Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

February 2, 2026

Re: Docket Number 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

Dear Sir/Madam,

The North American Millers' Association (NAMA) respectfully submits the below comments in response to the Citizen's Petition titled "Petition to Limit the Exposure of Refined Carbohydrates used in Industrial Processing in order to Prevent Obesity, Diabetes, and Cardiovascular Disease in Children and Adults," Docket Number FDA-2025-P-3071 (the Petition). NAMA appreciates the opportunity to provide these comments.

NAMA represents millers of wheat, corn, oats, and rye in the U.S. and Canada. Our members take raw grain and, through grinding and crushing, create flour and other products that are used to make favorite foods, such as bread, cereals, pasta, tortillas, cookies, cakes, and snack foods. We're proud to be the indispensable link between raw grain and healthy and delicious products that have sustained and enriched people's lives for centuries.

NAMA is very concerned about the broad implications of the Petition, which calls for FDA to revoke the generally recognized as safe (GRAS) status of processed refined carbohydrates and remove them from commerce unless they are authorized via a successful Food Additive Petition. These actions are not supported by the currently available science, nor do they comport with the statutory framework and implementation of the Federal Food, Drug, and Cosmetic Act (FDCA). As a preliminary matter, there is no fundamental difference between refined carbohydrates used in industrial food processing and those used at home, contrary to the Petition's claims. The Petition as drafted would result in a radically new interpretation and implementation of key provisions in the FDCA, without the benefit of legislative amendment or deliberative rulemaking addressing how food and food additives are regulated and assessed for safety. Granting the Petition's requests would further necessitate the removal of a significant portion of the food supply in short order and undermine the science and risk-based framework that the U.S. has operated under for more than seventy years. Importantly, there is no scientific consensus that refined

carbohydrates are unsafe, nor has there been consensus that under the current conditions of use, safety is no longer established. Rather, science regarding the health effects from refined carbohydrates and other so-called "ultra-processed foods" (UPFs) is still developing and limited to correlations without determination of causation.

NAMA supports strong, science-based regulation of food products and nutrition policy. Should FDA endeavor to reexamine the framework of the FDCA and the 1958 Food Additives Amendment, it should be undertaken in a thoughtful, systematic manner that considers the best available science to develop a framework that would apply in a consistent, predictable manner under clear rules and evidentiary standards.

For these reasons, which are explained in more detail below, NAMA respectfully requests that FDA deny that the refined carbohydrates named in the Petition should be subject to revocation of their GRAS status. Additionally, NAMA respectfully requests that FDA consider the larger legal, regulatory, and policy implications of the Petition—sound policy with the goal of supporting and improving the health of Americans cannot be built on arbitrary application of amorphous standards not based on scientific consensus.

I. The distinction between flour, sugar, and starches used in the home and those used in commercial processing is not supported by science or the Petition itself.

The Petition explicitly states that it excludes sugar, flour, and native starches commonly used in the home. Instead, it includes "flours and starches that are altered in industrial processing, such as by extrusion, which markedly changes the structure of the ingredient."[1] However, this distinction is fundamentally incorrect because these substances are defined by their composition, rather than how they are processed.

The Petition notes that refined flours include wheat, corn, tapioca, oat, and potato flour and states multiple times that it does not include ingredients used in the home.[2] However, these ingredients are all used in both commercial food production as well as in the home. There is no difference chemically in flours, sugars, and starches used in commercial food processing compared to those used in the home. Notably, these ingredients are regulated in the same way regardless of whether they are used industrially or in the home. For example, FDA has established standards of identity for various flours which apply to both

---

[1] David A. Kessler, *Petition to Limit the Exposure of Refined Carbohydrates used in Industrial Processing in order to Prevent Obesity, Diabetes, and Cardiovascular Disease in Children and Adults*, page 23 (August 2025).

[2] *Id.* at 3-4.

the flours that are used in processed foods, as well as the flour used as an ingredient in the home;[3] additionally, "sugar" refers to sucrose, which is affirmed as GRAS.[4]

The Petition draws a comparison between a homemade cake and one made in an industrial setting, noting that the combination of corn syrup and oils in an industrial cake causes the cake to maintain moisture, taste, and texture longer than a homemade cake made with butter and sugar.[5] We note that one of the most popular cake recipes in the New York Times Cooking section is Chocolate Guinness Cake, with a 5 star rating from 12,367 reviewers.[6] The recipe calls for 10 tablespoons of butter, 2 cups of superfine sugar, 2 cups of all purpose flour, and 1 cup of Guinness stout, among other ingredients. However, this popular recipe also combines sugars, carbohydrates, and fats as described in the Petition as no longer safe under the conditions of use (with apologies to Nigella Lawson).

Ultimately however, this distinction that the Petition makes is not supported by any analysis of how ingredients are used in the home, nor any assessment of difference in consumption patterns. It merely asserts that it is so and thus, entirely exempt from all the other arguments put forth. While the Petition states that "[t]here is no expert consensus that refined carbohydrates in ultraprocessed foods are safe under present conditions of use," the arguments it makes would and do apply to a broad range of home use applications for the same ingredients.

It is arbitrary and capricious to determine without sound basis that refined flours, starches, or sweeteners are unsafe in commercial processing applications, but not in a home setting when the same ingredients are used to make substantially similar foods.

II. The Petition misrepresents the current state of scientific consensus.

The Petition misstates the state of the science on refined carbohydrates and processed foods generally. There is currently no scientific consensus regarding whether refined carbohydrates specifically used in commercial processing should not be considered GRAS. Rather, current science indicates that healthfulness and appropriateness of food in the diet is primarily determined by nutrient composition and consumption patterns. Further,

---

[3] 21 CFR Part 137.

[4] 21 CFR 101.4(b)(20); 21 CFR 184.1854.

[5] Kessler at 29.

[6] Nigella Lawson, *Chocolate Guinness Cake*, New York Times Cooking (May 1, 2024) https://cooking.nytimes.com/recipes/1875-chocolate-guinness-cake.

processing serves many functions in nutrition, including improving safety and supporting an overall healthy dietary pattern.

a. The Petition does not establish a lack of consensus of the safety of the listed ingredients exists.

Processed food, including refined carbohydrates, can serve many beneficial purposes, such as improving food safety and nutrition. For example, fortified grain foods can be a critical source of under consumed nutrients, such as thiamin, folate, iodine, calcium, potassium, and vitamin D.[7] Notably, FDA requires fortification of enriched grains with folic acid and encourages fortification of corn masa flour with folic acid to prevent certain birth defects.[8]

Existing studies show no significant association between diets high in grain-based foods made with refined flours and obesity risk. This contrasts with claims in the book *Fast Carbs, Slow Carbs: The Simple Truth about Food, Weight, and Disease*, which is referenced heavily throughout the Petition and disregards the benefits of refined carbohydrates based on unsubstantiated correlations. In particular, foods made with refined carbohydrates can contribute to an overall healthy dietary pattern and help consumers meet their nutritional needs.

Recent research has found that both whole and refined grains play a role in a healthy dietary pattern, noting that people who consume grain foods also consume more fruits, vegetables, and lean proteins and that both types of grains are nutrient dense and deliver strong nutritional value.[9] Further, refined grains have been shown to have no association with risk of cardiovascular disease, stroke, or heart failure, despite being part of the

---

[7] Estell et al., Fortification of grain foods and NOVA: the potential for altered nutrient intakes while avoiding ultra-processed foods, 61 European J. Nutr. 935 (Oct. 19, 2021). https://pubmed.ncbi.nlm.nih.gov/34668030/; Weaver et al., Processed foods: contributions to nutrition, 99(6) Am J Clin Nutr. 1525-42 (June 2014).

[8] Food and Drug Admin., *Fortifying Corn Masa Flour Products with Folic Acid*, https://www.fda.gov/food/food-additives-petitions/fortifying-corn-masa-flour-products-folic-acid (last updated June 3, 2024).

[9] Adam Drewnowski et al., *Healthy Grains in Healthy Diets: The Contribution of Grain Foods to Diet Quality and Health in the National Health and Nutrition Examination Survey 2017-2023*, Nutrients (Aug. 18, 2025) https://www.mdpi.com/2072-6643/17/16/2674.

"Western dietary pattern," suggesting that the overall diet plays a larger role in disease risk.[10]

A recent literature review that examined data from nearly 2 million adults across 43 population cohorts assessed whether high-glycemic index (GI) foods contribute to obesity.[11] These high-GI foods include many grain-based foods made with refined flours. The review found that existing studies showed no consistent association between body mass index and dietary GI. Additional research disputes the Petition's claim that refined grain ingredients drive chronic diseases, such as a study that found no increased cancer risk from bread consumption, including breads made with refined carbohydrates.[12]

Overall, there is extensive evidence that supports the role of refined carbohydrates on improving nutrient intake and contributing to a healthy dietary pattern. However, the Petition disregards this evidence in favor of a simplistic view on specific types of ingredients while arbitrarily setting aside the systematic approach to evaluate safety that is used globally.

Dietary healthfulness is primarily determined by the nutrient composition of a food, rather than by the food's processing techniques, as reflected in policies implemented by both FDA and the U.S. Department of Agriculture (USDA), including the recently revised rule for using the term "healthy" on food labels. Under the new "healthy" rule, whether the term "healthy" may be used depends on a food's composition. Specifically, a "healthy" food is one that contains a specified amount of a food group equivalent and does not have amounts of added sugars, sodium, and saturated fat exceeding specific thresholds.[13]

Refined carbohydrates can serve an important role in a healthy diet as determined by composition rather than processing. Thus, the current state of science in relation to refined

---

[10] Glenn A. Gaesser, *Refined grain intake and cardiovascular disease: Meta-analyses of prospective cohort studies*, 34 Trends in Cardiovascular Medicine 1, 59 (Jan. 2024) *http*://sciencedirect.com/science/article/pii/S1050173822001116.

[11] Glenn A. Gasser et al., *Perspective: Does Glycemic Index Matter for Weight Loss and Obesity Prevention? Examination of the Evidence on "Fast" Compared with "Slow" Carbs*, 12 Advances in Nutrition 6, 2076 (Nov. 2021) https://www.sciencedirect.com/science/article/pii/S2161831322004926?via%3Dihub.

[12] Glenn A. Gaesser et al., *Bread Consumption and Cancer Risk: Systematic Review and Meta-Analysis of Prospective Cohort Studies*, 8 Current Developments in Nutrition 12, 104501 (Dec. 2024) https://cdn.nutrition.org/article/S2475-2991(24)02435-1/fulltext.

[13] 21 CFR § 101.65(d).

carbohydrates does not support the Petition's position that these substances are no longer considered safe under current conditions of use.

The Petition's discussion of safety under the FDCA and its implementing regulations is incomplete. FDA has defined safe as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use,"[14] and general recognition of safety must be based only on the views of qualified experts.[15] To establish such recognition, there must be a consensus of expert opinion regarding the safety of the use of the substance.[16] (See, e.g., *United States* v. *Western Serum Co., Inc.,* 666 F.2d 335, 338 (9th Cir. 1982) (citing *Weinberger* v. *Hynson, Westcott & Dunning,* 412 U.S. 609, 629-32 (1973)). Unanimity among experts regarding the safety of a substance is not required. (See, e.g., *United States* v. *Articles of Drug * * * 5,906 boxes,* 745 F.2d 105, 119 n. 22 (1st Cir. 1984); *United States* v. *Articles of Food and Drug (Coli-Trol 80),* 518 F.2d 743, 746 (5th Cir. 1975) ("What is required is not unanimous recognition but general recognition.")). However, the existence of a severe conflict among experts regarding the safety of the use of a substance precludes a finding of general recognition. (See, e.g., *Premo Pharmaceutical Laboratories* v. *United States,* 629 F.2d 795, 803 (2d Cir. 1980)).

The Petition also conflates current investigations into "Ultra-Processed Foods" (UPFs) as a lack of consensus on the safety of specific ingredients in this ill-defined politicized category of foods. These are not the same, and while the Petition attempts to bridge these issues to wedge arguments surrounding the evolving evaluation and assessment of currently available data for the undefined UPF category, there is not a rational line that can be drawn to the request to revoke the GRAS status of a broad range of common food ingredients.

b. <u>The evidence linking partially hydrogenated oils to negative health outcomes is robust and has been collected over many decades, in stark contrast to the arguments put forth in the Petition.</u>

The Petition references FDA's revocation of GRAS status for partially hydrogenated oils (PHO) to suggest a similar lack of scientific consensus exists with respect to the ingredients identified in the Petition.[17] This is a false and misleading comparison. FDA

---

[14] 21 CFR 170.3(i).

[15] 21 CFR 170.30(a).

[16]

[17] *See* Kessler footnote 112, citing 78 Fed. Reg. 67169, 67170 (Nov. 8, 2013).

published its final rule to amend its regulations providing for the use of PHOs in August 2023, stating that the amendments "are noncontroversial given the public health risks associated with PHOs."[18] The preamble to the final rule further explained that FDA issued a declaratory order in 2015 setting forth the Agency's final determination that "based on the available *scientific evidence and the findings of expert scientific panels*, that there is no longer a consensus among qualified experts that PHOs, which are the primary dietary source of industrially produced *trans* fatty acids, are GRAS for any use in human food."[19]

In FDA's Final Determination Regarding Partially Hydrogenated Oils, the Agency relied on evidence gathered across many decades, beginning with "landmark studies in the 1950s and 1960s," to conclude that there is a linear relationship between *trans* fat consumption and coronary heart disease risk.[20] Beyond FDA action, the World Health Organization has advocated for the elimination of commercially produced *trans* fat since 2018, including through replacing PHOs with other oils.[21] Through U.S. and global initiatives to remove PHOs from the food supply, it is clear that science has settled that PHOs are unhealthy and unsafe for human consumption. This is not the case for refined carbohydrates, and thus, the GRAS status for refined carbohydrates should not and legally cannot be revoked.[22]

This dichotomy in the Petition's approach to determining consensus, or lack thereof, is further demonstrated in its extensive discussion of the proceedings of the Select Committee on GRAS Substances (SCOGS), subsequent work of the FDA's Sugars Task Force, and finally the promulgation of subsequent GRAS Affirmation regulations. This systematic approach spanned two decades of deliberate review and assessment, producing true consensus statements from which the subsequent regulations were promulgated. The Petition argues that FDA should skip past best scientific practices and deliberative and robust assessment and simply revoke the GRAS status of significant components of the food supply based on disparate correlations in evolving science.

---

[18] 88 Fed. Reg. 53764, 53764 (Aug. 9, 2023).

[19] *Id.* at 53765 (emphasis added).

[20] 80 Fed. Reg. 34650, 34663 (June 17, 2015).

[21] World Health Organization, *An action package to eliminate industrially-produced trans fat from the global food supply*, https://www.who.int/teams/nutrition-and-food-safety/replace-trans-fat.

[22] FDA may revoke a prior-sanctioned use of a food ingredient where scientific data or information demonstrate that the prior-sanctioned use may be injurious to health and, thus, adulterates the food. *See* 21 CFR 181.1(b).

Prior to upending decades of precedent and best scientific practices, NAMA respectfully suggests that FDA examine its past efforts, processes, and approaches to evaluating the state of science and assessment of consensus and general recognition of safety and consensus of expert opinion.

c. <u>The Petition does not apply current law and regulation to listed ingredients; it creates a new standard of safety from whole cloth.</u>

The Petition's analysis would create a new framework for the determination of safety and how the standard for "reasonable certainty of no harm" is determined and applied. The Petition discusses palatability, "ultraformulation," and eating rates, boldly asserting that the "food industry designs food to go down in a whoosh",[23] citing a single patent to make its case. In doing so, it conflates total consumption and exposure with behavioral patterns in isolation.

However, the result of applying this approach would be to upend the current systematic evaluation of the safety of food ingredients and additives, resulting in what the Petition would propose—the rapid removal of significant components of the food supply.

NAMA agrees that scientific knowledge and evidence evolves and grows with time and data. However, it is critical that the scientific method, using rigorous, well-defined and robust processes, is used to verify and validate both the scientific understanding of cause along with correlation, and then applying that knowledge to the applicable legal and regulatory frameworks.

FDA, under its public health mandate, should undertake the constant evaluation of not only the published science, but new tools that are being used to develop our understanding of epidemiological data, new computational toxicological tools and assessments, and enhanced abilities to analyze large volumes of data. With a thorough evaluation, and deliberative process, FDA should then propose any new approaches to the determination of safety through notice and comment rulemaking under the authority granted to FDA by Congress.

III. Conclusion

Refined carbohydrates have many beneficial uses in the American food supply, including improving nutrition and comprising one part of an overall healthy diet. The current state of science supports these benefits. However, research does not support a determination that refined carbohydrates are no longer GRAS under the current uses and should be removed from commerce. The Petition's distinction between refined carbohydrates used in

---

[23] Kessler at 34.

industrial processing and those used in the home is a fallacious argument. Rather than revoking the GRAS status of these ingredients, more focus is needed on overall dietary patterns and the role that processed foods, including refined carbohydrates, can play. FDA should follow its practices and precedent, namely robust scientific evaluation through well designed processes, and should the Agency determine that new approaches to the evaluation of safety are warranted, engage in public notice and comment rulemaking so that uniform, repeatable, and predictable standards apply to all foods and ingredients.

NAMA respectfully submits the above comments and looks forward to continued engagement with FDA on related issues.