



Food Safety

The federal GRAS Loophole and What It Means for our Health

Summary

A major loophole in U.S. federal law governing food safety lets chemical companies decide in secret what additives and chemical compounds are safe to use in our food, food processing, and packaging. As a result, the public is exposed to harmful chemicals through food that the U.S. Food and Drug Administration (FDA) has not approved and may not even know is being used. The Toxic Free Food Act of 2021 (H.R. 3699), sponsored by Rosa DeLauro (D- IL), would require the FDA to close this loophole and end the secrecy and vested interest monopoly on decision-making about the safety of food chemicals.

Background

Thousands of synthetic chemicals are used in food, beverages, and to make any of the materials they come into contact with between harvest and our mouths. Over 10,000 chemicals are used in food processing and packaging in the U.S., of which approximately half are used as direct additives, and around 5000 are in so-called contact materials.¹ Chemicals are directly added to food to provide flavor, improve appearance and increase longevity (e.g., flavors, colors, preservatives). Chemicals are also used to make the materials that touch food and beverage all along the production chain (e.g., tubes, conveyor belts) or at the point of sale, including in the catering and serving sectors (e.g., container coatings, serving gloves). Chemicals that move from contact materials into the food and beverage are called indirect additives. Direct and indirect food additives are a big business: the North American food packaging sector was worth around \$92.3 billion in 2020.

Some of these chemicals are harmful to human health. Authoritative science links certain direct and indirect food additive chemicals to breast cancer, impaired development of healthy brains in children, fertility and other reproductive problems, metabolic illnesses including diabetes, other cancers, and more. Chemicals harmful to health and the environment are used throughout the spectrum of food manufacture, distribution, and sales/service: as direct additives; in the manufacture of contact materials for the production / processing stage; in the end packaging materials; and in the cooking, serving items, and utensils in restaurants and homes.

Health and scientific experts are raising the alarm over the presence of harmful chemicals in food and its impacts on our health. The American Academy of Pediatrics 2018 [Policy Statement](#) draws attention to “emerging child health concerns” related to chemicals used in materials that come into contact with food during processing and packaging, and direct chemical additives used for preserving, coloring or flavoring the food.² They note that accumulating evidence from both laboratory and epidemiological studies suggest “that chemicals used in food and food contact materials may contribute to disease and disability” and detail this in an accompanying technical report. The APP states “Substantial improvements to the food additives regulatory system are urgently needed.”

A peer-reviewed [Consensus Statement](#) published in 2020 by an international group of scientists expressed strong concern about chemicals migrating into food from food contact articles. Many of these chemicals are not sufficiently assessed for the impacts on human health, while others are known hazardous

¹ Muncke et al., Impacts of food contact chemicals on human health: a consensus statement, Environmental Health (2020) 19:25

² Trasande L, Shaffer RM, Sathyanarayana S, AAP Council on Environmental Health. Food Additives and Child Health. Pediatrics. 2018;142(2):e20181408



substances. The group of 33 scientists cross multiple disciplines, including developmental biology, endocrinology, epidemiology, toxicology, environmental science, and public health.

Recent media articles have raised the alarm about harmful chemicals like [PFAS 'Forever Chemicals' found in food packaging](#), as well as [phthalates \(plasticizers\) in fast food](#) such as burgers, fries and pizza.

Problem

For decades, a loophole created by the Food Additives Amendment of 1958 has allowed food processing and chemical manufacturers to self-certify chemicals added to food or used in processing or packaging of food as safe without obtaining FDA approval or even notifying the agency. The law amended the federal Food, Drug, and Cosmetic Act of 1938 and was intended to prohibit the use of food chemicals that are not adequately tested for safety, sending the chemicals through an explicit approval process. However, it also created an exemption for the use of common ingredients with established safety records like vinegar, salt, and flour under a 'Generally Recognized as Safe' (or GRAS) procedure.

Unfortunately, companies use this GRAS exemption for chemicals far beyond the scope and intent of the original 1958 amendment, undermining the safety of food additives and food processing and packaging chemicals. In practice, the FDA allows companies to self-certify the safety of chemicals in food processing or packaging. The companies convene expert panels to perform the certification, with the experts selected and paid by the companies—a practice rife with clear conflicts of interest. The companies are not required to notify the FDA of their certifications, nor make them public. There are no requirements for record-keeping, and the data on which the certifications are based are secret.

The GRAS certification has become the main procedural route by which companies put newly synthesized chemicals on the market for food processing and packaging; chemicals for which there are no established safety records. Between 2003 and 2013, nearly all new food chemicals put on the market were self-certified as GRAS by manufacturers.³ Under this form of untransparent self-regulation, an estimated 1000-3000 chemicals and new uses of chemicals have been certified as GRAS without any notification to the FDA.

Chemicals of concern that have been designated GRAS by companies include:

- methyl and propyl parabens (hormone disruptors, the latter having been shown to accelerate the growth of breast cancer cells; these parabens are used as anti-microbials in oils, processed fruit & vegetables, beverages, cheese, sweet sauces).⁴
- several possible cancer-causing flavors (benzophenone, ethyl acrylate, eugenyl methyl ether, myrcene, pulegone, and pyridine and styrene were certified GRAS by the Flavor and Extract Manufacturers Association; 6 had their GRAS status revoked after an NGO petition to the FDA; these chemicals are used to add a range for flavors – from floral, cinnamon, and mint to ripe pineapple, rum and whiskey in a variety of products, including baked goods, beverages, candy, and ice cream)
- partially hydrogenated oils, or trans fats (due to strong public criticism, GRAS status was revoked in 2015);
- butylated hydroxyanisole (BHA) (a California Proposition 65-listed carcinogen that causes hormone disruption and male reproductive toxicity; used in cereals; glazed fruits; dehydrated potato flakes; dry active yeast; mixes for beverages and desserts; chewing gum; potato chips; vegetable oil, and as packaging adhesive)

Public interest organizations—environmental, consumer and health NGOs—challenged the FDA in federal court on its 2016 GRAS rule, and how it interprets and implements the GRAS exemption. The court

³ The Pew Charitable Trusts, [Fixing the Oversight of Chemicals Added to Our Food](#), (pewtrusts.org) 2013

⁴ These substances were cleared by the Select Committee on GRAS substances fifty years ago so the science is very outdated.



judgement, which came out in October 2021, put the onus squarely on Congress to fix the GRAS secret self-regulation problem, ruling that the FDA's interpretation of the law is reasonable. Therefore, to protect public health and get toxic chemicals out of the food supply, the most direct way to close the GRAS loophole is for Congress to change the law to protect public health and keep toxic food chemicals out of the food.

Solution

Representative Rosa DeLauro has introduced H.R. 3699, the Toxic Free Food Act. This bill would require the FDA to close the GRAS loophole and make chemicals used in direct additives and in food packaging and processing materials subject to FDA approval. Specifically, the bill lays out:

- **Deadlines:** The FDA must propose a revised rule on GRAS procedures within 6 months, take public comment, and publish a final rule 3 months later. The rule must contain the following provisions:
- **Mandatory notification:** The manufacturer must notify the FDA of any GRAS substance or food that contains a GRAS substance.
- **Mandatory Data:** The manufacturer must give the FDA enough information to understand the GRAS designation including how the manufacturer addressed:
 - Cumulative effects,
 - Calculating safety buffers that are adequately protective,
 - Taking vulnerable populations and sensitive developmental phases into account when setting a safety buffer.
- **Transparency:** GRAS designations and supporting information made publicly available on the FDA website.
- **Public input:** FDA and public can review and object to any GRAS designation.
- **Exclusions:** No newly synthesized, novel, or carcinogenic chemicals can be GRAS.
- **Conflict of Interest:** Bars use of expertise from specialists with conflicts of interest.
- **Best Practice:** Deploys recommendations of a still-draft FDA Guidance on Best Practices for the industry-convened Panel which assesses the safety of potential GRAS substances.
- **Systematic reassessment:** FDA to set up a process for systematically reassessing any previously designated GRAS substances, aided by re-established Food Advisory Committee.

Contact

Lisette van Vliet, Senior Policy Manager, Breast Cancer Prevention Partners Lisette@bcpp.org

BCPP strongly supports this bill as a founding member of the Food and Chemicals Alliance and the Toxic Free Food FDA campaign.