

Unraveling FDA's Dangerous Secret:

Companies can self-certify new food chemicals as safe and add them to foods without telling the FDA. New York bill So8615/A9295 would require companies to publish those safety assessments.

"We simply do not have the information to vouch for the safety of many of these chemicals"
-FDA Deputy Commissioner for Foods and Veterinary Medicine (2010-2016), Michael Taylor¹

FDA does not know what chemicals are in our food

While the US Food and Drug Administration (FDA) does approve a small fraction of new food chemicals, the agency does not require premarket approval, notice, or its own safety review for the vast majority of chemicals before they are first used in foods. Companies can secretly determine that a new chemical is "generally recognized as safe" (GRAS) and add it to foods without informing or submitting evidence to FDA.² They can even use paid "experts" or their own employees to secretly determine that a chemical is GRAS.³ As a result, food chemicals can come to market with inadequate, biased, or no safety assessment, and the FDA and public may never know. Companies can abuse this "secret GRAS" pathway to introduce new chemicals that are not actually generally recognized as safe by experts.

For more information about the GRAS process and how it compares to the premarket approval process, see this [article](#) and [infographic](#).

FDA cannot protect consumers from unsafe chemicals until after they are in our foods

Because companies are not required to notify FDA when introducing new food chemicals, the agency is often unable to assess a chemical's safety until after it is widely consumed and poses a threat to public safety, as demonstrated with the following cases:

- **Tara Flour**: In 2022, Daily Harvest recalled approximately 28,000 units of its "Crumbles," a vegetable protein product. This product contained tara protein flour,⁴ a new ingredient with no FDA premarket notice or approval.⁵ By October 2022, the product had been associated with 393 adverse illnesses and 133 hospitalizations. Reported symptoms included liver damage, vomiting, diarrhea, nausea, body aches, fever, and jaundice.⁶ While FDA was unable to definitively determine what component of the product caused these adverse illnesses, it identified tara flour as an ingredient of interest.⁷ And while federal law requires companies to vet ingredients for safety before they are added to foods, there is no public information that any such a safety review occurred for tara flour.⁸ Through third party testing, Daily Harvest concluded that baikianin, a naturally occurring compound in tara, appeared to be the cause of the reported issues.⁹ One thing is clear from these events: tara flour should have been better studied and tested, and the results shared with FDA and the public, before it was added to foods.
- **Caffeinated Alcohol**: In the 2000's, without FDA premarket notice or approval, companies began adding caffeine to premixed alcoholic drinks, such as Phusion Projects LLC's Four Loko and Anheuser-Busch's Tilt.¹⁰ These drinks were heavily marketed in youth-friendly media,¹¹ and some studies, according to the FDA, showed that as many as 26 percent of U.S. college students used the combination of caffeine and alcohol.¹² Only after becoming popular did FDA research how these drinks could lead to hazardous and life-threatening situations. When faced with safety concerns,

some companies withdrew the products from the market,¹³ but FDA had to eventually ban these products by declaring that adding caffeine to alcohol was not generally recognized as safe.¹⁴ If companies had published an adequate safety review prior to marketing these beverages, the safety risks could have been flagged sooner.

These examples illustrate that allowing companies to certify our foods' safety in secret does not adequately protect public health. Unfortunately, because of the secret nature of GRAS, there is no way to know how many other secret GRAS chemicals are threatening our health and safety. FDA and state regulators cannot protect us if they don't know what threats are on the market.

S08615/A9295 takes the 'secret' out of food chemical safety

New York's S08615/A9295, takes the secret out of GRAS. Introduced by Senator Kavanagh and Assemblymember Dr. Kelles, the bill requires that industry notify the state of NY if they make a secret GRAS determination and market that secret GRAS chemical in New York without notifying FDA. This notification would include a summary of the company's evidence and assessment establishing the chemical's safety.

These notices would then be published in a publicly available database funded by reporting fees and maintained by the state. In effect, this bill prevents industry from secretly self-determining the safety of food chemicals and will enable public scrutiny of food chemical safety –allowing regulators and consumer advocates to spot any instances where no safety review was conducted at all! FDA and state regulators can utilize this database to better regulate food chemical safety.

When companies are required to provide their evidence establishing safety, unsafe chemicals can be more easily identified before they are widely consumed.

S08615/A9295's cost to industry is transparency

Even though safety determinations can be made secretly, companies are still required by federal law to assess all available safety data and establish that a new chemical is safe before adding it to foods.¹⁵ S08615/A9295 simply requires that a company submit its assessment and a summary of evidence before that food chemical can be used in New York. Other than the cost of reporting and the reporting fees charged to maintain the public database, S08615/A9295 does not add any additional premarket review requirements for industry. It also includes a small business exception so that large chemical and food companies can be held accountable for transparency without overburdening small businesses.

While the cost to industry is minimal, this bill represents the most important reform to the U.S. food chemical review process in decades. If this bill becomes law, those who stand to make money from the sale of food additives would not be allowed to put new chemicals in our foods with no oversight or transparency in New York. Of course, FDA and consumers in other states would have access to the New York database, making the state a true groundbreaker in this area.

For more information, please contact the Center for Science in the Public Interest at policy@cspinet.org

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