Comment on Docket No. FDA-2025-P-3071: Requests that the FDA Limit the Exposure of Refined Carbohydrates used in Industrial Processing in order to Prevent Obesity, Diabetes, and Cardiovascular Disease in Children and Adults
November 11, 2025

On behalf of FoodFight USA, we appreciate the opportunity to comment on and strongly support the petition submitted by Dr. David A. Kessler requesting that the Food and Drug Administration (FDA) revoke the "Generally Recognized as Safe" (GRAS) status of processed refined carbohydrates used in industrial processing. This petition represents a necessary and actionable first step toward re-evaluating outdated GRAS determinations and restoring FDA oversight of ingredients that contribute significantly to the nation's diet-related disease crisis.

The Case for Reassessing GRAS Status of Refined Carbohydrates

Processed refined carbohydrates are a primary building block of ultra-processed foods (UPFs), which now account for approximately 58% of total calorie intake in the United States and nearly three-quarters of all packaged foods sold.[1] Refined grains, starches, and sugars drive excess caloric intake, disrupt metabolic health, and have transformed the American diet. The 2025-2030 Dietary Guidelines Advisory Committee (DGAC) reported that only 2% of Americans meet the recommendation that half of grains they consume should be whole grains, while 93% overconsume refined grains.[2] The result is a national diet that is high in refined carbohydrates, saturated fats, and added sugars, but low in essential nutrients, such as fiber, protein, and potassium.[3]

When FDA originally affirmed the GRAS status of these substances decades ago, it did so under conditions of limited use and exposure. Today, those conditions have fundamentally changed. Processed refined carbohydrates are no longer occasional ingredients—they are chronic dietary exposures found across virtually all UPFs. Under the "cumulative effects" provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), this change in use patterns

[1] Martínez Steele E, Baraldi LG, Louzada ML, Moubarac JC, Mozaffarian D, Monteiro CA. Ultra-processed foods and added sugars in the US diet: evidence from a nationally representative cross-sectional study. BMJ Open. 2016 Mar 9;6(3):e009892. doi: 10.1136/bmjopen-2015-009892. PMID: 26962035; PMCID: PMC4785287.
[2] Scientific Report of the 2025 Dietary Guidelines Advisory Committee. Dietary Guidelines Advisory Committee; 2024. Accessed October 24, 2025. https://www.dietaryguidelines.gov/2025-advisory-committee-report
[3] Martínez Steele E, Popkin BM, Swinburn B, Monteiro CA. The share of ultra-processed foods and the overall nutritional quality of diets in the US: evidence from a nationally representative cross-sectional study. Popul Health Metr. 2017 Feb 14;15(1):6. doi: 10.1186/s12963-017-0119-3. PMID: 28193285; PMCID: PMC5307821.

warrants a full re-evaluation of their safety. As stated by FDA, GRAS status is time-dependent, and a substance cannot remain GRAS once there is no longer consensus regarding its safety.[4]

The petition presents clear evidence that these ingredients are associated with increased caloric intake, weight gain, insulin resistance, and metabolic dysfunction, which, in turn, elevate risks for obesity, Type 2 diabetes, cardiovascular disease, and other chronic illnesses. These findings demonstrate that the outdated assumptions underpinning their GRAS classification are no longer valid. As the 2015 DGAC concluded, strong evidence now links refined carbohydrates to obesity, diabetes, and heart disease, contrasting to FDA's 1988 affirmation of their safety, which relied on data from the 1970s and early 1980s.[5]

Revoking GRAS status does not require proving that processed refined carbohydrates are unsafe; it only requires acknowledging that their safety under current conditions of use is **no longer established**. This petition simply calls for FDA to promptly initiate proceedings to revoke existing GRAS regulations for processed refined carbohydrates and to require manufacturers to submit formal food additive petitions supported by modern safety data. FDA already has full statutory authority to take this action. No new legislation or congressional approval is required to enact the requests enumerated in this petition.

This action is pro-transparency, not anti-industry. Companies that have legitimately self-affirmed GRAS status should already possess the data necessary to file food additive petitions within the proposed timeline of 12 to 24 months. Revocation of GRAS status for these substances would only level the playing field by ensuring that all manufacturers operate under consistent, science-based safety standards and that none of them exploit regulatory loopholes at the expense of public health.

Revoking the GRAS status of processed refined carbohydrates is a practical and science-based step FDA can take immediately to protect Americans from preventable diet-related diseases. Doing so would reaffirm the agency's role as a guardian of public health, restore consumer confidence in the safety of the food supply, and align regulatory oversight with modern scientific understanding.

Building Momentum for Broader Reform

It is increasingly recognized that the United States lags behind other developed nations in the oversight of food ingredients and food chemicals. The European Union maintains a list of approximately **400 approved food additives** and **2,549 flavorings**, each subject to premarket safety evaluation.[6] In contrast, in the United States, FDA cannot state with certainty how many additives are currently in use, owing to the self-regulatory nature of the GRAS process. In effect, the U.S. food system has become the world's largest uncontrolled experiment in chronic

---

[4] Federal Register, "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information." Volume 78; no. 217. Nov 8, 2013 67169 at p. 67170

[5] Dietary Guidelines Advisory Committee. 2015. Scientific Report of the 2015 Dietary Guidelines. Advisory Committee: Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC.

[6] Food and Feed Information Portal Database. European Commission; 2025. Accessed October 29, 2025. https://ec.europa.eu/food/food-feed-portal/screen/home

chemical exposure, and the results are alarming. Americans experience far higher rates of obesity, metabolic disease, and diet-related illness than their European counterparts, despite having greater economic resources.

Comprehensive reform of the nation's food additive oversight framework is urgently needed. One of the primary obstacles to progress is what can only be described as a **regulatory "whack-a-mole"**: new ingredients, formulations, and additives enter the food supply far faster than FDA can assess their safety or respond to emerging concerns.

The current petition offers a promising model for change. By addressing **whole categories of ingredients** rather than proceeding one compound at a time, FDA can make meaningful progress in evaluating the more than **10,000 food additives** now present in the U.S. food supply.

Following the revocation and reassessment of GRAS status for processed refined carbohydrates, we recommend FDA take similar actions for additional categories of concern, including:

- Surface-active agents
- Stabilizers and thickeners
- Propellants, aerating agents, and gases
- Colors and coloring adjuncts
- Emulsifiers and emulsifier salts
- Flavoring agents and adjuvants (excluding spices and other natural seasonings and flavorings)
- Flavor enhancers (excluding spices and other natural seasonings and flavorings)
- Non-nutritive sweeteners

Ingredients in these categories are the hallmarks of **ultra-processed foods** and have been linked to adverse health outcomes[7] in the scientific literature. Evaluating GRAS status at the category level would allow FDA to act more efficiently, prevent substitution loopholes, and shift oversight from reactive enforcement to proactive protection.

Long-Term Policy Objective: Closing the GRAS Loophole

Ultimately, meaningful reform will require completely eliminating the **GRAS loophole**—the provision that allows manufacturers to self-certify ingredients as "Generally Recognized as Safe" without FDA review or public disclosure. This framework, established in 1958, was intended to

[7] Lane M M, Gamage E, Du S, Ashtree D N, McGuinness A J, Gauci S et al. Ultra-processed food exposure and adverse health outcomes: umbrella review of epidemiological meta-analyses BMJ 2024; https://www.bmj.com/content/384/bmj-2023-077310

expedite approval for simple, time-tested ingredients such as vinegar and baking soda. In today's complex and highly industrialized food system, however, the self-certification process has outlived its purpose and now undermines the integrity of federal food safety law.

As FDA's Deputy Commissioner acknowledged in 2014, "FDA simply does not have the information to vouch for the safety of many of the chemicals added to food.[8]" The agency's ability to protect the public depends on transparency and independent scientific consensus—yet the current system allows companies to make GRAS determinations based on proprietary data reviewed by their own scientists, often without notifying FDA or publishing their findings.

While FDA does not have direct authority to eliminate the GRAS loophole on its own, **decisive agency action**—beginning with the re-evaluation of high-risk ingredient categories—can demonstrate the scale of the problem and build political momentum for legislative reform. Ultimately, Congress must act to ensure that every substance added to food is subject to **formal FDA review, public scrutiny, and transparent safety assessment**.

By taking this first step, FDA can catalyze the modernization of U.S. food safety law and restore public confidence that the food on American tables is held to the same rigorous standards of safety as in other developed nations.

Conclusion

Dr. Kessler's Petition is a pragmatic, evidence-driven opportunity for FDA to reassert its role as the watchdog of America's food supply. FoodFight USA urges the agency to act swiftly, revoke the outdated GRAS status of processed refined carbohydrates, and begin a systematic review of other industrial food ingredients that undermine public health.

[8] Michael Taylor, FDA's Deputy Commissioner in 2014 (Washington Post, August 17, 2014)