



## **Inadequate Oversight of the Safety of Substances Added to Food: What Went Wrong and How to Fix It**

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Most people would be shocked to learn that there is no government oversight of an estimated 1,000 substances added to food in the United States—and little oversight of thousands more. In fact, the U.S. Food and Drug Administration (FDA) has permitted companies to secretly determine the safety of new food ingredients—and to add them to packaged and restaurant foods without ever telling FDA what they are or their scientific basis for believing a substance is safe.

CSPI — with allies—is challenging that absurd and risky situation. CSPI is putting FDA and the food industry on notice that this system is illegal under federal law, which requires FDA to monitor the safety of foods, and must be fixed. CSPI is urging FDA to instead adopt a modern, comprehensive, data-driven system for assessing risks, and to bring all food substances out of the shadows and into the public eye, where they belong. In addition, FDA should insist that additive manufacturers adopt measures to counter inherent conflicts of interest in safety determinations and ensure that risky substances are properly reviewed before they are used in the food supply.

### **A History of Decay and Disrepair**

**How did such lax oversight happen?** In a 1958 law, Congress told FDA to assure the safety of the food supply and “to prohibit the use in food of additives which have not been adequately tested to establish their safety.” Congress also recognized that many foods were safe, and that it made little sense to require pre-market testing of long-used foods or substances well-recognized by scientists as safe. The law allows certain substances to be used without premarket testing and review by FDA and the public, but only if a use is both safe and its safety is generally recognized by knowledgeable scientists. This new class of substances are called “generally recognized as safe,” or GRAS, substances.

For decades, FDA asserted its authority over GRAS in waves, each better defining the limits of GRAS. The agency made GRAS lists, conducted investigations into the safety of GRAS additives, and, in rules, defined reasonable requirements for how companies should document safety, what a general recognition of safety entailed, and clarified that the safety standard that applied to substances considered GRAS was the same as that for food additives – that there had to be a “reasonable certainty of no harm.”

In 1997, FDA proposed a system that has resulted in a far-reaching change. The system allows companies to ask for FDA review on a voluntary basis, but, outrageously, even if the agency raises questions about a substance's safety, the company may withdraw the notice and use the substance in food anyway. Since 1997, companies have increasingly used secret industry panels of hired experts to "approve" the safety of substances of an estimated 1,000 substances—never telling the FDA or public of their use or safety record.

Although a final regulation was never issued, in 2014, the non-profit Center for Food Safety sued the agency, asking FDA to finalize its proposed rule, and the agency agreed to publish a rule on GRAS by August 2016.

But finalizing such a shoddy rule would be a terrible idea. Even FDA officials admit that the system is badly broken and that the GRAS loophole has swallowed the law: as Deputy FDA Commissioner for Foods Michael Taylor remarked in August 2014, **"We simply do not have the information to vouch for the safety of many of these chemicals."**

### **FDA Can and Must Fix the GRAS Program**

In a lengthy legal comment, CSPI and our allies argue that the FDA's program is illegal and that the agency must fix it to protect the public's health. The comment indicates the basis for a legal challenge to the regulation, should FDA finalize its 1997 proposal.

The program is illegal for two main reasons:

- 1) FDA has failed to appropriately limit companies' use of the GRAS**

**exemption to substances that are clearly safe and supported by a general recognition of safety. Instead, even carcinogens and novel chemicals can currently be GRAS – and are classified as GRAS by companies – violating the clear intent of the 1958 law.**

- 2) FDA allows GRAS determinations to remain secret. That means that the agency cannot fulfill its basic assignment of assuring the safety of the food supply because it does not know what is in our food.**

As we demonstrate, those two profound flaws in the system devastate FDA's ability to fulfill its assignment from Congress. For example:

*Due to a lack of appropriate limits on GRAS determinations:*

- FDA has no binding limits on the use of nanotechnology in foods, despite the fact that the agency admits that specific toxicology tests should be required. Only a voluntary guidance applies.
- Taste modifiers are being used without any showing to FDA that they are safe. Because they are hidden on the label under the name "artificial flavorings," both FDA and the public are in the dark.
- Flavorings that are known carcinogens are used as GRAS in foods.
- Quorn foods – which are made with mycoprotein, a clearly novel product engineered from mold as a meat substitute – has been linked to two deaths and thousands of severe adverse reactions, and yet remains

GRAS after a “no questions” letter from FDA was issued to the company.

*Due to the secrecy of GRAS determinations:*

- Companies’ estimates for the safety of consumers’ caffeine exposures – including from energy drinks, which have been linked to 34 deaths – are all over the map. Because companies vary in their analysis of both public exposure to caffeine and its harms, it is more difficult for FDA to evaluate the risks, especially for children and adolescents.
- Substances that were withdrawn by one company from FDA’s notification program for GRAS due to questions about their safety have been used by other companies.
- Conflict-laden secret expert panels on the industry’s tab decide the safety of ingredients in the food supply without oversight by FDA.
- Both FDA and the food industry lack meaningful cumulative exposure and probable consumption data on substances that are either GRAS or were approved as food additives, violating the statutory requirements.
- FDA lacks the ability to intelligently and systematically assess risks to human health posed by substances – or combinations of substances – in the food supply because it lacks updated and comprehensive exposure and safety data.
- The public health community also cannot evaluate the safety of GRAS substances.

## **How to Fix FDA’s Failed GRAS Program**

*First, FDA should limit the eligibility of substances to be considered GRAS:*

- 1) To exclude novel ingredients, since there can be no general recognition of their safety;
- 2) To exclude substances identified as risks to human health;
- 3) To exclude ingredients that are harmful for human health, broadly defined;
- 4) To accept only those substances with a safety record based on peerreviewed, published research;
- 5) To accept only those substances for which there is adequate science to determine their safety.

*Second, FDA must drag companies’ GRAS determinations into the light:*

- 1) FDA must require public notice in an agency database of GRAS determinations and the documents that support this conclusion;
- 2) FDA must require companies to periodically submit updated and current exposure data to assist the agency in measuring cumulative effects and probable exposure to chemicals and classes of chemicals.

*Third, FDA must fix the process.*

- 1) FDA should outline a binding program of rules and public disclosures to address and reduce conflicts-of-interest in GRAS determinations;
- 2) FDA must develop a comprehensive regulatory program to reassess the substances secretly declared GRAS

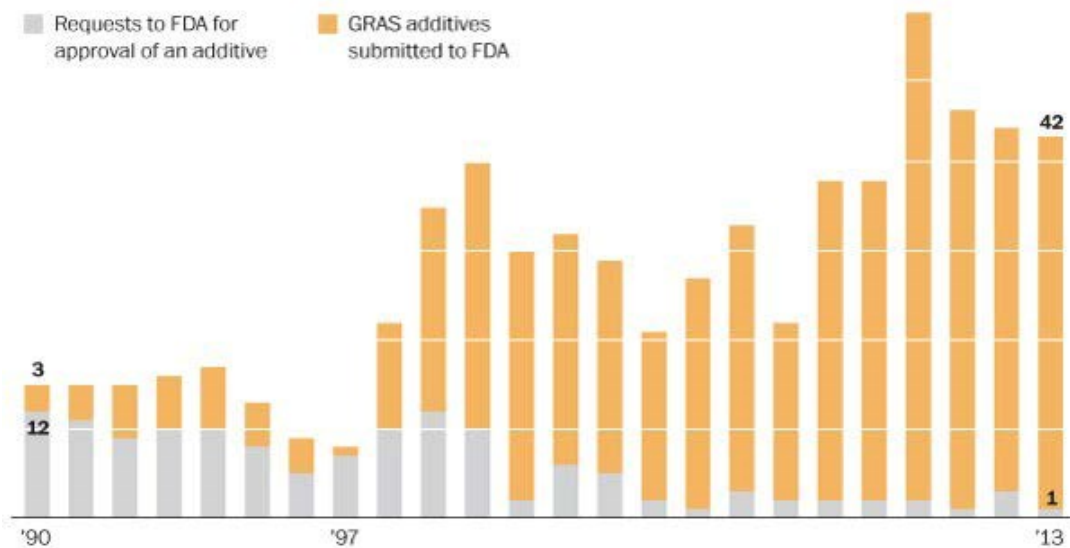
by companies and periodically procure the updated exposure and consumption information needed to reassess safety on an ongoing basis.

Taken together, the changes we urge would transform the GRAS system from badly broken to functional. Independent determinations of the safety of substances in the food supply would remain, but would come out of the shadows into the public eye, where they belong.

By reasserting its legitimate power over the scope and substance of safety determinations with reasonable definitions and requirements, FDA could restore the rightful—and narrow—position of GRAS in the statutory scheme and reestablish public confidence in the agency’s oversight.

The reforms would accomplish what FDA hoped for – and failed to achieve – in its 1997 rule. More importantly, they would equip the agency with tools to effectively monitor public exposures and to analyze evolving questions impacting public health, just as Congress intended.

### How GRAS Took Over the Food Additive Approval Process



*Source:* Graphic by Kimberly Kindy and Cristina Rivero for the Washington Post, August 17, 2014. Data Sources: Natural Resources Defense Council, Food and Drug Administration, Center for Science in the Public Interest, Pew Charitable Trusts.