How a legal loophole allows unsafe ingredients in US foods

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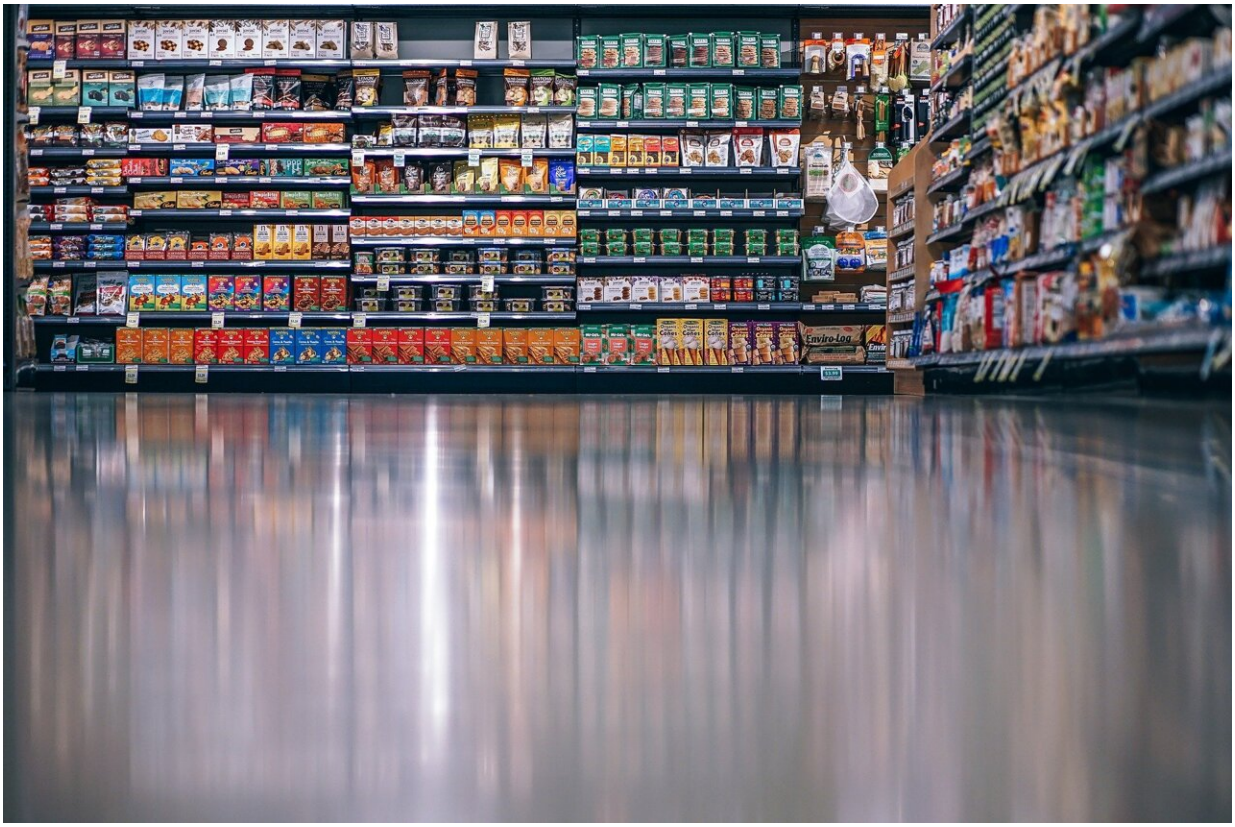

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The Food and Drug Administration (FDA) is tasked with overseeing the safety of the U.S. food supply, setting requirements for nutrition labeling, working with companies on food recalls, and responding to

outbreaks of foodborne illness. But when it comes to additives already in our food and the safety of certain ingredients, FDA has taken a hand-off approach, according to an article in the *American Journal of Public Health*.

The current FDA process allows the food industry to regulate itself when it comes to thousands of added ingredients—by determining for itself which ingredients should be considered "generally recognized as safe," or GRAS—and deciding on their own whether or not to disclose the ingredients' use and the underlying safety data to the FDA. As a result, many new substances have been added to our food supply without any government oversight.

"Both the FDA and the public are unaware of how many of these ingredients—which are most commonly found in ultra-processed foods—are in our food supply," said Jennifer Pomeranz, associate professor of public health policy and management at NYU School of Global Public Health and the study's first author.

Classifying GRAS

Since 1958, the FDA has been responsible for evaluating the safety of new chemicals and substances added to foods before they go to market. However, food safety laws distinguish between "food additives" and "GRAS" ingredients. While compounds considered "food additives" must be reviewed and approved by the FDA before they are used in foods, ingredients considered GRAS are exempt from these regulations.

The GRAS designation was initially established for ingredients already found in foods—for instance, vinegar and spices. But under a rule used since 1997, the FDA has allowed the food industry to independently determine which substances fall into this category, including many new substances added to foods.

Rather than disclose the new use of these ingredients and the accompanying safety data for FDA review, companies can do their own research to evaluate an ingredient's safety before going to market, without any notification or sharing of the findings.

The FDA suggests—but does not require—that companies voluntarily notify the agency about the use of such substances and their findings, but in practice, many such substances have been added without notification.

In their analysis, the researchers review the history of the FDA's and industry's approach to adding these new compounds to foods and identify the lack of any real oversight. This includes a federal court case in 2021 upholding the FDA's hands-off approach.

"Notably, the court did not find that the FDA's practices on GRAS ingredients support the safety of our food supply," said Pomeranz. "The court only ruled that the FDA's practice was not unlawful."

"As a result of the FDA's policy, the food industry has been free to 'self-GRAS' new substances they wish to add to foods, without notifying FDA or the public," said study senior author Dariush Mozaffarian, director of the Food is Medicine Institute and distinguished professor at the Friedman School of Nutrition Science and Policy at Tufts University.

"There are now hundreds, if not thousands, of substances added to our foods for which the true safety data are unknown to independent scientists, the government, and the public."

What's on our shelves?

According to the researchers, the FDA also lacks a formal approach and adequate resources to review those food additives and GRAS substances already on the market. After an ingredient is added to foods, if research

later suggests harms, the FDA can review the new data and, if needed, take action to reduce or remove it from foods. In a rare exception, the FDA announced in March that it would be reviewing 21 chemicals found in foods, including several food ingredients—a tiny fraction of the thousands of food additives and GRAS substances used today.

An example of the 21 food additives to be reviewed is potassium bromate, a chemical added to baked goods and drinks with evidence that it may cause cancer. Potassium bromate is banned in Europe, Canada, China, and Japan; California recently passed a law to ban its use, along with three other chemicals, and similar bills have been introduced in Illinois, New York, and Pennsylvania.

"This is a stark example of the FDA's regulatory gap," said Pomeranz. "We're seeing states starting to act to fill the regulatory void left by the FDA's inaction over substances increasingly associated with harm."

The FDA's oversight of GRAS ingredients on the market is also limited. The agency rarely revokes GRAS designation (an FDA inventory only shows 15 substances that were considered GRAS and then later determined to not be), nor does the FDA review foods on an ongoing basis with GRAS ingredients that can be safe when added at low levels but not in large quantities—for instance, caffeine, salt, and sugar.

"In 1977, the FDA approved caffeine as a GRAS substance for use in sodas at a low level: 0.02%," said Pomeranz. "But today, caffeine is added to energy drinks at levels far exceeding this, which is causing caffeine-related hospitalizations and even deaths. Given that the FDA regulates the use of GRAS substances, the agency could set limits on the amount of caffeine in energy drinks."

"The sheer number of GRAS substances and food additives on the market, combined with the lack of knowledge about the existence of self-

GRAS ingredients, insufficient resources, and documented time delays even for well-supported action, renders reliance on post-market authority flawed and unreliable to ensure a safe food supply," said study co-author Emily Broad Leib, director of Harvard Law School Center for Health Law and Policy Innovation and founding director of the Harvard Law School Food Law and Policy Clinic.

"The FDA is only starting to utilize its post-market powers to review a tiny number of ingredients in the food supply, even though evidence of harm has been present for decades."

Stronger protections

The authors' analysis provides the FDA and Congress with several potential actions to better assess and oversee the safety of both GRAS substances and food additives.

This could include a new requirement that companies must publicly notify the FDA of the use of GRAS ingredients, and share their underlying safety data, before they are put in foods; creating a robust review process to reevaluate the safety of GRAS ingredients and food additives once they are already on the market; and clarifying the distinction between GRAS ingredients and food additives.

In order to fund this stronger oversight of the food supply, the researchers suggest that Congress could allocate additional resources to the FDA or establish a user fee program in which food companies pay for the FDA to review the safety of their ingredients before they are added to foods.

"Both the FDA and Congress can do more to enable the FDA to meet its mission of ensuring a safe food supply," said Pomeranz.

More information: Regulation of Added Substances in the Food Supply by the Food and Drug Administration Human Foods Program, *American Journal of Public Health* (2024). DOI: 10.2105/AJPH.2024.307755