How the FDA Opens the Door to Risky Chemicals in America's Food Supply

The FDA's restraints on food ingredients are limited and relatively feeble, especially compared with those in Europe.

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Joseph Shea, who sells athletic wear in Myrtle Beach, South Carolina, wonders and worries about the food he eats.

The chemical ingredients with mystifying names. The references on product labels to unspecified natural or artificial flavors. The junk food that fits his budget but feels addictive and makes him feel unwell.

Shea, one of 1,310 people who responded to a poll the health policy research group KFF conducted on health care priorities, said he assumes the FDA is making sure the ingredients are safe.

In many cases, it is not.

The FDA's restraints on food ingredients are limited and relatively feeble, especially compared with those in Europe, a KFF Health News examination found. There are at least 950 substances in our food that are not permitted in Europe, according to one expert's estimate, and chemicals linked to health concerns show up in hundreds of products that line the shelves of American supermarkets.

Robert F. Kennedy Jr., the new head of the Department of Health and Human Services, has railed about the risks of food additives for years and has said he wants to end "the mass poisoning of American children." At a March 6 confirmation hearing, Marty Makary, President Donald Trump's nominee to head the FDA, expressed concern about foods "with a lot of molecules that do not appear in nature."

"These are chemicals that the industry insists are safe, a subset of which are concerning," he said.

But the Trump administration's initial moves to reduce staff at the FDA led the director of its food safety unit, Jim Jones, to resign last month and raised fears among food safety specialists that the administration could weaken oversight.

To a great extent, the FDA leaves it to food companies to determine whether their ingredients and additives are safe. Companies don't have to tell the FDA about those decisions, and they don't have to list all ingredients on their product labels.

Though pharmaceutical companies are required to share research on humans with the FDA, the agency is largely blind to what food-makers know about their products.

"The food industry does massive amounts of research that we have no access to," Robert Califf told a Senate committee in December on his way out as FDA commissioner.

As a result: The FDA's oversight of food additives is much weaker than its oversight of prescription drugs.

"There is good reason to be concerned about the chemicals that are routinely included in much of our food," Califf testified.

Food is a big business. American consumers spend almost $1.7 trillion annually on food and beverages, according to Circana, a research and advisory firm.

Yet American food companies keep secret much of what they put in their products.

KFF Health News asked nine of the largest food manufacturers — The Coca-Cola Co., Conagra Brands, General Mills, Kellanova (successor to Kellogg), The Kraft Heinz Co., Mondelēz International, Nestlé, PepsiCo, and Unilever — for the number of ingredients, if any, that go unnamed on their product labels and the names of those ingredients deemed safe without involvement by the FDA, and substances used in their products in the United States but not in Europe, and vice versa.

None provided answers to those questions.

"We focus on the quality of the ingredients that we use, and all comply with applicable regulatory requirements," Nestlé spokesperson Dana Stambaugh said.

Chemicals such as titanium dioxide and potassium bromate, whose safety has been debated, are allowed in foods in the United States but not in Europe.

Corporations may turn a blind eye to potential dangers, a July 2024 FDA-funded report warned.

Potentially harmful ingredients "are not necessarily required to be named on a product label," the Reagan-Udall Foundation for the FDA, an adjunct to the agency, said in the report, which was based largely on interviews with representatives of companies across the food supply chain.

"Companies may choose not to track the presence of these ingredients/compounds due to concern about future litigation," the report said.

Some additives can remain hidden from the public behind such catchall terms as "spices" and

“artificial flavors,” as the Center for Science in the Public Interest has reported, or shrouded by other exemptions from disclosure requirements.

And some ingredients that should have been listed on product labels — potential allergens such as milk, wheat, eggs, and dyes — have at times gone undisclosed, according to a series of food recalls. Gaps in oversight have alarmed political leaders on both sides of the aisle, the U.S. Government Accountability Office, watchdog groups such as the CSPI, and academic researchers.

Adding to the concern: the profusion of ultra-processed foods, which use a wide array of chemicals to add flavor and color, extend shelf life, reduce cost, control texture or consistency, and generally tempt people to eat more. Ultra-processed foods now make up 73% of the U.S. food supply, researchers have estimated. Sen. Bernie Sanders of Vermont, the ranking member of the Senate Health, Education, Labor and Pensions Committee, has said there’s growing evidence they are “deliberately designed to be addictive,” contributing to an epidemic of obesity — a rare point of agreement between him and Kennedy.

At his confirmation hearing, Makary said some ingredients cause a chronic, low-grade inflammatory reaction in the gastrointestinal tract. “And what are we doing? We are drugging our nation’s children at scale,” he said.

The KFF poll found that 58% of respondents want the Trump administration to prioritize setting stricter limits on chemicals in the U.S. food supply.

The Consumer Brands Association, which represents many of the largest food-makers, defends the regulatory system as “rigorous,” “evidence-based,” and “proven.” The system enables companies “to innovate to meet consumer demand,” Sarah Gallo, the association’s senior vice president of product policy, said in a statement to KFF Health News.

“Food manufacturers attest to the safety of an ingredient through the development of extensive scientific evidence and third-party expert review,” Gallo added.

More than a decade ago, Pew Charitable Trusts estimated that there were about 10,000 additives allowed in food in the United States — and that the FDA had not reviewed the safety of about 3,000 of them.

“The system is fundamentally broken,” said Thomas Neltner, one of the authors of the Pew study. “It’s so bad, nobody knows — not even FDA knows — what’s in our food.”

Banned Abroad

The FDA allows titanium dioxide to be used to enhance the appearance of foods, among other purposes. According to an Environmental Working Group database, it’s listed as an ingredient in more than 1,900 products, including many candies.

The European Union takes a more cautious approach. In 2021, an EU regulatory panel concluded that titanium dioxide "can no longer be considered as safe when used as a food additive." The panel said it couldn't rule out the possibility that titanium dioxide could damage chromosomes.

The FDA allows potassium bromate to be used in baking, and, according to the EWG database, it's listed as an ingredient in more than 200 products, including bread, buns, and bagels.

Potassium bromate has been banned from food in many countries, including those of the European Union, Canada, India, and Peru. In 2023, California banned it from food effective in 2027. The United Kingdom prohibited it in 1990. The International Agency for Research on Cancer identified it as possibly carcinogenic more than 25 years ago. A joint committee of the United Nations and the World Health Organization identified it as a "genotoxic carcinogen" in 1992.

On its website, the FDA says it has worked with industry to minimize potassium bromate levels and is reviewing the chemical, among others.

The EWG says that it created the database to help consumers make healthier choices and that the raw data on product labels is supplied by Label Insight — which is owned by NielsenIQ, a major provider of data to industry. The EWG has called for tighter regulation of foods.

Based on a review of FDA and European Commission databases, it appears that at least 950 more additives are used in foods in the United States than are allowed in the European Union, said Erik Millstone, an emeritus professor at the University of Sussex in England who has been studying food safety policy since the 1970s.

Direct comparisons are difficult because the two regulatory systems and the way they keep their records differ greatly.

A definitive count is elusive because the FDA doesn't require industry to inform it of everything used in foods in the United States.

"That kind of casual neglect totally would be unacceptable in Europe," Millstone said.

'Several Decades Behind Europeans'

When the FDA formally approves substances for use in food, it can let decades pass without reassessing them — even when subsequent research raises doubts about their safety.

In January, when the FDA banned Red Dye No. 3 from foods, it cited research published in 1987. (The FDA said it had no evidence the dye puts people at risk; invoking one of the stricter consumer protections, it said a law from 1960 prohibits the use of additives found to induce cancer in animals.)

In the European Union, substances used in foods must pass regulatory approval before being introduced. The EU has also required that its regulators reassess all additives that were on the

market before Jan. 20, 2009, a process that is ongoing.

“In the FDA, although we have authorization to do post-market reviews, there’s no statutory mandate to do them,” Jones, the former deputy commissioner of the FDA’s Human Foods Program, told a Senate committee in December. “We are several decades behind Europeans and our Canadian counterparts because they have legal mandates to reevaluate chemicals that have been authorized at some point in the past.”

The FDA website lists 19 post-market determinations since 2010 that substances were not “generally recognized as safe.” Four involve chemical constituents of one mushroom and the mushroom itself. Others include an anabolic steroid, caffeinated alcoholic beverages, cannabidiol (CBD), Ginkgo biloba, melatonin, and partially hydrogenated oils.

Meanwhile, trichloroethylene, banned by the Environmental Protection Agency in December as “an extremely toxic chemical known to cause liver cancer, kidney cancer, and non-Hodgkin’s lymphoma,” is still allowed under FDA rules for use as a solvent in the production of foods.

FDA spokesperson Enrico Dinges said the agency will work with new leadership at HHS “to safeguard the food supply through pre-market and post-market safety evaluations of chemicals in the food supply.”

‘The Loophole Swallowed the Law’

The biggest gap in the FDA’s oversight of foods goes back generations.

In 1958, Congress mandated that, before additives could be used in foods, manufacturers had to prove they were safe and get FDA approval. However, Congress carved out an exception for substances “generally recognized as safe,” which came to be known simply as GRAS.

As conceived, GRAS promised regulatory relief for standard ingredients like salt, sugar, vinegar, and baking powder — along with many chemicals.

Over time, “the loophole swallowed the law,” said a 2014 report by Neltner and Maricel Maffini for the Natural Resources Defense Council.

Companies can unilaterally decide their ingredients are already recognized as safe and use them without asking the FDA for permission or even informing the agency.

A better translation of GRAS would be “Generally Recognized as SECRET,” the Natural Resources Defense Council report said.

A federal watchdog reached a similar conclusion. “GRAS substances can be marketed without FDA’s approval or even its knowledge,” the Government Accountability Office warned in 2010.

That spared the FDA from spending time reviewing countless substances.

For advice on whether ingredients are GRAS, companies may convene panels of specialists. The FDA has noted that panel members could be paid by the companies commissioning the review, but, in guidance to industry, it says “such compensation is not itself an unacceptable conflict.”

About 3,000 flavoring ingredients have been deemed GRAS by a panel of scientists working for an industry group, the Flavor and Extract Manufacturers Association of the United States, known as FEMA, said George Southworth, the organization’s executive director.

The scientists on the FEMA panel “adhere to stringent conflict-of-interest policies,” and their GRAS determinations are submitted to the FDA, which includes them in an online database, Southworth said.

Southworth described the panel as independent, and the FEMA website says panel members have never been employees of companies in the food industry.

Asked how many times FEMA’s panel found that a flavoring didn’t meet the test, Southworth wouldn’t say. He indicated that some reviews are called off before a conclusion is reached.

“Publicly reporting these numbers without full context could lead to misinterpretations about the safety of substances,” he added.

Another Way

Food companies have another option: They can voluntarily notify the FDA that they believe their product is GRAS for its intended use and lay out their reasons — giving the FDA a heads up and essentially seeking its blessing.

If they take that route, they don’t have to wait for an answer from the FDA to begin marketing the product, the agency has said.

And they don’t risk much. If the FDA spots weaknesses in a company’s argument or reasons to worry about a chemical’s safety, it routinely calls off its review instead of declaring the substance unsafe.

FDA records posted on the agency’s website show that the FDA often coaches companies to ask the agency to cease its evaluation. That, too, leaves the company free to sell the product, food watchdogs said.

For companies that voluntarily run their products past the FDA, victory is a letter saying the agency has no questions.

But if companies market products as “generally recognized as safe” without firm grounds, they run the risk that the FDA could one day take enforcement action, such as issuing a warning or stopping sales. That’s if the FDA notices.

Psyched Out

On March 8, 2022, a Canadian company, Psyched Wellness, issued a news release saying it had a green light to market products in the United States.

An "independent review panel of scientific experts" concluded that an extract the company developed, AME-1, was "Generally Recognized As Safe," paving the way for it to be sold in bulk and used as an ingredient, the company said.

The company described the panel's judgment as a successful "certification" and "a key milestone." The extract was derived from a hallucinogenic mushroom, Amanita muscaria, which the company said "has incredible healing and medicinal powers." As the company later put it in a news release, it had obtained "self-Gras status."

In June 2024, the company announced that it would soon release Amanita muscaria watermelon gummies.

However, the FDA later took issue with the company and its product.

In a memo dated Sept. 9, 2024, an FDA toxicologist said Psyched Wellness' claim of GRAS certification was false. The firm failed to show that its extract was generally recognized as safe, the FDA memo said.

Speaking of the mushroom, its extracts, and its known "pharmacologically active constituents," the FDA memo posted on the agency's website said they have "potential for serious harm and adverse effects on the central nervous system."

The FDA was focusing on the mushroom against the backdrop of a spate of medical problems linked to another company's "Diamond Shruumz" brand chocolate bars, gummies, and infused cones. When it recalled those products in June 2024, that other company announced that a chemical found in Amanita mushrooms was a possible cause of symptoms, including seizures and loss of consciousness.

The FDA memo discussed that recall and said one death and 30 hospitalizations might have been related.

The memo did not connect Psyched Wellness to the outbreak or the Diamond Shruumz products.

The chief executive of Psyched Wellness, Jeffrey Stevens, did not respond to an interview request or written questions.

As recently as Feb. 1, Psyched Wellness said in a securities filing that it will "continue to market its products in the U.S. using the Self-GRAS designation."

'Probably Poisoning Us'

If food ingredients cause acute reactions — sending people to emergency rooms, for example — the potential dangers may be relatively easy to identify, and regulatory action might naturally

follow. Some critics of the system say they worry more about health effects that could take years or decades to develop.

Then, when it’s too late, it could be hard to trace the harm to any particular ingredient.

All that leaves Joseph Shea of Myrtle Beach in a tough spot.

For a while, Shea tried shopping at a market that has a lot of organic offerings, he said in an interview. That proved too expensive.

Shea said the entire picture is “incredibly frustrating.”

“They’re probably poisoning us, and we don’t know,” he said. “We’ll figure it out 30 years down the road when we get sick.”

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http://beta.docker.poz.com/article/fda-opens-door-risky-chemicals-americas-food-supply