Many of those close to the health secretary have strong ties to the supplement industry. Dr. Mark Hyman, a longtime friend, sells a variety of supplements on his website. Calley Means, an adviser to Mr. Kennedy, co-founded Truemed, a company that helps people buy supplements and other health products with pretax money.

What happens next is unclear. But the fight highlights a tension inherent in Mr. Kennedy's movement as it wields power in Washington: the desire to restrain what it sees as predatory food and health care industries, while easing the government's gate-keeping power over alternative health practices.

How a Food 'Loophole' Benefits the Supplement Industry

The GRAS designation was introduced as part of the Food Additives Amendment of 1958, which Congress passed to restore public confidence in food safety. The amendment required companies to receive F.D.A. approval before they could use any new ingredients in food. But to keep agency regulators from becoming overwhelmed, it permitted manufacturers to self-certify common ingredients, such as vinegar or baking soda, as safe.

As food processing became more common and complex, the designation became a way to fast-track many of the chemicals and ingredients used in packaged foods. According to an analysis by the advocacy nonprofit Environmental Working Group, almost 99 percent of chemicals introduced in foods since 2000 have been self-certified using GRAS.

"The loophole swallowed the rule," said Tom Neltner, a food-safety advocate who has studied the designation.

For the supplement industry, it provided a workaround of a different sort. The Dietary Supplement Health and Education Act of 1994 requires supplement companies to formally notify the F.D.A. about any new dietary ingredient added to a supplement, and demonstrate that it can "reasonably be expected to be safe." The process takes several months, and requires filing documents that become available to the public for review.

It is not technically binding; the F.D.A. could raise questions about a product and it could still go to market. But far simpler for supplement companies is to use the route available to food companies, by adding new ingredients to a food product, like a health shake, and self-certifying them as safe using GRAS. Once that food product is on the market, the company can legally and quickly add the ingredient to a supplement.

This process provides a way for supplement companies to "routinely and systematically" bypass the official process for clearing new supplement ingredients, Mr. Neltner said.

Companies can notify the F.D.A. of a new ingredient they've self-certified — some prefer their ingredients undergo F.D.A. review — but doing so is voluntary, and the F.D.A. raises few questions during the process compared with during the more stringent dietary notice process. Steve Mister, the chief executive of the Council for Responsible Nutrition, a dietary supplement trade association, said the process eliminated guesswork for manufacturers. Companies weren't "trying to evade oversight," he said, but it provided the "certainty and predictability that allows them to plan."

In practice, supplement makers do sometimes withdraw GRAS notices of a new ingredient and then bring them to market anyway. The Environmental Defense Fund reviewed 46 such notices submitted between 2014 and 2021, and found roughly one quarter of the ingredients were later included in supplements.

In one more extreme case, the maker of the memory supplement Prevagen, Quincy Bioscience, submitted a GRAS notice for apoaequorin, a synthetic version of a protein found in jellyfish. The company had already failed twice to obtain an F.D.A. greenlight through the traditional process for supplements, during which the agency expressed "significant concerns."
Through GRAS, Quincy Bioscience self-certified apoaequorin as safe after putting it in a drink called Neuroshake and submitted a voluntary notice. When the F.D.A. reportedly raised questions once again, the company withdrew the notice. Apoaequorin remains on the market to this day. The company did not respond to a request for comment.

"We describe it as the wild west," said Jensen Jose, the regulatory counsel at the Center for Science in the Public Interest, a food advocacy group in Washington. "There's a sheriff but there's not much he can do."

A 'Litmus Test' for Kennedy and the F.D.A.
Mr. Kennedy hasn't announced his next steps on the pathway, and the Department of Health and Human Services did not respond to questions about a timeline or potential accommodations for supplement makers.

“This may be a good litmus test for how serious this administration is about addressing the problems with GRAS,” said Melanie Benesh, the vice president for government affairs at the Environmental Working Group.

Supplement industry representatives said they were open to strengthening the rule. Mr. Mister’s trade group, for example, has suggested a public listing of new dietary supplements and their ingredients so the F.D.A. knows what is on the market.

And several trade associations for supplement makers have called for additional funding to support agency enforcement of the current laws regulating supplements — a challenging task given the administration’s recent cuts to the agency.

Food-safety advocates would like Congress to go further and overhaul the law that established the designation, or at least close the pathway for food companies and supplement makers. At a minimum, they want companies to inform the F.D.A. of any new self-certified ingredients so the agency can confirm the chemical’s use is generally recognized as safe, and make public any concerns.

In Congress, two Democratic senators this month introduced a bill that would reshape GRAS, essentially eliminating self-certification and mandating that any ingredients previously affirmed using the designation be submitted for government review. A companion bill will soon be introduced in the House.

Ms. Benesh said the broader point was clear: “GRAS should not exist as a backdoor to bring supplements into the marketplace, especially when they don’t have adequate safety testing.”
A version of this article appears in print on Aug. 7, 2025, Section A, Page 1 of the New York edition with the headline: In Targeting Unhealthy Foods, Kennedy Also Imperils a Cause.