Place on appropriate letterhead [if applicable]

DATE

Attn : Dockets Management Staff

Food and Drug Administration

5630 Fishers Lane, Rm. 1061, Rockville, MD

Rockville, MD 20852

**DELETE THIS PARAGRAPH BEFORE SENDING** Comments are due by October 23, 2025 and should be submitted on the following website [Regulations.gov](https://www.regulations.gov/document/FDA-2025-N-1793-0001)*.* Find this particular information collection by putting “FDA-2025-N-1793” into the search bar of the regulation’s website. Here is a link to the request for comments for your convenience: [Ultra-Processed Foods; Request for Information](https://www.federalregister.gov/documents/2025/07/25/2025-14089/ultra-processed-foods-request-for-information). Throughout this template, we have highlighted opportunities for Tribes/Tribal organizations to tailor this letter to your unique circumstances, if you are comfortable doing so. If you wish for your comments to be confidential, you can submit written/paper copies only. The ROI page here has additional instructions to follow to keep your comments confidential and not published in the comment docket.

Re: **Ultra Processed Foods; Request for Information**

On behalf of [INSERT NAME OF TRIBE/ORGANIZATION], I am submitting the following comments to the Food and Drug Administration, the Department of Health and Human Services, and the Department of Agriculture on the request for information regard ultra-processed foods.

**(1) What, if any, existing classification systems or policies should we consider in defining UPFs? What are the advantages and challenges in applying these systems (or aspects of them) to classify a food as ultra-processed? What are characteristics that would or would not make a given system (or aspect of the system) particularly suitable for the U.S. food supply? Please provide supporting data and explain your rationale in your response.**

The NOVA classification is a popular system of food classification proposed in 2009.[[1]](#footnote-2) Foods are classified into four groups. Group 1 includes minimally processed foods, which are naturally occurring foods without added sugar or fat, like meat, eggs, milk, and fresh or frozen fruits and vegetables. Group 2 includes processed culinary ingredients, which are foods from Group 1 that have been altered by pressing, refining, grinding and/or milling, including butter, salt, sugar, and vinegar. These ingredients are used in home and restaurant kitchens to prepare, season and cook Group 1 foods. Group 3, processed foods, includes foods from Group 1 that have sugar, oil, and/or salt added to increase shelf-life or enhance taste. Canned beans and vegetables, smoked meats, cheese, and freshly made bread fall into this category. Group 4 covers ultra-processed foods (UPFs), which are “industrially produced” food products created with the addition of multiple ingredients that may include some Group 2 ingredients as well as additives to enhance the taste and/or convenience of the product, such as hydrolyzed proteins, soy protein isolate, maltodextrin, high fructose corn syrup, stabilizers, flavor enhancers, non-sugar sweeteners, and processing aids such as stabilizers and bulking and anti-bulking agents.”[[2]](#footnote-3) This includes commercially prepared bread, flavored yogurts, breakfast cereal, and soft drinks.[[3]](#footnote-4)

However, this system presents a challenge in its treatment of UPFs. Group 4 includes inherently healthful foods like hummus, whole grain bread, and flavored Greek yogurt, all of which can be a part of a balanced diet. The system also creates potential confusion or unintended consequences when applied to foods used in federal food assistance programs. For example, 11 foods available in the Food Distribution Program on Indian Reservations (FDPIR) would be classified as ultra-processed. This includes sliced deli meat, peanut butter, dried eggs, dehydrated potato flakes, peanut butter, canned beef stew, crackers, instant dry nonfat milk, American cheese, cream of chicken soup, cream of mushroom soup, and bakery mix.[[4]](#footnote-5) Nine of these products are shelf-stable, which is crucial for the FDPIR program as they must be transported long distances and stored for extended periods of time. Similarly, products provided through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), such as breakfast cereals, shelf-stable dairy alternatives, tofu, and pasteurized liquid eggs[[5]](#footnote-8659), could also fall under the ultra-processed classification. Food assistance programs like FDPIR and WIC play a vital role in ensuring food access and security in Tribal and rural communities, often serving large numbers of elders and children.

[ADD EXAMPLE OF THE IMPORTANCE OF THESE PROGRAMS TO YOUR TRIBE/ORGANIZATION]

Nutrient density, which refers to the amount of essential nutrients in a food relative to its calorie count, plays an important role in evaluating how healthy a food is.[[6]](#footnote-5630) Many foods classified as ultra-processed, particularly those included in food assistance programs, are often rich in important nutrients, like protein, fiber, vitamins, and minerals, despite being processed. The earlier example of whole grain bread provides essential nutrients that improve diet quality, like fiber and B vitamins.[[7]](#footnote-28009) The NOVA classification system does not distinguish between nutrient-dense processed foods and those that are less healthful, which can unintentionally exclude foods that are beneficial for health and critical for food safety.

The lack of distinction between ultra-processed and nutrient-dense foods could have a serious impact on Tribal farmers and producers. Many Tribal communities engage in traditional food preservation methods, like fermenting, drying, and smoking, that allow for safe, shelf-stable foods. These methods may inadvertently be categorized as ultra-processed under the NOVA system. As a result, if potential regulations are not carefully drawn, we could see traditional Tribal foods like ground blue cornmeal, bison products, wild rice products, and hominy classified as ultra-processed despite their nutritional value and importance to Tribal Nations. Labeling such foods as ultra-processed could also impact rural agricultural economies, as farmers and ranchers would face barriers to market access for these products, limiting their ability to support local economies, create jobs, and bring healthy foods to market.

[IF YOU ARE COMFORTABLE DOING SO, YOU CAN ADD DISCUSSION OF RELEVANT TRADITIONAL FOOD PRODUCTION FOR YOUR TRIBE/ORGANIZATION HERE. If you wish for your comments to be confidential, you can submit written/paper copies only. The ROI page linked at the top of this letter has additional instructions to follow to keep your comments confidential and not published in the comment docket.]

Rather than solely relying on the NOVA classification, we recommend it be used as a screening tool, with foods falling in Group 4 undergoing further analysis for nutrient density and overall health impact. This would ensure that beneficial traditional and shelf-stable foods are not excluded because of their processing levels, while still addressing concerns about food quality. A more nuanced approach would recognize the importance of processing both for food safety and food access, and the need to reduce intake of non-nutritive or highly refined additives.

Another option would be to look at California’s recently passed AB 1264, which provides a comprehensive and detailed definition of UPFs that could serve as a model for national efforts. According to the bill, UPFs are classified based on both their ingredient composition and nutritional content.[[8]](#footnote-15105) Foods containing industrial substances, such as emulsifiers, stabilizers, and artificial colors, which are not commonly found in home cooking. It also sets clear thresholds for high levels of saturated fat, sodium, and added sugar (≥ 10% of total energy from fat and sugar, and ≥ 1mg of sodium per calorie). The bill also factors in the presence of artificial, nonnutritive sweeteners like sucralose and xylitol. This definition also excludes foods such as raw agriculture commodities, USDA-provided commodity foods like those provided by FDPIR, and minimally processed foods. This is a more nuanced approach to the ultra-processed classification. By including both ingredient-based and nutritional thresholds, this definition could serve as a useful model for a more adaptable classification system, addressing some concerns about both food quality and access in Tribal and rural communities.

**(2) FDA-required ingredient labeling provides important information to consumers about what is in packaged foods. The ingredient declaration on a food label lists each ingredient by its common or usual name (21 CFR 101.4(a)(1)). This ingredient name sometimes provides information on specific forms of the ingredient used, such as “flour” versus “whole grain flour.” Additionally, ingredients are declared in descending order of predominance by weight (21 CFR 101.4(a)), which may help a consumer determine the relative proportion of whole versus processed ingredients. For certain types of ingredients, such as flavorings, colorings, and chemical preservatives, labeling must also provide the function of the ingredient (see 21 CFR 101.22). The following questions focus on the ingredient list on the labeling of packaged foods.**

**a. In considering ingredients that appear toward the beginning of an ingredient list (that is, ingredients that likely form most of a finished food by weight), what types of ingredients ( e.g., ingredients that may share a similar composition, function, or purpose) might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.**

Using the presence of certain ingredients, like emulsifiers and other additives, towards the beginning of ingredient lists is not an appropriate way to identify a food as ultra-processed. Ingredient order reflects quantity, not necessarily nutritional impact or level or modification.[[9]](#footnote-6) Many shelf-stable nutrient dense foods, like fortified cereal and nut butters, may have to list these ingredients early due to formulation needs.

In food assistance programs like FDPIR, where shelf-stability and transportation needs are critical, these ingredients play a functional role in ensuring safety, palatability, and accessibility. Using ingredient list placement as a classification tool could unintentionally limit access to nutritious foods. If ingredient prominence is used, it must be considered in context, with exemptions or additional analysis for foods distributed by programs serving Indian Country.

These programs often rely on shelf-stable, fortified foods out of necessity, and without contextual evaluation, applying ingredient-based thresholds could disqualify products that are nutritionally beneficial. Additionally, the presence and placement of an ingredient should not outweigh the overall nutrient density of a food when considering its classification. Nutrient-rich foods that contribute to health and meet dietary needs- especially in food-insecure communities- should not be penalized for the use of functional ingredients.

**b. Ingredients that appear toward the end of an ingredient list may contribute minimally to the overall composition and weight of a finished food (for example, ingredients may sometimes be listed as containing 2% or less by weight of the finished food (21 CFR 101.4(a)(2))). What types of these less prominent ingredients ( e.g., ingredients that may share a similar composition, function, or purpose) might be used to characterize a food as ultra-processed?**

Ingredients towards the end of the list, like artificial sweeteners, synthetic preservatives, and artificial colors, may serve as indicators of ultra-processing, especially when used to enhance the shelf-life, flavor, or texture beyond what is typical in minimally processed foods. However, care must be taken to distinguish between functional additives that support food safety and stability (critical for shelf-stable products in Tribal communities) and those additives primarily aimed at modifying food for marketability purposes. A balanced approach should recognize the role of these minor ingredients play without unfairly excluding foods that are nutrient dense. In particular, processed foods developed to meet the needs of Tribal food sovereignty or traditional food preservation should not be penalized due to the use of ingredients in trace amounts. Nutrient density should remain the central consideration in these cases.

**c. To what extent, if any, should the relative amount of an ingredient used in a food influence whether the food should be characterized as ultra-processed? Please provide supporting data and explain your rationale in your response.**

The relative amount of an ingredient should be a key factor in characterizing a food as ultra-processed. Ingredients present in very small amounts (e.g. 2% or less by weight) likely have minimal impact on the food’s overall nutritional quality and health benefits. Overemphasizing trace additives risks unfairly categorizing foods that are otherwise nutrient dense and beneficial. In Tribal and rural food systems, where food choices may already be limited, nuance in evaluating ingredient amounts is essential to avoid unintended consequences.

**d. What, if any, other ingredients or ingredient-related criteria not discussed previously should or should not be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.**

Beyond ingredients already discussed, criteria such as the degree of industrial alteration and the presence of additives specifically designed to increase palatability and encourage overconsumption, like artificial sweeteners or fat replacers, should be considered when categorizing food as ultra-processed. However, care must be taken to ensure ingredients essential for food safety or nutritional fortification are excluded from consideration. Traditional and regionally significant ingredients (like ash used in corn processing or Indigenous preservation methods) may appear “processed” but serve essential culinary and/or health-related functions and should be exempt.

**(3) FDA defines “manufacturing/processing,” in part, to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients (21 CFR 117.3; see also 21 U.S.C. 321(gg) for the statutory definition of “processed food”). Certain FDA regulations, such as standards of identity, may prescribe methods of production or formulation (see, e.g.,21 CFR part 133). Processing of a food is often achieved by a combination of physical, biological, and chemical methods; however, while processing information is sometimes found on food labeling, manufacturers are not always required to disclose processing information on food labeling. The following questions focus on the processing of an ingredient or a mixture of ingredients into the finished food and whether certain processing methods may contribute to a food being considered ultra-processed.**

**a. Processing** **a food through physical means may include cutting, extracting juice by an application of force, heating, freezing, extrusion, and other physical manipulations. What physical processes might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.**

Physical processing methods such as cutting, freezing, heating, and juice extraction are essential techniques that preserve food safety, extend shelf-life, and maintain nutritional quality, and therefore should not be broadly categorized as ultra-processing. These alterations help make food more accessible and convenient without fundamentally altering their nutrition profile. [IF YOU ARE COMFORTABLE DOING SO, ADD DETAILS ABOUT LOCAL OR TRADITIONAL FOOD PROCESSING RELEVANT TO YOUR TRIBE/ORGANIZATION HERE. The template letter uses wild rice as an example.]

For example, wild rice is often parched or heat-dried to preserve it.[[10]](#footnote-15642) This traditional physical processing enhances shelf-life and flavor but does not make the rice “ultra-processed.” This classification system must be sensitive to such practices.

**b. Processing a food through biological means may include non-alcoholic fermentations of the food by microorganisms (for example, bacteria and yeasts), enzymatic treatment, and other biological manipulations. What biological processes might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.**

Biological processing methods, such as fermentation, are traditional techniques that often enhance nutritional value, digestibility, and safety of foods and should not be broadly considered markers of ultra-processing. For example, fermentation by bacteria or yeasts used to produce nutrient-rich food, like yogurt, kimchi, and bread can support gut health and provide beneficial probiotics.[[11]](#footnote-8) Similarly, traditional preservation methods used in Tribal communities, including fermenting corn and fish, drying berries and meat, or natural pickling,[[12]](#footnote-1521) play a vital role in food security. However, biological processes that involve extensive use of enzymes or genetically modified microorganisms to create highly altered ingredients or additives are more indicative of ultra-processing. These more intense biological manipulations can significantly transform the food matrix and nutrient profile. Therefore, while it is important that traditionally processed, nutrient dense foods are not misclassified due to their method of preparation, more industrial-scale or highly modified biological methods may warrant consideration when characterizing UPFs.

[IF YOU ARE COMFORTABLE DOING SO, ADD DETAILS ABOUT BIOLOGICAL FOOD PROCESSING RELEVANT TO YOUR TRIBE/ORGANIZATION]

**c. Processing a food through chemical means may include pH adjustment and other chemical manipulations. What chemical processes might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.**

Chemical processing methods such as excessive pH manipulation, hydrogenation, chemical bleaching, or the addition of synthetic preservatives and emulsifiers should be considered when classifying food as ultra-processed. These chemical manipulations often alter the food’s natural composition, nutrient profile, and bioavailability, sometimes creating compounds linked to adverse health effects.[[13]](#footnote-9) For example, hydrogenation produces trans fats, which are associated with increased risk of cardiovascular disease.[[14]](#footnote-10) While some chemical modifications, like mild acidification (e.g., pickling), are traditional and can preserve nutritional value, more intensive chemical modifications commonly found in UPFs are markers of higher processing levels. However, classification decisions should reflect whether such processing materially affects the food’s overall nutrient density. Some chemically processed foods remain significant sources of essential nutrients, particularly in food-insecure or remote communities, and should not be excluded from food distribution programs due to processing methods.

[IF YOU ARE COMFORTABLE DOING SO, ADD DETAILS ABOUT CHEMICAL FOOD PROCESSING RELEVANT TO YOUR TRIBE/ORGANIZATION]

**(4) Is the term “ultra-processed” the best term to use, or is there other terminology that would better capture the concerns associated with these products? If there is another term to consider, please name and define that term and provide specific scenarios and citations (if available) to support its use.**

The term “ultra-processed” is widely recognized but can be overly broad and sometimes misleading, as it groups a variety of foods with different nutritional qualities. For example, both hot dogs and premade hummus would be categorized as ultra-processed under the NOVA classification. This broad labeling risks limiting access to affordable, shelf-stable, and relevant foods critical to Tribal communities. A more precise term, such as “industrially reformulated foods,” might better reflect the concern with hyper-palatable, nutrient-poor products, while allowing room for processed foods that contribute positively to dietary quality. Any terminology used should clearly distinguish between processing for safety, accessibility, and tradition, and processing that undermines nutrition. Care should be taken to avoid over-generalization that could inadvertently exclude foods essential for nutrition and food security.

**(5) FDA and USDA are aware of ongoing research on nutrition and other attributes relating to the health outcomes associated with consumption of UPFs. As noted in the background, FDA is also initiating a joint effort with NIH to answer questions such as how and why UPFs can harm people's health.**

**a. In considering nutritional attributes (such as information presented on the Nutrition Facts label), to what extent, if any, and how, should nutritional composition or the presence of certain nutrients be incorporated in a definition of UPFs? Please provide supporting data and explain your rationale in your response.**

Nutritional composition should play a central role in defining UPFs, as nutrient profiles can indicate the health outcomes of eating the food. While the degree of processing should be considered, many foods classified as UPFs vary widely in their nutrient density and health impacts. Incorporating key nutritional attributes, such as added sugar, saturated fats, sodium levels, and fiber content, can provide a more accurate assessment of a food's nutrient density. For example, high levels of added sugars and sodium have consistently been linked to increased risks of obesity, hypertension, and cardiovascular disease,[[15]](#footnote-11) while high levels of dietary fiber are associated with improved digestive health, reduced risk of chronic disease, and better overall diet quality.[[16]](#footnote-12) Including nutritional criteria alongside processing characteristics ensures that nutrient-dense foods are not unfairly excluded. This approach would help ensure that nutrient-rich foods are not excluded due to processing alone and would better align with public health goals.

**b. What other attributes, such as energy density or palatability, might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response. If relevant to your answer, please also provide suggestions on how these attributes can be measured and/or potentially be incorporated into a definition of UPFs, if they are not readily apparent on the food labeling.**

Attributes that may help characterize a food as ultra-processed include the degree of ingredient modification, loss of the natural food matrix (e.g. the chemicals that make up the food and how they interact with each other and the body), and the multiple industrial additives not typically used in home cooking. For example, food composed largely of reconstituted powders, isolates (like protein), or oils combined with cosmetic additives (colors, flavors, emulsifiers) are more likely to reflect industrial formulations designed for shelf-life, not nutrition. The breakdown of the food matrix has also been linked to faster digestion and less satiety, which can contribute to overeating. These attributes are not readily apparent on food labels, and would need to be assessed through procedure disclosures, ingredient sourcing information, or manufacturing methods.

**(6) FDA and USDA are exploring whether and how to incorporate various factors, such as the ones discussed in the questions above, into a uniform definition of UPFs. How might these factors be integrated in the classification of a food as ultra-processed in a way that can be systematically measured and applied to foods sold in the U.S.? And what considerations should be taken into account in incorporating such a classification in food and nutrition policies and programs?**

To systematically classify a food as ultra-processed, factors such as ingredient type, degree of processing, and nutritional profile should be integrated into a tier or point-based system. Foods could be evaluated based on the presence of industrial ingredients (e.g., protein isolates, synthetic additives), the extent of matrix breakdown, and levels of added sugar, sodium, and saturated fat. This type of system could be adapted from existing systems like NOVA but modified to reflect both nutritional impact and the functional role of processing. However, to ensure fairness and practicability, any classification system should be transparent, scientifically validated, and flexible enough to account for context, such as the need for shelf-stability, food access, and food costs. Nutrient density should be a foundational criterion within this system, not an afterthought. This ensures foods with significant health value are not inappropriately classified, especially in low-access areas.

When defining UPFs for federal food and nutrition programs, agencies must be especially cautious not to unintentionally restrict access to affordable, nutritious, and shelf-stable foods that meet the needs of Tribal and other underserved communities. These programs often rely on processed foods for logistical reasons, and approved foods are classified as ultra-processed despite providing essential nutrients. Any UPFs classifications should be used as a tool for evaluation, not exclusions, and be paired with nutrient profiling to ensure decisions support both health and equity.

We appreciate the government’s efforts to improve food quality and better understand the role of UPFs in public health by exploring how a consistent definition could support dietary guidance and food policy. However, any definition or framework developed must be grounded in sound science, account for economic and logistical realities, and avoid a one size fits all solution that could limit access to affordable and nutritious food.

Respectfully,

Insert Signature

1. Examining the Nova Food Classification System and the Healthfulness of Ultra-Processed foods. Academy of Nutrition and Dietetics. Jan 1, 2023. <https://www.eatrightpro.org/news-center/practice-trends/examining-the-nova-food-classification-system-and-healthfulness-of-ultra-processed-foods> [↑](#footnote-ref-2)
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11. Fermented foods for better gut health. Harvard Health. September 12, 2023. <https://www.health.harvard.edu/blog/fermented-foods-for-better-gut-health-201805161607> [↑](#footnote-ref-8)
12. Processing and preservation techniques to enhance Indigenous food sovereignty, nutrition security, and health equity in North America. Danielle Heaney, et al. Frontier of Nutrition. June 19, 2024. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11221487/> [↑](#footnote-ref-1521)
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14. Trans Fats. American Heart Association. September 9, 2025. <https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/fats/trans-fat> [↑](#footnote-ref-10)
15. Limit fat, salt, and sugar intake. World Health Organization. (n.d.). <https://www.emro.who.int/nutrition/reduce-fat-salt-and-sugar-intake/> [↑](#footnote-ref-11)
16. Dietary fiber: essential for a healthy diet. Mayo Clinic. December 11, 2024. <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/fiber/art-20043983> [↑](#footnote-ref-12)