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ISSUE BRIEF | Center for a Healthy America

Make America Healthy Again by Ensuring Safe Foods

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TOPLINE POINTS

- Growing numbers of Americans suffer from obesity and chronic diseases. In 2022, nearly 2 million individuals lost their lives to these debilitating conditions.
- Several academic studies suggest that certain artificial substances in ultra-processed foods may contribute to the development of chronic diseases. The Food and Drug Administration (FDA) allows food manufacturers to insert these substances into products without notifying the agency or demonstrating the substances' safety.
- Policymakers should consider strengthening the FDA's oversight of artificial substances to minimize the health risks of ultra-processed foods.

Overview

Tens of millions of Americans suffer from obesity and chronic diseases that require costly and ongoing medical care. In recent years, several scientific studies have suggested that ultra-processed foods, composed of industrially produced substances, may be contributing to the proliferation of excessive weight gain and certain chronic diseases among Americans.

In 1958, Congress passed the Food Additive Amendment (FAA) to the Federal Food, Drug, and Cosmetic Act (FDCA) to empower the Food and Drug Administration (FDA) to protect the public from potentially harmful food additives and other substances. The FAA defines food additives as substances that are intended to result in or are expected to result in becoming a component or affecting the characteristics of a food product. To add a newly developed additive to food, manufacturers must submit evidence to the FDA that demonstrates it can be safely consumed and receive permission from the agency. However, a loophole in the FAA allows food manufacturers to introduce new substances into their products without FDA oversight. Food manufacturers may insert substances without

approval from the FDA if the substance is "generally recognized as safe" ("GRAS") by scientific experts who are qualified to evaluate food safety. The scientific experts who evaluate GRAS substances often have conflicts of interest with food manufacturers, which can undermine their capacity to objectively evaluate these substances. Furthermore, manufacturers are not legally required to inform the FDA when they insert a new GRAS substance into their products. Policymakers should consider a variety of reforms to close this loophole and protect consumers from potentially harmful substances that may contribute to chronic diseases.

Many Americans Suffer from Obesity and Chronic Diseases

Chronic diseases pose as one of the most significant health threats to Americans today. These diseases, including diabetes, cancer, and cardiovascular disease, are long-lasting conditions that require ongoing medical care. Between 2001 and 2018, the estimated percentage of Americans with multiple chronic conditions increased from 21.8% (Ward & Schiller, 2013) to 27.2% (Boersma et al., 2020). For every $10 Americans spend on health care each year, $9 goes to treat individuals with chronic diseases (Buttorff et al., 2017). In 2022, these illnesses claimed the lives of 1.9 million Americans, accounting for 8 out of the 10 leading causes of death (CDC, n.d.).

One potential contributor to the rise in chronic diseases among Americans is the increasing prevalence of obesity. Obesity is a medical condition that is defined by excessive body fat. Adults are considered obese if they have a body mass index (BMI) score of 30 or greater. Between 1999 and 2023, the share of American adults who are obese increased from 30.5% (Hales et al., 2017) to 40.3% (Emmerich et al., 2024). Multiple studies have identified obesity as a risk factor for conditions such as high blood pressure (Garrison et al., 1987), insulin resistance (Verkouter et al., 2019), and fatty liver disease (Ruhl & Everhart, 2003). These conditions can lead to the development of several chronic diseases, including cardiovascular disease (Fuchs & Whelton, 2019) and type 2 diabetes (CDC, 2024).

More Americans are Eating Ultra-Processed Foods that Contain Artificial Substances

A potential driver of increasing obesity and chronic disease rates is the widespread consumption of ultra-processed foods. The NOVA classification system[1] defines ultra-processed foods as industrially manufactured products composed of five or more ingredients, which typically include artificial substances such as flavor enhancers, emulsifiers, and color dyes (Monteiro et al., 2016). Some examples of ultra-processed foods include pre-prepared dinners and frozen desserts and pastries. By contrast, minimally processed foods are plant and animal-based products that have been submitted to cleaning, drying, fermenting, pasteurizing, or other processes. These processes may remove certain parts of the food but do not involve adding external substances. Examples include frozen vegetables, chilled meat, and plain yogurt. Most research on ultra-processed foods over the past several years defines these products using the NOVA system (Chen et al., 2020). However, there is currently no federal definition of ultra-processed food in the United States.

[1] The NOVA classification system is a framework developed by Brazilian researchers that categorizes foods based on how much processing they undergo before they reach the grocery store.

As of 2011, America's food supply contained an estimated 6,397 distinct substances[2] (Neltner et al., 2011). High-fructose corn syrup is commonly added to snacks, cereals, and candy to enhance sweetness. Dairy products like cottage cheese, ice cream, and coffee creamers often include carrageenan, which acts as a thickener, emulsifier, and preservative. Processed meats frequently contain sodium nitrate and monosodium glutamate, commonly referred to as MSG, to enhance salty and savory flavors (Ajmera, 2018).

Ultra-processed foods make up a significant portion of the American diet. A 2023 study published in the *Journal of the Academy of Nutrition and Dietetics* found that between 2001 and 2019, the share of food purchases in the United States containing artificial substances rose from 49.6% to 59.5%. During the same period, the average number of substances per product increased from 3.7 to 4.5 (Dunford et al., 2023).

Ultra-Processed Foods Containing Artificial Substances May Contribute to Obesity and Chronic Diseases

Research indicates that Americans' increasing consumption of ultra-processed foods may be a contributing factor to the rising prevalence of obesity. A 2020 study in the *European Journal of Nutrition* analyzed the diet and health outcomes of roughly 22,000 adults in the UK between 2006 and 2019 (Rauber et al., 2020). The findings revealed that individuals who consumed a greater share of ultra-processed foods as part of their total calories were 79% more likely to become obese than those who consumed the smallest share.

In addition to contributing to obesity, eating ultra-processed foods may be linked to an increased risk of heart-related chronic diseases. A 2019 study in the *British Medical Journal* surveyed the health status of roughly 105,000 adults in France between 2009 and 2018 (Srour et al., 2019). During this period, participants who ate a greater share of ultra-processed foods as part of their total calories had higher rates of cardiovascular disease, coronary heart disease, and cerebrovascular disease than those who consumed the smallest share.

Ultra-processed foods could advance the development of certain chronic diseases through several pathways. A 2019 study in the *Journal of Preventive Medicine* evaluated the diet and blood samples of roughly 6,300 American adults between 2009 and 2014 (Steele et al., 2019). During this period, individuals who ate a greater share of ultra-processed foods as part of their total calories were 28% more likely to experience high blood pressure, high blood sugar, and excessive levels of triglyceride fat in their blood than those who consumed the smallest share. These conditions can increase the likelihood of a person developing cardiovascular disease and type 2 diabetes.

Excessive consumption of ultra-processed foods may also promote chronic disease by contributing to fat

[2] This figure excludes indirect additives and other substances that come into contact with food during production but are not intended to have any effect on the final product.

accumulation in the body and liver. A 2022 study in the *Journal of Nutrients* reviewed the diet and liver health of roughly 5,800 individuals in Spain in 2013 (Konieczna et al., 2022). Their review found that individuals who ate large amounts of ultra-processed foods had higher levels of liver fat and higher BMI scores, which can increase their risk of developing cardiovascular disease.

The FDA Has Not Effectively Evaluated the Health Risks of Artificial Substances in Ultra-Processed Foods

Under the FAA, the FDA is required to follow a pre-market approval process to regulate additives in food products (21 U.S.C. 321, 1958). Under this law, food manufacturers must apply for permission to insert a newly developed additive into their products. The application must include scientific research that demonstrates the additive can be safely consumed under the conditions of its intended use (21 U.S.C. 348, 1958). Once the FDA approves an additive, it is added to the *Substances Added to Food* inventory (FDA, n.d.).

However, the FAA allows manufacturers to insert new substances into a product without pre-market approval if it is "generally recognized as safe" (GRAS) by "experts qualified by scientific training and experience to evaluate its safety" (21 U.S.C. 321, 1958). Congress created this exemption to allow substances that were widely used and widely known to be safe in 1958, such as nutmeg and paprika, to continue to be used without undergoing FDA review. However, this exemption also allows newly developed artificial substances that scientific experts accept as safe to be inserted into food products. Companies have no legal requirement to inform the FDA when they insert ingredients labeled as GRAS into their products.

Given the voluntary nature of the GRAS framework, the FDA has struggled to effectively monitor GRAS substances in food and to ensure their safety (Beyranevand, 2013). The FDA has implemented several measures to encourage manufacturers to disclose their substances voluntarily. The agency initially consulted with manufacturers to develop a list of substances that companies designated as GRAS (Beyranevand, 2013). In 1969, scientists discovered that an ingredient on the agency's GRAS list, cyclamate salt, could potentially cause bladder tumors (Jukes, 1976). In response, the FDA established a GRAS affirmation process whereby food manufacturers could request that the agency formally recognize their GRAS determinations through a notice and comment process (62 F.R. 18938, 1997).

The current regulatory process began in 1997 when the agency proposed a regulation to replace the GRAS affirmation process with a new voluntary notification procedure (62 F.R. 18938, 1997). Under this new procedure, companies can determine whether a substance is GRAS and notify the FDA of the new ingredient's GRAS status. The FDA requires food manufacturers to demonstrate an ingredient is GRAS based on "generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles." GRAS status may also be "corroborated by the application of unpublished scientific data, information, or methods" (21 C.F.R. 570.30, 2016). Like previous GRAS frameworks, the notification procedure enforces no legal responsibility on manufacturers to notify the FDA of their GRAS determinations.

When the FDA established the voluntary GRAS notification system, the agency asserted that the previous GRAS affirmation process was extremely costly and time-consuming (62 F.R. 18938, 1997). It reasoned that outsourcing safety determinations to manufacturers would allow the FDA to focus its resources on investigating specific food substances that may threaten general public health.

The Voluntary GRAS Program Provides Little Oversight of Artificial Substances

As a result of the voluntary nature of the policy, the GRAS notification process fails to provide the FDA with full visibility of all the substances in America's food supply. A 2010 report by the Government Accountability Office concluded that the FDA has no information on the substances that manufacturers determined to be GRAS and chose not to report to the agency (GAO, 2010). The report cited one manufacturer that made five GRAS decisions every year that were not reported to the FDA.

Some health experts believe that food manufacturers have never disclosed a large number of GRAS substances in America's food supply to the FDA. A 2011 study in the *Comprehensive Reviews in Food Sciences and Food Safety Journal* reported that food manufacturers notified the FDA of 237 substances they introduced to their products under the GRAS program between 1997 and 2011 (Neltner et al., 2011). These substances represented 3.7% of the total estimated number of substances in food products in the United States. In contrast, the study estimated that 1,000 GRAS substances, roughly 15% of all substances in the food supply, have never been reported to the agency.

Even when manufacturers decide to notify the FDA of new GRAS substances, these substances often lack sufficient evidence to demonstrate their safety. A 2013 study in the *Journal of Reproductive Toxicology* found that no publicly available feeding toxicology studies were conducted on roughly 61% of GRAS substances that manufacturers reported to the FDA between 1997 and 2012 (Neltner et al., 2013). These studies are designed to estimate the quantity of a substance that can be eaten safely. Without these studies, it is less likely that manufacturers will be able to ensure individuals can safely consume their substances.

The scientific evidence behind GRAS decisions is often riddled with conflicts of interest. A 2013 study of the scientific evidence behind GRAS decisions that were reported to the FDA found that 22.4% were made by an employee of the manufacturer, 13.3% were made by an employee of a consulting firm selected by the manufacturer, and 64.3% were made by a group of experts selected by either the manufacturer or a consulting firm selected by the manufacturer (Neltner et al., 2013). These conflicts of interest could undermine the ability of these experts to evaluate the safety of substances objectively.

As a result of these factors, it is unlikely that the FDA can ensure that many GRAS substances in America's food supply are safe under its current policies. The agency typically investigates the safety of substances by tracking new developments in the scientific community about potential safety concerns surrounding them. The agency also occasionally investigates specific substances on a case-by-case basis after receiving public complaints (GAO, 2010).

The scientific community can play an important role in notifying the FDA about potential safety issues with substances that manufacturers publicly disclose to the FDA. In 2018, for

example, the FDA revoked approval for six artificial food dyes after several citizen petitions provided research that suggested they induced cancer in humans (21 C.F.R. Parts 172 and 177, 2018). Unfortunately, the FDA is limited in its ability to investigate potential safety issues of substances when companies choose not to disclose them publicly.

How States and Other Nations Limit Harmful Substances

In the wake of the FDA's failure to regulate artificial substances, states are taking proactive measures to limit consumer exposure to some of these substances. In recent years, lawmakers in West Virginia (HB-2534, 2025) and California (AB-418, 2023) have enacted legislation that prohibits manufacturers from producing or selling any products that contain substances such as propylparaben, potassium bromate, or Red Dye No. 3 in their state. Lawmakers in 25 other states, including Texas, Arkansas, and Florida, introduced similar proposals to curtail the use of certain substances in food served in grocery stores, restaurants, and other public settings (Myers, 2025). Following the lead of these states, the FDA moved in January to ban the use of Red Dye No. 3 due to evidence that it can induce cancer when consumed (21 C.F.R. Part 74, 2025).

Beyond the United States, other countries also recognize the potential health risks of certain additives and other substances and impose stricter safeguards on their use in food. For example, the European Union (EU) requires that all additives undergo a scientific review by the European Food Safety Authority (EFSA) before they can be added to foods (Regulation (EC) No 1333, 2008). If the EFSA determines that the additive can be consumed daily over a person's lifetime without risking the person's health, another agency known as the European Commission drafts a proposal to add the substance to the EU's list of approved additives. EU member states then vote on the additive proposal for final approval. Under this process, only 411 additives (European Commission, n.d.) are currently permitted in the EU—a stark contrast to the estimated 6,397 additives and other substances used in American products as of 2011 (Neltner et al., 2011).

Policy Recommendations

U.S. policymakers should consider a range of reforms to reduce the potential health risks of GRAS-labeled substances in America's food supply.

1. Minimize Conflicts of Interest: The FDA could ensure that the science backing GRAS determinations is free of conflicts of interest and other incentives that could lead to a harmful GRAS determination. The agency could prohibit individuals who are employed by a food manufacturer or who receive direct financial compensation from a food manufacturer from making a GRAS determination for the same company's products.

The agency could also establish regulations that instruct third parties, such as consultants and food manufacturer trade associations, to make GRAS determinations that are free from conflicts of interest. The Flavor and Extract Manufacturers Association (FEMA), for example, employs panels of scientists that make GRAS determinations for substances developed by their

members. Individuals on this panel do not know which company submitted the substances they review (FEMA, n.d.). These individuals are barred from receiving any financial compensation from the association's member companies. In addition, the panel's criteria for evaluating ingredient safety are published in peer-reviewed journals (Smith et al., 2005). The FDA could develop requirements for third parties to make GRAS determinations based on the best practices of FEMA and other organizations that operate effective GRAS panels.

2. Require Systematic Review of Substances in America's Food Supply: The FDA could systematically review the list of GRAS substances that food manufacturers have disclosed to the agency. The agency could evaluate the scientific evidence that manufacturers submit to demonstrate the safety of their substances and verify if this research meets the standards of the FAA. If a manufacturer fails to provide publicly available research that demonstrates reasonable certainty of safety, the FDA could consider prohibiting the ingredient from being used in food production. The FDA should ensure such decisions do not disrupt America's food supply or increase the cost of groceries for Americans.

Alternatively, the FDA could conduct annual audits on a subset of GRAS substances that food manufacturers have disclosed. Priority for these audits should be given to substances flagged as potentially hazardous in citizen petitions, enabling the agency to focus oversight on these substances.

3. Require GRAS Transparency: Congress could strengthen GRAS standards by requiring food manufacturers to disclose to the FDA all the substances they currently use in their products, including their intended uses and publicly available research that demonstrates they are safe to consume. Lawmakers should also provide sufficient funding to the FDA to evaluate the potential health risks of the full list of substances that food manufacturers insert in their products. Policymakers could also ensure other food and beverage products (such as beers, wines, and spirits) are required to disclose their substances so consumers can make informed shopping choices (U.S. Department of Treasury, 2022).

4. Define Ultra-Processed Food: Policymakers could also establish a federal definition for ultra-processed foods and provide public information on the health risks of these products.

Conclusion

The American people task the FDA with protecting consumers from unsafe substances. Unfortunately, the GRAS exemption allows manufacturers to introduce artificial substances into their products without proving that these substances are safe for consumers. Several scientific studies suggest these substances have contributed to the increase in obesity and certain harmful chronic diseases among Americans.

Policymakers should consider empowering the FDA with greater oversight of the substances currently in America's food supply. By implementing these reforms, policymakers could better protect consumers from potentially harmful substances, reduce the burden of chronic diseases, and promote a healthier future for all Americans.

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