

September 12, 2025

Dockets Management Food and Drug Administration 5630 Fishers Lane, Rm 1061 Rockville, MD 20852

Dear Claudine Kavanaugh, Meadow Platt, and Eve Stoody:

On behalf of Oldways, an educational nonprofit dedicated to inspiring people to embrace the healthy and sustainable joys of the old ways of eating, and its Whole Grains Council program, we are writing to provide comments and information in response to Docket No. FDA-2025-N-1793 for "Ultra-Processed Foods; Request for Information."

A Summary of Our Main Points

Processing is not an appropriate or accurate measure of nutrition quality, nor does it necessarily reduce the nutritional aspects of a product. Nutrition policy should focus on evidence-based best practices that are proven to improve health, rather than focusing on how foods are produced. A classification system that is processing-based can lead to unintended consequences, grouping healthy foods with unhealthy foods, and steering people away from foods they should be eating, such as whole grains. Instead, focusing on nutrient density, rather than processing characteristics will achieve an affordable, accessible, and healthier food supply.

About Oldways and the Whole Grains Council

Oldways is a 501(c)3 educational nutrition nonprofit, founded in 1990 and dedicated to inspiring good health through cultural food traditions. We are perhaps best known worldwide for creating the Mediterranean Diet Pyramid in 1993 with the Harvard School of Public Health and for our work promoting whole grains and creating the Whole Grain Stamp.

The Oldways Whole Grains Council is an Oldways program, initiated in 2003, with the threefold mission of (1) helping consumers to find whole grain foods and understand their health benefits, (2) helping manufacturers and restaurants create delicious whole grain products and meals, and (3) helping the media write accurate, compelling stories about whole grains. We fulfill this mission through our many educational programs, and through our administration of the Whole Grain Stamp program. Our iconic Stamp packaging symbol helps shoppers easily identify products which contain significant amounts of whole grain ingredients.



Avoiding Unintended Consequences in Defining Ultra-Processed Foods

Having worked in the public health and nutrition education space for more than thirty years, we are encouraged to see FDA/USDA's continued efforts to look for strategies and policies to improve the American diet and reduce rates of chronic disease. However, we have serious concerns about any classification of "ultra-processed foods" (UPFs) and the implications that a blanket condemnation of these foods would likely have on whole grain intake, in particular.

Your team aptly points out in its supplementary information, "foods considered to be ultraprocessed may also include foods such as whole grain products or yogurt, which are known to have beneficial effects on health and are recommended as part of healthy dietary patterns. It is important therefore to consider unintended consequences of an overlyinclusive definition of UPFs that could discourage intake of potentially beneficial foods."

While many of the foods that various classification systems categorize as UPFs are foods that are high in added sugars, sodium, saturated fat, and overall calories, the UPF category is extremely broad, and not all UPFs contain high levels of these adverse nutrients. Some foods, like hummus, whole wheat pita, frozen salmon burgers, or muesli, have added salts or preservatives to maintain shelf-life, but offer a huge nutritional benefit despite that. We urge your team to be very cautious about introducing any classification system that could vilify recommended foods that make important nutritional contributions to the diet.

Processing-Based Classifications Conflict with Longstanding Dietary Guidance

Any definition of UPFs is likely to conflict with existing dietary guidance because processing level is not an appropriate proxy for nutrient density. When we look at the whole grain food category, conflicts between science-based nutrition advice and UPF classifications arise immediately.

Since 2005, the Dietary Guidelines for Americans (DGAs) have recommended that adults consume six ounce-equivalents of grain foods per day, at least half of which should be whole grain. And yet, under the NOVA classification system, for example, 90% of whole grain foods would be classified as UPFs, putting NOVA at odds with long-standing dietary guidance. Critically, nearly all the top sources of whole grain in the American diet—breads, rolls, tortillas, and ready-to-eat cereals—count as UPFs under the NOVA system. If Americans are told to reject these foods altogether, we worry about the impact it could have on whole grain intake, which already falls far below recommended levels, contributing significantly to rates of chronic disease. Similarly, if a majority of the whole grain foods offered by school meal programs or WIC were suddenly excluded because of



their processing status, it could undermine the progress made in increasing whole grain intake among children and at-risk populations who rely on these programs.

The mismatch between processing-based classification systems and longstanding dietary guidance around whole grain intake also risks confusing consumers, many of whom already find it difficult to understand what they should eat in a media environment where nutrition misinformation is common. In addition to being at odds with the current DGAs, processing-based systems' negative classification of many whole grain foods conflicts with FDA's very recent definition of "healthy" foods. Most whole grain breads and breakfast cereals that qualify to use the term "healthy" would also qualify as a UPF under a system like NOVA. It would seem to defy logic to simultaneously promote a product as healthy and to discourage people from buying it because of its processing status. From a nutrition education perspective, this is a very difficult pair of messages to reconcile.

Why Encouraging Whole Grain Intake Matters for Public Health

Decades of nutrition research have demonstrated the link between increased whole grain consumption and reduced risk of many diseases, including cardiovascular disease, stroke, type 2 diabetes, and colorectal cancer. But, despite overwhelming evidence that we should be eating more whole grains, Americans struggle to meet recommended levels of intake—in fact, 98% of the US population fails to meet their daily recommended intake of whole grains (48 g/d). The 2019 Global Burden of Disease Study found that "low intake of whole grains was the leading dietary risk factor for [disability adjusted life years] among men and women and the leading dietary risk factor for mortality among women" ahead of high sodium intake, high trans-fat intake, and high sugar-sweetened-beverage intake.

In other words, increasing consumption of beneficial food groups like whole grains is just as important, if not more so, than decreasing consumption of detrimental ingredients such as sodium or added sugar.

Health economics research shows that there are significant healthcare cost savings associated with increasing whole grain consumption because of the resulting reductions in chronic disease rates. A recent US study found if whole grain intake was increased to meet recommended levels (and increase of 2.24 ounce-equivalents of whole grain per day), the estimated direct medical cost savings from reduced risk of cardiovascular disease could be about \$21.9 billion annually. An additional \$14 billion could be saved by the reduction of incidents of coronary heart disease. Notably, the study found that even very modest increases (of just 0.25 ounce-equivalents of whole grain per day) could result in substantial savings.



Whole grain foods are encouraged in dietary guidance around the world and have played an important role in heritage diets for tens of thousands of years. The 2019 EAT-Lancet Commission Report found that whole grains will be an essential part of feeding a growing global population with a diet that is both nutritious and sustainable, and recommends people get more of their calories from whole grains than from any other food group. As we work to bolster the health, nutrition, and security of our food system, whole grains must continue to play a prominent role.

The Importance of Processing, Especially for Whole Grains

Food processing is not inherently bad, <u>nor does it necessarily lower the nutritional or health aspects</u> of a product. On the contrary, food processing serves many positive purposes. It can improve texture and nutrient bioavailability. It can extend shelf-life, and reduce factors that decrease food safety, such as oxidation, fat rancidity, and mold growth. Processing also tends to make foods more convenient and more affordable, both of which are important considerations that can increase consumer access to nutritious options.

Processing is particularly important for whole grains and often improves their nutrient bioavailability. Unlike fruits and vegetables, grains cannot be harvested from the field and eaten as is—they must undergo processing to become an ingredient that is safe, edible, convenient, accessible, and tasty to eat. And while more minimally processed whole grain options exist (like rolled oats, and brown rice), most whole grain foods are classified as UPFs under processing-based classification systems such as NOVA. It's hard to imagine that discouraging these foods will have a positive impact on overall nutrition. On the contrary, we could end up in a situation where Americans struggle even more to meet their whole grain intake recommendations.

Importantly, <u>nutrition research demonstrates</u> that the whole grain subcategory of UPFs <u>offers protective health benefits</u>, in contrast with research showing that UPFs more generally are associated with adverse health outcomes—and <u>the evidence for whole grain health benefits is much stronger than the evidence that UPFs increase chronic disease risks. A <u>study last fall</u> showed that while high UPF intake overall was associated with a 46% increase in risk of type 2 diabetes, high intake of UPFs in the bread, biscuit, and breakfast cereal subcategory was separately associated with a 35% *decrease* in type 2 diabetes risk.</u>

These results are not surprising given that <u>decades of nutrition research</u> demonstrating the health benefits of whole grains have been conducted using widely available whole grain products such as sandwich breads and breakfast cereals—the same products that now fall into this subcategory of UPFs.



How Processing-Based Systems Can Mislead Consumers

Prioritizing processing rather than nutrient density can result in situations where less healthy products are being promoted and healthier products are being discouraged, which undermines the goal of promoting healthier food options.

For example, consider that under some processing-based systems a baguette (with refined flour, water, yeast, and salt) would be classified as a processed food (PF), while a whole grain sandwich bread containing 18g of whole grain but including more than four ingredients and utilizing a dough conditioner would be classified as a UPF. Under the NOVA system, for example, the baguette would be favored even though it lacks many of its original nutrients and most of its original fiber, and despite its refined grain flour, which is inherently more processed than whole grain ingredients. On the other hand, the whole grain bread would be discouraged despite boasting a much better nutritional profile.

Here, a reliance on a processing-based system misleads consumers to choose the less healthy option and fails to recommend the whole grain product over the refined one. Examples like this raise questions about which foods consumers will shift to eating if they are encouraged to stop choosing most whole grain foods.

Focusing on Nutrient Density, rather than Processing, to Achieve an Affordable, Accessible, Healthier Food Supply

While minimally processed whole grain foods exist, they tend to take more time and skill to prepare and can be more expensive and less readily available. Additionally, consuming only unprocessed and minimally processed foods (MPFs) can result in nutritional gaps in the diet. A dietary modeling study in Australia found that when PFs and UPFs were removed from the diet in favor of MPFs, intake of whole grains, dietary fiber, cereal fiber, folate, iodine, iron, and B vitamins all decreased significantly.

In contrast, research shows that diets that rely heavily on UPFs can be affordable, accessible, and healthy. In a 2023 study, government nutrition scientists developed a 7-day menu designed to meet nutritional needs, of which 91% of the calories were from healthy UPFs, such as whole wheat English muffins, pasta with marinara sauce, and salad with salad dressing. The authors of the study concluded that "healthy dietary patterns can include most of their energy from UPF, still receive a high diet quality score, and contain adequate amounts of most macro- and micronutrients." For most Americans, this type of diet would be a huge step in the right direction for reducing diet-related disease.

There is a very practical need for nutrient-dense, affordable, and convenient food options in our food supply, and processing itself is not the enemy. Nutritious food can be found



across every level of the processing spectrum. By turning our attention away from the vilification of particular food choices, and by supporting greater access and continued reformulation and innovation within the food industry, we will be helping to create a healthier America, meal by meal.

For these reasons, we urge your team to be very cautious about introducing a processing-based classification system that could vilify recommended foods that make important contributions to the diet and to the good health of all Americans.

Sincerely,

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