



October 23, 2025

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Re: Ultra-processed Foods; Request for Information, Docket No. FDA-2025-N-1793

Dear Drs. Kavanaugh and Stooddy,

On behalf of The Grain Chain, a grains industry coalition from farm to fork, we respectfully submit the following comments to the U.S. Departments of Agriculture and Health and Human Services (the Agencies) in response to the Request for Information (RFI) that aims to develop a definition for ultra-processed foods (UPFs) for human food products in the U.S. food supply. The Grain Chain and its members have a longstanding history of engaging in federal nutrition policies and programs to advance nutrition goals. The Grain Chain appreciates the opportunity to provide comments on this RFI and looks forward to continued collaboration with the Agencies to support access to healthy, nutritious foods, like grains, for all Americans. We are pleased to submit the enclosed comments to help inform the Agencies' evolving research and policy priorities both on this topic of UPFs and within the broader context of nutrition efforts. The following points outline key themes included in our comments:

- The term "ultra-processed foods" and the level of processing do not indicate the nutritional composition or value of foods and therefore should not be used in dietary guidance.
- Both refined and whole grains contribute nutrients, including fiber, iron, B vitamins, and magnesium, with enrichment and fortification of grains playing a critical role in addressing nutrient gaps and supporting health across the lifespan.
- Grains serve as staple foods that are nutrient-dense, shelf-stable, affordable, and widely accessible – contributing to nutritious diets across preferences, income levels, and life stages. They act as foundational components of balanced meals and drive the consumption of other nutrient-dense foods like fruits, vegetables, and lean proteins.
- American farmers have been at the forefront of grain production innovation, supplying Americans with nutrient-dense grains that improve diet quality and support food and nutrition security.
- Transparency throughout the comment and rulemaking process is essential to ensure that stakeholders can meaningfully contribute to evidence-based policy and regulatory actions.

Whole and Enriched Grain Foods are Part of a Healthy, Nutritious Diet

Grains have long served as a foundational component of healthy dietary patterns, consistently recommended across decades of Dietary Guidelines of Americans (DGA), and currently represent one-quarter of USDA's MyPlate.ⁱ Federal dietary guidance established by the 2020-2025 DGA advises that individuals aged two and older consuming a 2,000-calorie per day diet, should include six servings (or ounce equivalents) of grains daily. For children aged 12 to 23 months, the recommendation is up to three servings per day.

Current DGA state, “make half your grains whole grains” and that refined-grain choices should be enriched. Established dietary patterns illustrate that all grains can be an integral part of healthy eating patterns. The RFI even notes that “foods considered to be ultra-processed may also include foods such as whole grain products... which are known to have beneficial effects on health and are recommended as part of healthy dietary patterns” which reiterates that the health and nutrition benefits of grains are well-known and established.

Grains provide vitamins and minerals such as B vitamins, magnesium, potassium, iron, dietary fiber, folic acid, and more. Dietary fiber, iron, and folic acid are considered nutrients of public health concern due to underconsumption for the general population and/or for specific populations. Iron is a nutrient of public health concern for infants ages 6-11 months who are human milk-fed, for adolescent females, and for females ages 20-49. Iron is also a nutrient of public health concern for pregnant individuals ages 20-44, folate is a nutrient of public health concern during preconception and during the first trimester of pregnancy, and iodine is a nutrient of public health concern for those who are pregnant. Grain foods contain many nutrients that Americans are under-consuming, providing approximately 23% of dietary fiber, 34% of dietary folate, 30% of iron, and 14% of magnesium daily in the total diet – showcasing how grains help in closing nutrient gaps for Americans.^{ii iii} This is critically important as nearly all Americans, 98%, do not meet the dietary recommendations for whole grains, and less than 10% of Americans ages 1 and older meet the dietary recommendations for fiber.^{iv} While increasing whole grain consumption remains a key public health objective, enriched and fortified grain-based foods – such as white bread, pasta, tortillas, rice, and ready-to-eat cereals – also play a pivotal role in helping to close nutrient gaps. These foods contribute significantly to the intake of several nutrients of public health concern, especially for vulnerable populations, as identified in the 2020-2025 DGAs.

Grain consumption has been found to lower the risk of common, and costly, nutrition-related chronic diseases such as obesity, coronary heart disease, diabetes, and colorectal cancer.^{v vi vii} A study examining commonly consumed grain food patterns in US adults and nutrient intakes, with a focus on 2015-2020 DGA shortfall nutrients, found that adults consuming pasta, cooked cereals, and rice, had lower body weight and waist circumference (3.4 kg and 3.0 cm, respectively) compared to those who consume no grains.^{viii} Additionally, research has found a positive association between eating at least one daily serving of rice (white or brown) and reducing the likelihood of being overweight or obese. Within the 19–50-year-old subgroup, rice consumption was associated with a reduced likelihood of being overweight or obese, a 34% reduced risk of high blood pressure, a 27% reduced likelihood of having an increased waist circumference, and a 21% reduced risk of metabolic syndrome^{ix} Consumption of iron-fortified infant rice cereal for those ages 0-24 months has been associated with improved nutrient intake and healthier dietary patterns.^x Analysis of data from the National Health and Nutrition Examination Survey (NHANES) found that infants who consumed iron-fortified rice cereal had higher intakes of key nutrients – including iron, calcium, magnesium, zinc, and vitamin E – compared to non-consumers.^{xi} These findings underscore the role of nutrient-dense grain foods in supporting nutritional needs during critical stages of growth and development.

Consumption of grains has also been found to lower the risk of cardiovascular disease (CVD). Research published in the *BMJ* that included 45 studies on the impact of whole grain consumption and the risk of cardiovascular disease, among other conditions, found that about three servings of whole grains per day (1 serving = 30 grams), but up to seven to seven and a half-servings per day, reduced the

risk of CVD, coronary heart disease, and stroke. Further examination also determined that specific types of whole grains, including whole grain bread, were associated with reduced risks of CVD.^{xii} Enriched grains, which constitute 95% of refined grains, also play a protective role in cardiovascular health. Enriched grains contribute important B vitamins (thiamin, niacin, riboflavin, folic acid) as well as iron. Research has shown a possible role in thiamine deficiency and the development of cardiovascular diseases, highlighting the importance of meeting recommended intakes of thiamine.^{xiii} Additionally, data from 2005-2016 NHANES that included over 10,000 adults found that riboflavin intake was inversely associated with CVD mortality, and the association was positively modified by folate intake.^{xiv} This emphasizes the importance of all grain consumption in promoting cardiovascular health from both enriched and whole grains.

Both whole and refined grains also play a role in preventing or reducing the risk of prediabetes and type 2 diabetes. A systematic review and meta-analysis published in 2024 was conducted to determine the effects of whole grains on diabetes prevention. The researchers found that whole grain intake reduced the risk of type 2 diabetes and significantly reduced fasting blood glucose while also having modest effects on HbA1C levels.^{xv} Additionally, a 2022 article published as part of the Mayo Clinic Proceedings examined refined grain intake and type 2 diabetes risk, noting that while current recommendations advise replacing refined grains with whole grains to reduce diabetes risk, this may not be necessary according to the author's analysis.^{xvi}

Whole and refined grains have been found to lower the risk of cancer, as well as site-specific cancers. Meta-analyses of cohort and case control studies published in December 2020 consistently found that whole grain intake is associated with both lower risk of total and site-specific cancer, emphasizing the importance of dietary recommendations to increase the consumption of whole grains.^{xvii} Additionally, across 11 meta-analyses that examined refined grain intake, there was no association between refined grain intake and cancer.^{xviii} Regarding breast cancer specifically, research has examined particular grain products and their role in breast cancer risk with one meta-analysis published in 2018 finding that intermediate and high intake levels of whole grains were associated with a modest reduction in breast cancer risk.^{xix} The impact of whole grain consumption on the reduced risk of colon and colorectal cancer has been well established in the literature, particularly in terms of dietary fiber intake. An article published in *The Lancet* in 2019 further emphasized the importance of dietary fiber that leads to protection from conditions like colorectal cancer, noting that the highest dietary fiber consumers compared to the lowest dietary fiber consumers, had a 15-30% decrease in all-cause and cardiovascular related mortality, and incidence of coronary heart disease, stroke incidence and mortality, type 2 diabetes, and colorectal cancer.^{xx} The authors also noted that higher dietary fiber intake could provide even greater benefit to protect against chronic diseases, including colorectal and breast cancers.

Grains also drive consumption of other healthy foods, like fruits, vegetables, and lean proteins. A recently published study in *Nutrients* examined the diets of Americans using data from the National Health and Nutrition Examination Survey (NHANES) from 2017 to 2023.^{xxi} Not only did the authors find that people who consumed more healthy grain foods had better overall diet quality and higher intakes of key nutrients like fiber, iron, calcium, potassium, and magnesium, but they also found that among those who ate the most healthy grain foods, they consumed more fruits, vegetables, and lean proteins.^{xxii} Another study that explored associations of whole grain and cereal fiber intake to cardiovascular risk factors also found that participants with higher intake of whole grains and fiber also

had higher consumption of daily fruit and vegetable servings.^{xxiii} This research reaffirms how grain foods support an overall healthy eating pattern and can drive consumption of other nutrient dense, under-consumed food groups.

Fortification and enrichment of grains have made significant, long-lasting, and cost-savings contributions to improve the health of Americans. The fortification of folic acid in certain grain foods has contributed to the significant reduction of neural tube defects, like spina bifida.^{xxiv} Overall, women of reproductive age do not consume enough folic acid, which is why folate is considered a nutrient of public health concern for this population. With the addition of folic acid to the enrichment formula in grains in 1998, the prevalence of neural tube defects, one of the most common birth defects in the US,^{xxv} decreased by 36% after fortification – from 10.8 per 10,000 in 1995 to 6.9 at the end of 2006.^{xxvi} It is also estimated that this mandatory fortification saves over \$600 million in U.S. health care costs annually due to the reduction of spina bifida alone.^{xxvii}

A recently published study in *American Journal of Preventive Medicine* which utilized NHANES data from 2007 to 2020, examined modifiable risk factors for birth defects in women of reproductive age, including folate concentrations.^{xxviii} The authors found that only 12.6% of participants consumed supplements that had ≥ 400 $\mu\text{g/day}$ of folic acid and that 19.5% had red blood cell folate concentrations below the threshold (748 nmol/L) for optimal neural tube defect prevention. This highlights the important role of fortification in helping this population meet nutritional needs.

In addition to folic acid, iron is a vital nutrient during pregnancy that supports fetal development.^{xxix} Breads, cereals, pasta, and other foods made with enriched flour supply about one-half of the iron consumed in the US.^{xxx} Iron deficiency anemia during pregnancy is associated with having a low-birth-weight baby and postpartum depression, and severe iron deficiency during pregnancy can increase the risk of premature birth which is defined as delivery before 37 weeks of pregnancy.^{xxxi} Consuming iron-fortified grain foods has been found to significantly reduce iron deficiency and anemia among pregnant women.^{xxxii}

Grains play a foundational role in promoting health and nutrition, offering essential vitamins and minerals and contributing to a reduced risk of nutrition-related chronic diseases. Enrichment and fortification further enhance the nutritional value of refined grains, helping to prevent nutrient deficiencies, especially in vulnerable populations, by providing key nutrients like folic acid and iron. Given their broad contributions to public health and their role in improving health and nutrition across the lifespan, any dietary guidance and/or regulatory efforts that would lead to reduced grain consumption risks undermining science-based dietary guidance and nutrient adequacy. Such guidance could inadvertently widen health disparities and compromise the effectiveness of nutrition policies and programs rooted in evidence-based dietary patterns.

Focus on Nutritional Quality over Classification Systems - Question 1

Current classification systems for ultra processed foods (UPFs), most notably the NOVA framework, have gained traction in public health discourse, yet they fall short in accounting for the nutritional value and health contributions of many foods. The term “UPF” itself implies that the degree of processing is the primary determinant of a food’s health impact – a framing that overlooks the critical reality that processing is not inherently harmful, nor is it a reliable proxy for nutritional quality or

healthfulness. Classification systems like NOVA and others do not consistently reflect the nutritional value of foods. By prioritizing processing level over nutrient composition and healthfulness, these systems risk oversimplifying the food landscape and mischaracterizing fortified, enriched, and nutrient-dense products that play a vital role in addressing dietary gaps and supporting public health. This is particularly concerning in light of 2022 research analyzing over 50,000 grocery store items, which found that more than 70% were classified as ultra processed (according to FPro), underscoring the impracticality of treating such a vast amount of the food supply as uniformly harmful.^{xxxiii} As outlined here in our comments, studies have shown that many foods classified as UPFs, like fortified cereals and enriched grain products, contribute meaningfully to health-promoting dietary patterns that are not only nutrient-dense, but are also more realistic for Americans to achieve and maintain. Conflating processing with poor health outcomes not only stigmatizes safe, accessible, affordable, and universally accepted foods, but also undermines public health strategies aimed at addressing health disparities.

Research has challenged the assumption that ultra processed foods, according to classification systems like NOVA, are inherently “unhealthy” or detrimental to health. A proof-of-concept study published in 2023, which included researchers at USDA, set out to determine the feasibility of building a menu that includes $\geq 80\%$ of kcals from UPFs, as defined by NOVA, but still aligns with recommendations for a healthy dietary pattern based on the 2020-2025 Dietary Guidelines for Americans (DGA).^{xxxiv} The authors created 7-day, 2,000 kcal/day menus with foods from different categories of NOVA, including the UPF category, that were then assessed for nutrient content and diet quality using the Healthy Eating Index (HEI). Within the ultra-processed DGA menu, 91% of kcals were from UPF, or NOVA category 4, and resulted in an HEI score of 86 out of 100 which is much higher than the average HEI score of Americans ages 2+ (58).^{xxxv} The study also found substantial variability in nutrient profiles within each NOVA category, especially among UPFs. While the sample majority UPF menu did not achieve a perfect score primarily due to excess sodium and an insufficient amount of whole grains, it did provide adequate amounts of all macro- and micronutrients except for vitamins D, E, and choline. This research is only one example of how a defined healthy dietary pattern can include mostly UPFs, receive a high diet quality score, and include adequate amounts of most macro- and micronutrients.

A recently published study that was conducted with 55 adults in England provided participants with two 8-week diets following the UK’s Eatwell guide – one consisting of ‘minimally processed foods’ (MPF) and the other consisting of ‘ultraprocessed foods’ (UPF).^{xxxvi} The primary outcome was within-participant difference in weight change between diets from baseline to week 8. While headlines stated that ‘avoiding ultraprocessed foods might double weight loss’ this mischaracterized the results of the study. While greater weight loss was observed on the MPF diet, weight loss was also observed on the UPF diet. The authors noted that weight and BMI were statistically lower at 8 weeks from baseline on *both diets* and that waist circumference did not differ significantly. Additionally, total cholesterol was significantly lower at 8 weeks compared to baseline on *both diets* and changes in blood pressure and heart rate did not differ significantly between diets.

Research like this continues to challenge the utility of NOVA and other UPF classification systems as standalone tools for dietary recommendations and nutrition policy. It underscores the need for guidance focused on nutritional composition, health benefits, and chronic disease prevention. The issuance of this RFI reiterates the absence of a unified definition and the fragmented consequences that have emerged from it. It also highlights the sheer volume and inconsistencies of existing definitions which proves the complexity in attempting to define UPFs.

Across academic literature, regulatory proposals, and public health narratives, UPFs are described through varying lenses, some that emphasize ingredient lists, others that focus on manufacturing techniques, and some with consideration for perceived health outcomes. This lack of definitional alignment underscores a deeper challenge: the concept of UPFs lacks scientific consensus because it cannot be reliably or uniformly defined in a way that supports actionable, evidence-based dietary guidance or nutrition policy. Rather than attempting to reconcile these inconsistencies into a single definition, it is more productive to shift the focus toward nutrient dense dietary patterns with measurable health outcomes – criteria that offer greater clarity, scientific rigor, and relevance to public health which are already established through dietary guidelines.

Food Processing can Advance Access, Safety, and Health – Question 3

Food processing, including that of grains, plays a critical role in enhancing the accessibility, safety, and nutritional value of the food supply. Some food categories, such as grain foods, are not consumable directly from the field and require processing to be edible. Techniques such as milling, which has been used for centuries, also extend shelf life, making grain-based products more stable and widely available across geographies and income levels.^{xxxvii} This shelf-stability not only reduces food waste and improves supply chain efficiency but also ensures that nutrient-rich grain products remain accessible in low food access areas and institutional programs like school meal programs. Also, grain products, such as bread, rice, sorghum, pasta, and cereals, are culturally familiar, widely accepted, and affordable, making them foundational staples in dietary patterns for various populations.

Processing of grain products also serves as a vehicle for improving public health through enrichment and fortification. Enrichment restores naturally occurring nutrients lost during milling, such as B vitamins and iron, while fortification introduces essential micronutrients like folic acid, which is critical for maternal health and neural tube defect prevention. In addition, folic acid present in fortified foods is generally more bioavailable than naturally occurring folate found in folate-rich foods like leafy greens, legumes, and some fruits.^{xxxviii} Enrichment and fortification have been instrumental in reducing nutrient deficiencies at the population level, particularly among women, infants, and low-income individuals. Given the important role that enrichment and fortification play, these programs are mandatory in many countries around the world – highlighting the importance of grains in helping meet the unique dietary needs of vulnerable groups while supporting broader nutrition and public health goals.^{xxxix}

When viewed through the lens of public health, processing is an important tool in our food supply. Processing methods, including the cooking and baking of grains, play a vital role in enhancing food safety by providing a kill step, while also supporting shelf stability, palatability, and cultural relevance across different dietary patterns. Processing methods can also increase the bio accessibility and bioavailability of some nutrients as well. For example, research has shown that the processing technique nixtamalization can significantly enhance the bioaccessibility of protein in sorghum, highlighting how processing can be beneficial in helping Americans meet nutrient needs.^{xl} Dismissing foods like grains based solely on their manufacturing methods overlooks their proven contributions to nutrient density, chronic disease prevention, and safe, affordable food access. A more nuanced understanding of processing recognizes its role in supporting nutrition security, food safety, and evidence-based dietary guidance.

Challenges with Defining UPFs – Questions 1, 4 & 6

As mentioned prior, current classification systems, such as NOVA and others, rely heavily on the degree of industrial processing as a proxy for healthfulness which we believe is a misguided approach that risks mischaracterizing nutrient-rich, fortified, enriched, and universally accepted foods. These classification systems fail to account for the nutritional contributions of foods like fortified cereals and enriched grain products, which play a critical role in addressing population-level nutrient gaps. For example, enriched grains, of which 95% of refined grains are, restore essential nutrients lost during milling and have long been recognized for their public health benefits, particularly in supporting iron and folate intake. These classification system approaches overlook the broader context of dietary patterns and nutrient density, and risk minimizing or decreasing the measurable contributions that grain foods make to meeting public health and nutrition needs. Rather than focusing on dietary guidance related to processing, a more effective strategy to improving health and nutrition is to evaluate foods based on their contribution to an overall nutritious diet, emphasizing nutrient density, dietary patterns, and measurable health outcomes as outlined in the DGA.

Efforts to develop or implement dietary guidance based on processing level alone may lead to unintended consequences. For example, incentivizing reformulation strategies that prioritize compliance over nutritional quality, such as reducing enrichment or fortification, or replacing affordable, accessible staple foods like grains with less nutritious alternatives. There is also a risk of undermining innovation in food technology and public-private partnerships that aim to improve access to nutrient-dense options. Dietary guidance should remain grounded in the science of nutrient density, overall dietary patterns, and measurable outcomes, as reflected in the DGA, not in the level or type of processing.

To inform ongoing discussions around food classification and public health, the Institute for Advancement of Food and Nutrition Services convened a working group and conducted a targeted literature review.^{xli} The team developed nine guiding principles emphasizing the importance of transparent documentation, reproducible definitions, and biologically relevant properties linked to health outcomes. They cautioned against relying on preliminary associations lacking robust causal evidence and underscored the need to consider how formulation and processing affect a food's composition and structure in relation to health-related endpoints. These principles should offer useful context as the Agencies evaluate the implications of UPF-related frameworks or definitions.

Impacts to Public Health & Nutrition Policy when Defining UPFs – Questions 1, 5 & 6

Efforts to define ultraprocessed foods (UPFs) by the Agencies risk creating confusion for consumers, misalignment across regulatory bodies, and compliance challenges for manufacturers. If the Agencies move forward with creating a definition of UPFs, they would have to ensure clear coordination across existing frameworks and regulations which include current labeling standards, ingredient lists, standards of identify, Nutrition Facts Panels, health claims, the criteria for using the term “healthy,” and any final rule on Front-of-Package Labeling (FOPL) schemes as to not create inconsistencies for consumers or manufacturers. A definition that relies solely on subjective markers, like levels of processing, would be difficult to enforce and open to interpretation, undermining its utility in policy and program implementation.

Any policy application of a UPF definition would make it difficult to not penalize nutrient-dense, shelf-stable, accessible, affordable, or universally accepted foods, many of which are foundational to federal nutrition programs like SNAP, WIC, and school meals and contribute to the collective goal of improving nutrition and ending childhood chronic disease – core components of the Make America Healthy Again agenda. These programs rely on accessible, nutrient-dense products to meet the dietary needs of low-income populations, pregnant women, and children – products made possible through a robust agricultural system of committed American producers that ensures consistent supply, affordability, and quality. Overly broad or reductive definitions could inadvertently stigmatize foods that are safe, widely accepted, and nutritionally beneficial, thereby undermining public health goals and exacerbating health and nutrition disparities. Dietary guidance should remain anchored in the evidence-based DGA, which prioritize nutrient density and overall dietary patterns – not the method or level of processing of a food. Introducing a UPF classification system or definition that conflicts with these evidence-based, established recommendations would risk confusing consumers, undermining dietary guidance, and creating inconsistencies across regulatory and programmatic frameworks.

Recommendation to Strengthen and Target Research of UPFs

“Ultraprocessed” foods have gained significant attention in the public discourse, policy discussions, and scientific literature, yet definitions vary widely, and the current body of evidence is limited and inconsistent. As interest in defining and potentially regulating UPFs grows, it is critical to recognize the research gaps that exist. The 2025-2030 Dietary Guidelines Advisory Committee (DGAC) conducted a systematic review to address the question “What is the relationship between consumption of dietary patterns with varying amounts of ultra-processed foods and growth, body composition, and risk of obesity?” They examined this question in five populations – infants and young children up to 24 months, children and adolescents, adults and older adults, individuals during pregnancy and individuals during postpartum. The DGAC concluded that there was insufficient evidence to draw any conclusions based on the reviewed evidence for three of the five populations and for the remaining two (children and adolescents and adults and older adults) they only found associations based on evidence graded as “limited.”

Federal agencies should prioritize investments and resources in rigorous, multidisciplinary research that will allow the scientific, food, nutrition, and health communities to better understand this topic. The RFI states that research has found associations or links between UPF consumption and a ‘range of negative health outcomes’. However, an association or correlation does not imply causation. FDA partnering with NIH through the NIH-FDA Joint Nutrition Regulatory Science Program and USDA’s research roadmap about processed foods, food processing, and human health in the context of the US food system, are opportunities for federal agencies to lead research efforts related to UPFs. Strengthening the research base is essential to any further efforts made by the agencies to define UPFs and to inform policy or regulatory decisions.

Conclusion

As the Agencies continue their important work to make America healthier, we commend the Administration’s commitment to improve public health and nutrition. It is essential that all nutrition policy efforts, including those related to ultraprocessed foods, are grounded in evidence-based science and broad stakeholder input. We encourage robust engagement through the current Request for

Information (RFI) and any future evaluation processes that reflect evolving evidence and the realities of the food supply. Transparency through comment and rulemaking processes is critical to ensuring that policies are practical and aligned with public health goals. Above all, nutrition guidance must prioritize nutritional value and health outcomes, not processing level, as the foundation for sound dietary recommendations. Grain foods, including enriched and fortified products, play a vital role in supporting food and nutrition security in a variety of dietary patterns. Their inclusion in federal nutrition assistance programs underscores their importance in promoting health across populations. The Grain Chain shares the Administration's vision for a healthier nation, and we are available as a resource and a partner in shaping effective, science-based food and nutrition policies. We look forward to our continued collaboration together.

Sincerely,

Undersigned Members of The Grain Chain

American Bakers Association
American Institute of Baking
Cereals and Grains Association
Independent Bakers Association
National Association of Wheat Growers
National Pasta Association
National Sorghum Producers
North American Millers Association
Retail Bakers of America
USA Rice Federation
Wheat Foods Council

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