



By Electronic Submission

October 23, 2025

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

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

Dear Sir or Madam,

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) and the U.S. Department of Agriculture's (USDA's) Request for Information on Ultra-Processed Foods (UPFs). As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

FMI and our members share the important role of protecting and improving the health of all Americans. The food industry has always played an important role in supporting food safety and consumer health, and will continue to provide broad access to safe, affordable and nutritious food and beverage choices.

FMI and our members share the Agencies' goal of reducing diet-related chronic disease and are committed to ensuring that consumers have ample options to promote the development of a healthy overall dietary pattern. However, as noted in the RFI, concerns have been raised about the full ability of "UPF" classification systems to accurately capture the characteristics of processed foods and evaluate any health impacts. We welcome the opportunity to comment on the RFI and discuss some of these concerns in greater detail.

It is widely noted in the scientific community and recognized by the FDA and USDA that there is no universally accepted definition of "ultra-processed foods," and current "UPF" classification systems vary significantly and have limitations. An overly inclusive definition of "UPFs" could discourage intake of potentially beneficial foods, cause confusion for consumers, and ultimately undermine the intended goal of improving public health. It is paramount that any efforts around nutrition education and research, including any development of a food classification system, should be precise, grounded in science, and focused on helping Americans develop a healthy dietary pattern that suits their needs, lifestyles, and dietary preferences.

As we will discuss further in our comments, the concept of "ultra-processed foods" is not sufficiently "ripe" from a scientific standpoint to serve as the basis for regulatory classification. This RFI serves as a critical first step in collecting the multidisciplinary insights necessary to comprehensively evaluate the impacts of a classification system.



General Considerations

1. Nutrient density is a more important metric than the type or level of processing.

With a global food supply and consumer demand for a wide variety of foods, flavors and convenience, there are many examples of processed foods that are highly nutritious, helping individuals to meet specific nutrient and dietary needs. The nutritional quality of foods should be paramount when providing guidance for consumers. Not all processed foods are nutritionally poor, and not all nutritionally poor foods are processed. Characterizing foods based on their level or method of processing could result in nutrient-dense foods being characterized as “UPFs” and subsequently have the unintended consequence of discouraging such foods. Instead, the focus of any definition or classification system that informs food policy should be the nutritional contributions of a final food product to an overall healthy dietary pattern.

In addition to the overall nutrient contribution of processed foods, many processed foods meet special dietary and/or medical needs and should not be limited or mischaracterized for consumers who rely on these products:

- Plant-based milks for individuals with cow’s milk allergy
- Plant-based meat alternatives for those who do not consume animal products
- Gluten-free items for those with celiac disease and/or gluten allergy or non-celiac gluten sensitivity
- Nutritional supplement beverages
- Protein bars and drinks
- Energy supplements for athletes
- Hydration beverages

2. Food Processing is essential for food safety, food security and nutrition security.

Food processing is necessary for safety, stability, sensory attributes, shelf life, nutrient availability, convenience and flavor. We must embrace food processing as an essential step in ensuring our nation’s food supply continues to be safe, available, affordable and nutritious. Existing definitions of processing are in regulations promulgated under both FDA and USDA. There is recognition that processing is necessary for a safe and secure food system and a regulatory framework to provide for the safety, labeling and wholesomeness of food intended for consumption in the US.

The FDA definition of manufacturing/processing follows:

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type

*facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.*¹

The USDA definition of processed foods follows:

*Processed food item means a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or that has been combined with at least one other covered commodity or other substantive food component (e.g., chocolate, breading, tomato sauce), except that the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption, would not in itself result in a processed food item. Specific processing that results in a change in the character of the covered commodity includes cooking (e.g., frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g., salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g., emulsifying and extruding). Examples of items excluded include roasted peanuts, breaded chicken tenders, and fruit medley.*²

USDA also has a policy for specific labeling terms and the term “natural” is defined as:

*A product containing no artificial ingredient or added color and is only minimally processed. Minimal processing means that the product was processed in a manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term natural (such as “no artificial ingredients; minimally processed”).*³

These definitions in the *Code of Federal Regulations* and policy documents demonstrate the long-term use and application of food processing to support a modern food system.

3. Nutrition education should be widely available and delivered with clear, actionable, and consistent science-based guidance.

The basic components of a healthy diet are generally understood by consumers, but do not always serve as the foundation for their dietary patterns. This demonstrates clear differences between awareness, intention, and action, all of which are important when considering potential classification systems based on processing. We address below more specific considerations that we believe will help the Agencies evaluate potential classification systems and their impact on consumer understanding.

Avoiding consumer confusion must be a priority of the Agencies. Prior to initiating any effort to define “ultra-processed foods,” it is essential for the Agencies to evaluate how a definition would be used in conjunction with existing nutrition labeling, dietary guidelines, nutrient content claims, health claims, structure/function claims, definitions such as “healthy” and other existing federal laws and regulations designed to provide consumers with information to select foods that meet their individual health needs. Confusing or contradictory messaging can be damaging to consumers, especially at-risk communities, and could result in unintended consequences. Any guidance, policy and recommendations should be science-based and encourage consumption of

¹ 21 CFR 117.3

² 7 CFR 65.220

³ USDA. (2024). *Meat and Poultry Labeling Terms*. <https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/meat-and-poultry-labeling-terms>.

healthy diets rather than shaming or warning consumers to avoid specific ingredients, foods or food groups.⁴

It is important to clarify the purpose and desired outcomes as part of the RFI process. We encourage the Agencies to evaluate the intended scope and goals of such a system. We pose the following questions to consider as you begin the process of collecting information:

- What outcomes do the Agencies hope to achieve as a result of defining or categorizing processed foods?
 - Improved dietary patterns?
 - Reducing chronic conditions like obesity or cardiovascular disease?
 - Reduction in consumption of certain foods or nutrients (e.g., sodium, added sugar, etc.)?
 - Increasing food safety or availability?
- Is there evidence that suggests the desired outcome will be achieved by defining or classifying food processing?
- Will the focus be solely on packaged foods or will all foods be considered?
- Are the Agencies evaluating foods or ingredients in foods?

Food classifications should be objective and grounded in sound science. The Agencies should consider the impacts of processing in terms of food accessibility, availability and affordability for all consumers in all communities. Systems that are broad and oversimplistic could imply that foods are inherently harmful without a scientific basis for this implication.

Finally, the Agencies must evaluate and consider how consumers interpret any intended messaging provided by FDA and USDA.

4. The Term “Ultra-Processed Food” is Not Suitable for a Definition for Policy Purposes

As an initial matter, as mentioned above, the concept of “ultra-processed foods” is not sufficiently “ripe” from a scientific standpoint to serve as the basis for a regulatory classification or for use in policymaking. In the Request for Information, the Agencies state that a uniform definition of “UPFs” will allow for consistency in research and policy, but we contend that scientific consensus in the space should be the key driver for any regulatory definition.⁵ There is a critical lack of scientific consensus on the biological mechanism connecting food’s processing or formulation and potential health outcomes, and the science in this space is continuing to evolve every day.⁶ Proposed processing- and formulation-based classification systems continue

⁴ Dietary Guidelines for Americans. (2025). *Dietary Guidelines for Americans, 2020-2025*.
<https://www.dietaryguidelines.gov/resources/2020-2025-dietary-guidelines-online-materials>.

⁵ 90 Fed. Reg. 35305, 35307 (July 25, 2025).

⁶ See, e.g., Whelan, K., Bancil, A.S., Lindsay, J.O. *et al.* Ultra-processed foods and food additives in gut health and disease. *Nat Rev Gastroenterol Hepatol* 21, 406–427 (2024) (“A causal role of food processing on disease risk is challenging to identify as the body of evidence, although large, is almost entirely from observational cohorts or case-control studies, many of which measured UPF exposure using dietary methodologies not validated for this purpose (continued...)”).

to be the source of scientific debate, with experts identifying fundamental weaknesses in proposed schemes including internal inconsistencies and, crucially, the lack of any established causal link between a food's processing or formulation and potential health outcomes, independent of other key factors such as nutrient content.⁷ Such deficiencies illustrate that a regulatory or policy definition is premature. In sum, FDA and USDA should let the science inform a regulatory or policy definition – not the other way around.

The development of any definition should be done through notice-and-comment rulemaking, consistent with the Administrative Procedure Act. As the Agencies are aware, defining “UPFs” would have a large impact on the food and beverage industry and could steer regulatory activity in other jurisdictions. Accordingly, it is appropriate for any regulatory definition to be developed through notice-and-comment rulemaking so that all interested parties can formally submit comments for the Agencies' review.

Finally, any Agency efforts in this space must be tailored in a way that aligns with existing regulations and policies, including, for example, the Dietary Guidelines for Americans, FDA's “healthy” nutrient content claim definition, FDA's requirements for authorized and qualified health claims (which recognize a relationship between substances in a food and reduced risk of certain chronic diseases), and the Food Safety and Inspection Service's “natural” claims policy, which recognizes numerous packaged foods as “minimally processed” as part of confirming eligibility for a natural claim. Any potential regulatory definition for “ultra-processed foods” must fit within these frameworks to avoid conflicting regulatory requirements and confusing guidance for consumers.

and few were adjusted for the known dietary risk factors for those diseases.”); *see also, e.g.*, Poti JM, Braga B, Qin B. Ultra-processed Food Intake and Obesity: What Really Matters for Health-Processing or Nutrient Content? *Curr Obes Rep.* 2017 Dec;6(4):420-431 (“Little research has examined whether ultra-processed foods have effects on health independent of their nutrient content.”).

⁷ *See, e.g.*, Visioli F, Marangoni F, Fogliano V, et al. The ultra-processed foods hypothesis: a product processed well beyond the basic ingredients in the package. *Nutrition Research Reviews.* 2023;36(2):340-350 (“We contend that the NOVA system suffers from a lack of biological plausibility so the assertion that ultra-processed foods are intrinsically unhealthful is largely unproven, and needs further examination and elaboration.”); *See also, e.g.*, *See, e.g.*, Astrup, C A Monteiro, Does the concept of “ultra-processed foods” help inform dietary guidelines, beyond conventional classification systems? *NO, The American Journal of Clinical Nutrition*, Volume 116, Issue 6, 2022, Pages 1482-1488, ISSN 0002-9165 (“[Hall et al. (2019)], however, cannot be taken as evidence that shows that a UPF-based diet causes long-term weight gain and obesity, and even the observed short-term effect can be explained by differences in energy density and qualitative aspects of macronutrients, including added sugar and dietary fiber composition . . . Accordingly, the results of that RCT cannot be taken as evidence for an independent effect of UPFs on obesity beyond those of previously recognized dietary risk factors. Instead, these data suggest that the main differences between UPFs and non-UPFs can be understood through conventional dietary metrics.”); *See also, e.g.*, Michael J Gibney, Ciarán G Forde, Deirdre Mullally, Eileen R Gibney, Ultra-processed foods in human health: a critical appraisal, *The American Journal of Clinical Nutrition*, Volume 106, Issue 3, 2017, Pages 717-724, ISSN 0002-9165 (“On balance . . . there seems to be little advantage from the use of the NOVA classification compared with the current epidemiologic approach, which relies on the linkage of nutrient intakes to chronic disease with subsequent identification of foods that merit consideration in public health nutrition strategies.”).

Responses to Questions Posed by FDA and USDA

- 1. What, if any, existing classification systems or policies should we consider in defining UPPs? 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.**

As mentioned above, we do not think the concept of “UPFs” is sufficiently ripe from a scientific standpoint to serve as the basis for regulatory classification of foods. However, we recognize that numerous food classification systems have been developed in recent years. These food classification systems lack consistency and raise significant questions regarding utility and scientific basis. Should FDA and USDA consider developing such a food classification system, such as defining “UPFs”, there are a number of important principles the Agencies should consider.⁸

Frameworks for the classification of foods based on processing

There are several frameworks and evaluations on the development of criteria for classification systems for food processing.

First, the Institute for the Advancement of Food and Nutrition Sciences (IAFNS) has developed principles for food classification systems through the work of scientific experts. These principles are designed to assist researchers and policy makers in considering the science of processing and formulation of foods, as well as the impact on health.⁹

Second, the International Union of Food Science and Technology (IUFOST) through the Task Force on Food Processing for Nutrition, Diet and Health, developed an approach known as the IUFOST Formulation and Processing Classification scheme.¹⁰ This approach emphasized the separation and quantification of formulation and processing impact on variables included in the report. Additionally, the Task Force documented the primary properties that are relevant to consumers as safety, sustainability, palatability, convenience and affordability. Nutritional value of end products is considered in the approach.

We recommend that these frameworks be considered by FDA and USDA as you work through the process of determining if classification based on processing is appropriate and the scientific evaluation of existing and future systems.

⁸ Trumbo, P. R., Bleiweiss-Sande, R., Campbell, J. K., Decker, E., Drewnowski, A., Erdman, J. W., et al. (2024). Toward a science-based classification of processed foods to support meaningful research and effective health policies. *Frontiers in Nutrition*, 11. <https://doi.org/10.3389/fnut.2024.1389601>.

⁹ The Institute for the Advancement of Food and Nutrition Sciences. (2021). *Principles for Food Classification Focused on Processing and Formulation in Support of Public Health*. <https://iafns.org/food-classification-principles/>.

¹⁰ Ahrné, L., Chen, H., Henry, C. J., Kim, H. S., Schneeman, B., & Windhab, E. J. (2025). Defining the role of processing in food classification systems—the IUFOST formulation & processing approach. *npj Science of Food* 9(1), 56. <https://doi.org/10.1038/s41538-025-00395-x>.

Limitations exist within current classification systems used in science research

Multiple scientific papers have evaluated classification systems for food processing and noted a lack of evidence and scientific consensus in such systems. There are limitations to all existing systems that have been evaluated in the scientific literature, and all lack the consistency needed for rigorous comparative analysis, making research complicated and unreliable. More research is needed to evaluate the foundational elements in the systems, impact on consumer behavior and the potential unintentional consequences of classification systems.

Additionally, there have been multiple studies published on evaluating classification systems, comparisons between such systems and trying to evaluate public health outcomes of existing systems.¹¹ Multiple references are listed at the conclusion of this comment letter as an appendix.

Independent expert panels convened globally have found limitations in existing classification systems and have not implemented recommendations based on processing level of foods. Examples include the Nordic Council¹², the United Kingdom Scientific Advisory Committee on Nutrition (SACN)¹³, the French Agency for Food, Environmental and Occupational Health and Safety¹⁴, and the US Dietary Guidelines for Americans Advisory Committee.¹⁵

The most commonly researched food processing classification system and perhaps the first such system was NOVA, which was developed over 15 years ago by a group of researchers in Brazil.¹⁶ While NOVA has become the most recognized and cited classification system, NOVA has significant drawbacks in that it does not contemplate the nutritional quality of the food items classified. NOVA describes four discrete categories of food depending on the amount of processing. Foods are assigned to groups based on the type of processing and the location of production, private home vs commercial facility, which has no impact on the nutritional quality of the food. It is also difficult to determine these factors and accurately assign a product to the correct group when conducting research. We work through an example below of how one specific food, chickpeas, would be classified under NOVA.

¹¹ Medin, A. C., Gulowsen, S. R., Grouth-Jacobsen, S., Berget, I., Grini, I. S., & Varela, P. (2025). Definitions of ultra-processed foods beyond NOVA: a systematic review and evaluation. *Food & Nutrition Research*, 69. <https://doi.org/10.29219/fnr.v69.12217>.

¹² Nordic Nutrition Recommendations. (2023). *Ultra-processed foods (UPFs)*. <https://pub.norden.org/nord2023-003/ultra-processed-foods.html>.

¹³ Science Advisory Committee on Nutrition. (2025). *Independent report: Processed foods and health: SACN's rapid evidence update summary*. <https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update/processed-foods-and-health-sacns-rapid-evidence-update-summary>.

¹⁴ The French Agency for Food, Environmental and Occupational Health & Safety (ANSES). (2024). *Opinion of the French Agency on Food, Environmental and Occupational Health and Safety on Characterising and Assessing the Health Impacts on Consuming "Ultra Processed" Foods*. <https://www.anses.fr/sites/default/files/NUT2022-SA-0155-EN.pdf>.

¹⁵ Dietary Guidelines for Americans. (2025). *Scientific Report of the 2025 Dietary Guidelines Advisory Committee*. <https://www.dietaryguidelines.gov/2025-advisory-committee-report>.

¹⁶ Monteiro, C. A., Levy, R. B., Claro, R. M., Castro, I. R. R. D., & Cannon, G. (2010). A new classification of foods based on the extent and purpose of their processing. *Cad Saude Publica*, 26(11), 2039-49. <https://doi.org/10.1590/S0102-311X2010001100005>.

NOVA Category	Description	Example of a food
Group 1	Whole and minimally processed: foods in their natural state, altered to remove inedible parts, or processed minimally, such as drying	Dried chickpeas
Group 2	Processed culinary ingredients: ingredients typically added to other foods, such as oils, sugar and salt	Dried cooked chickpeas, Hummus made from dried chickpeas with added salt and oil as ingredients
Group 3	Processed foods: food products that usually retain the basic constituents of a whole or minimally processed food, plus at least one processed culinary ingredient	Canned chickpeas with salt and oil
Group 4	Ultra-processed foods: foods with ingredients created by industrial techniques beyond those described in the other three Nova categories	Commercially processed hummus, Chickpea chips

In addition to the information provided in the table, an example can illustrate the possible confusion that would come from such a classification system. If hummus is made at a food processing facility, it would classify as NOVA Group 4. If one makes hummus from the same ingredients at home, it would classify as NOVA Group 2. Yet, there could be no detectible difference in the nutritional benefit provided by the two different products.

There are notable limitations with the use of the NOVA criteria, and we are concerned about unintended confusion and avoidance of foods that can be a part of a healthy dietary pattern. Significant inconsistencies are documented in research with the use of the NOVA definition. Existing studies examine a mix of processed foods with high and low nutritional quality. It is very difficult to talk about health outcomes when nutritional quality is not included as a parameter. It is also very difficult to compare and/or combine research studies with variations of the NOVA definition, which is most often applied retroactively. Inconsistencies make drawing conclusions about the health effects of “UPFs” very difficult, as noted even amongst top nutrition researchers.

Current research does not definitively indicate whether consumption of “UPFs” is the cause of negative health outcomes or just a correlation. Research is needed to identify and clarify if any harmful health outcomes arise from foods with a higher degree of processing or are attributed to diets lacking essential micro and macro nutrients and nutrient-dense foods. Multiple studies cite the need to differentiate variables. There is a growing range of processed foods available, and some products are a positive addition to an overall healthy diet and are a source of beneficial nutrients.

We do not believe there are any systems currently available that are appropriate for classification based on processing.

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.

2(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.

2(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?

Further, ingredients that function as flavorings are either natural flavors or artificial flavors; colorings are either certified (for instance, “FD&C Red No. 40”) or non-certified (for instance, “colored with beet juice”) (21 CFR 101.22).

Should these various types of flavors and colors be considered separately when characterizing a food as ultra-processed? Please provide supporting data and explain your rationale in your response.

2(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.

2(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.

No single ingredient or category of ingredients should be used to determine if a food is “ultra-processed.” Formulation and processing are very different and should not be conflated, although there tends to be confusion between the two.¹⁷

Food is comprised of one or more ingredients and processing is the method in which the food is produced. It is important to distinguish between the two.

The examples provided in Question 2 of the RFI primarily address formulation and not processing. The inclusion of any specific ingredient or category of ingredients should not be a sole or overriding factor in the determination to characterize a food as “ultra-processed.”

¹⁷ Ahrné, L., Chen, H., Henry, C. J., Kim, H.S., Schneeman, B., & Windhab, E.J. (2025). Defining the role of processing in food classification systems—the IUFoST formulation & processing approach. *npj Science of Food*, 9(1), 56. <https://doi.org/10.1038/s41538-025-00395-x>.

Ingredients (including food additives) are intentionally added to food to serve a particular functional effect. Functions of ingredients vary significantly and might be used to acidify, stabilize, emulsify or to enrich products or fortify products (e.g., folic acid, vitamin D, and iodine), to name a few. In other instances, the use of certain ingredients is prescribed by FDA and USDA standards of identity. As required by the Food Drug and Cosmetic Act, the safety of these ingredients must be established through regulation or other specified mechanisms. Safety analysis includes a review of various information, such as composition, conditions of use, physical effects data, technical effects data, and results of safety studies, among others. To summarize, the safety of these ingredients for their intended use has already been established.

Additionally, FDA labeling regulations require that ingredients be accurately displayed on the label, meaning consumers already have transparency in this regard.

Making a determination based on the presence of an ingredient does not account for the role a product can play in a healthy diet. The same ingredient can be a component of vastly different products that provide vastly different levels of nutrition and key nutrients. The overall nutritional attributes of a product should be the primary consideration when evaluating the healthfulness of a food. Focusing on individual components of a food does not capture the product's potential to be part of a healthy diet or contribute key nutrients.

(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.

3(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.

3(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.

3(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.

3(d). What, if any, other processing-related techniques should or should not be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.

There are not any food processing methods that should be used to characterize a food as “ultra processed.” Food processing is utilized for many reasons including, but not limited to, safety, shelf life, palatability, taste, convenience (frozen or fresh cut vegetables), and nutrient availability. Companies use a variety of processing methods to increase choices available to consumers, and to provide products that fit within their nutritional needs, personal tastes, and lifestyle constraints. Processing allows foods that would otherwise not be available in certain regions to be consumed year-round. Food processing is used to significantly increase the shelf life of a food and is often necessary to make certain raw ingredients edible, palatable, or digestible. Similar to the use of food ingredients, processing methods are used intentionally by companies to produce products that meet consumer needs for a variety of reasons.

Historically, many common foods have utilized processing and/or exist solely because of processing. Looking back in history, there are many common foods that utilize processing. One such example is whole grains. Grains are not edible in the plant form and require milling to separate the edible and inedible portions. The process of milling can be complex and historical evidence of flour milling dates back thousands of years. Cheese is another example of a common, processed food with historical roots. Cheese production can use physical, biological, and chemical processing methods as outlined in the question posed by the Agencies and these processes may be required by Standards of Identity – making processing inherent to the nature of the food. Other examples of foods that are required to be processed are yogurts and fermented foods such as kimchi. These foods go through multiple process steps, look different than the original food, and often maintain or build nutrients as they are processed.

In addition to historically established methods of processing and common staple foods, innovative categories of products designed to meet unique needs have been created using various processing techniques. Examples include:

- Specialized Medical or Clinical Foods: Medical or clinical needs for specialized foods should be considered outside the scope of any food classification system contemplated. Clinical settings such as hospitals or nursing homes frequently serve specialized and processed foods to individuals with acute medical conditions. Thickened liquids, pureed diets, general or specialized nutrition supplements, diets for individuals with metabolic disorders are all very common dietary modifications in clinical settings. Labeling that characterizes these products as unhealthy and deters their use will create patient harm.
- Alternative products to accommodate allergies and other dietary needs: For example, production of milk for lactose intolerant individuals consists of several processing steps including enzymatic processing (lactase) and possibly filtration to remove remaining lactose, in addition to pasteurization (thermal treatment) that is used in most milk products. Plant-based milk alternatives can provide options for individuals with food allergies or intolerances. Without the enhanced palatability provided by processing, these foods would not be viable alternatives. Another example is the use of non-nutritive sweeteners which can be very important to making nutritionally dense foods palatable while helping consumers reduce their added sugar intake.

- Infant formula and follow up formulas: Infant formula, often the sole source of nutrition for babies in the first year of life, is recognized as the only safe alternative for parents who cannot or elect not to breastfeed. Infant formulas must comply with strict regulatory requirements and are regulated as a critical food by FDA. Infant formulas are inherently complex to manufacture and rely on significant processing steps to meet nutritional needs and stringent regulatory requirements.

Follow-up formulas, or toddler nutritional drinks, are specially formulated to meet the nutritional needs of young children aged 12 to 36 months. These products are nutrient dense and can contribute to a diet as a young child, or toddler, transitions from infant formula or breastmilk to the family diet, helping to increase the consumption of nutrients that they may be lacking. They are formulated to help support nutrient gaps during a critical period of growth, including iron, calcium, vitamins and DHA, an omega-3 fatty acid, and contribute to healthy growth and development.

We encourage the Agencies to consider the value and necessity of processing in our food system in delivering key nutrients and creating products that consumers rely on to satisfy their nutritional needs. There are no processing methods that should, by default, classify a food as “ultra-processed.” Characterizing foods based on their level or method of processing could result in nutrient dense foods being characterized as “UPFs” and subsequently have the unintended consequence of discouraging such foods. Instead, the focus of any definition or classification system that informs food policy should be the nutritional contributions of a final food product to an overall healthy dietary pattern.

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.

For any terminology developed, the Agencies should conduct consumer surveys and research to evaluate how the terms or classification is perceived by consumers and how such a system might impact consumer understanding and behavior. Consumer understanding and behavior are both vital to ensuring Agency goals, once developed, can be met by any proposed classification system. We are aware that FDA and USDA are monitoring ongoing research on nutrition and other attributes relating to the health outcomes associated with consumption of “UPFs.” In early 2025, FDA announced a joint effort with NIH to answer questions such as how and why “UPFs” can affect health. This is important research, and we look forward to reviewing the literature when published.

As noted above, processing does not make a food healthy or unhealthy and it is important to ensure that any terminology used avoids vilifying nutrient rich foods. The impact of including sources of beneficial nutrients on overall health status should be emphasized rather than the effect of processing. Furthermore, more focus should be directed on the nutrient value of foods rather than the form. In most cases, processing is necessary to make a product consumable and can have a positive impact on overall nutrient availability. Consumer avoidance of foods based on level or method of processing could present nutritional challenges. Examples include lack of required vitamins and minerals (folic acid and B Vitamins) with the avoidance of fortified foods and an increased gap in identified nutrients of concern (fiber, potassium, calcium and Vitamin

D)¹⁸ with the avoidance of enriched foods and beverages. There is concern among food and nutrition professionals that a focus on “UPFs,” without clarifying evidence-based nutrition guidance, will unintentionally steer consumers away from otherwise nutritious choices that should be included in an overall healthy diet.

It is also important that Agencies consider how any proposed terminology will interact with consumer understanding of existing food labels. More specifically, existing food labeling regulations require information that alerts consumers to a number of food attributes, such as positive nutrients and nutrients to limit. Examples include the Nutrition Facts Label, ingredient statements, voluntary use of the “healthy” claim, nutrient content claims, and health claims, among others. Defining “ultra-processed” in a way that overlaps or conveys similar product information as compared to existing food labels would be duplicative and confusing to consumers.

For any terminology developed, consumer surveys and research should be done to evaluate how the terms or classification is perceived by consumers and how such a system might impact consumer preference and behavior.

5(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.
5(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.

The nutritional quality of foods should be paramount when providing guidance for consumers. Not all processed foods are nutritionally poor, and not all nutritionally poor foods are processed. Characterizing foods based on their level or method of processing could result in nutrient-dense foods being characterized as “UPFs” and subsequently have the unintended consequence of discouraging such foods. Instead, the focus of any definition or classification system that informs food policy should be the nutritional contributions of a final food product to an overall healthy dietary pattern.

FDA’s nutrition labeling regulations have been in existence for decades and require that ingredients and key nutritional attributes be declared on the Nutrition Facts Label. Authorized nutrient content claims must also be truthful and not misleading to consumers.

In light of FDA’s recent final rule defining the nutrient content claim “healthy,” it is important to avoid consumer confusion in the event a food qualifies as “healthy” but could fall within “UPF” categorization. As noted above, we recommend that the existing nutrition guidelines and labeling regulations be considered. Defining “ultra-processed” in a way that overlaps or conveys

¹⁸ Weaver, C.M., Dwyer, J., Fulgoni, V.L, King, J.C, Leveille, G.A, MacDonald, R.S, Ordovas, J., & Schnakenberg, D. (2014). Processed foods: contributions to nutrition. *The American Journal of Clinical Nutrition*, 99(6), 1525-1542. <https://doi.org/10.3945/ajcn.114.089284>.

similar product information as compared to existing food labels would be duplicative and confusing to consumers. Instead, we encourage the Agencies to consider food products holistically and in conjunction with existing regulations.

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?

FDA and USDA should clearly define their goals with regard to establishing a definition for “UPFs” and carefully evaluate existing programs with similar objectives. Over the past six decades, there have been numerous public health campaigns encouraging the consumption of healthy foods and providing dietary guidance for consumers. There are existing regulations providing consumers with access to transparent, consistent and accurate information on food labels for all packaged food products. There are numerous potential conflicts that could cause consumer confusion unless nutrition policies and programs are considered in unison (*e.g.*, the Nutrition Facts Label, ingredient statements, voluntary use of the “healthy” claim, nutrient content claims, and health claims, among others). We urge the Agencies to consider all nutrition policies and programs in tandem to avoid policies that might allow for contradictory labeling and cause consumer confusion.

Across the industry, our members are committed to protecting, supporting and improving the health of customers, employees and local communities. There are many industry-lead strategic programs to support public health goals and promote healthy eating, often developed and administered by in-house registered dietitians and nutritionists. Key messages include limiting consumption of foods with low nutritional quality as well as encouraging the consumption of fruits, vegetables, whole grains, dairy and protein sources that are nutrient rich and beneficial to overall health.^{19, 20}

A consumer-centric approach that encourages the inclusion of beneficial foods, particularly those associated with the lowest risk of obesity and chronic disease, such as fruits, vegetables, whole grains, fish, nuts, legumes, and yogurt has the potential to be more impactful in reducing chronic disease. The role of lifestyle choices should not be forgotten. In addition to healthy meal patterns, portion control, lifestyle choices and physical activity are major factors in avoiding chronic disease and supporting health.

¹⁹ FMI. (2024). *Report on Food Industry Contributions to Health & Well-being*.

²⁰ FMI. (2025). *Protecting and Improving the Health of America, 2025 Report on Food Industry Initiatives*.

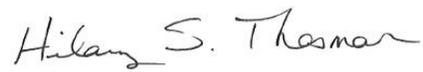
Summary

Food processing is essential to food accessibility, availability, safety, and security as well as nutrition security.

We encourage the Agencies to carefully evaluate goals as well as unintended consequences when determining if a definition or criteria for ultra-processed foods is appropriate or would be helpful beyond existing labeling information.

The primary question remains unanswered: what is the goal of classifying foods by processing, and how do we educate and motivate individuals to consume a diet that will support health based on evidence-based nutrition recommendations?

Sincerely,

A handwritten signature in cursive script that reads "Hilary S. Thesmar".

Hilary S. Thesmar, PhD, RD
Chief Science Officer

Appendix

Resources on Ultra-Processed Foods

Ahrné, L., Chen, H., Henry, C. J., Kim, H. S., Schneeman, B., & Windhab, E. J. (2025). Defining the role of processing in food classification systems—the IUFOST formulation & processing approach. *npj Science of Food*, 9(1), 56. <https://doi.org/10.1038/s41538-025-00395-x>.

Bernstein, J., Brown, A., Burton-Freeman, B., Estevez, M., Hess, J., Hubert, P., & Latulippe, M. (2025). Perspective: guiding principles for science-based food classification systems focused on processing and formulation. *Preprints*. <https://doi.org/10.20944/preprints202507.1896.v1>.

de Araújo, T.P., de Moraes, M.M., Afonso, C., Santos, C., & Rodrigues, S.S. (2022). Food processing: comparison of different food classification systems. *Nutrients*, 14(4), 729. <https://doi.org/10.3390/nu14040729>.

Eicher-Miller, H. A., Fulgoni III, V. L., & Keast, D.R. (2012). Contributions of processed foods to dietary intake in the us from 2003-2008: A report of the food and nutrition science solutions joint task force of the Academy of Nutrition and Dietetics, American Society for Nutrition, Institute of Food Technologists, and International Food Information Council. *The Journal of Nutrition*, 142(11), 2065S-2072S. <https://doi.org/10.3945/jn.112.164442>.

Eicher-Miller, H.A., Fulgoni, V.L., & Keast, D.R. (2015). Processed food contributions to energy and nutrient intake differ among US children by race/ethnicity. *Nutrients*, 7(12), 10076-10088. <https://doi.org/10.3390/nu7125503>.

Estévez, M. (2025). Special issue on ultra-processed foods. *Journal of Food Science*, 90(2), 0022-1147. <https://doi.org/10.1111/1750-3841.70052>.

Forde, C.G. (2023). Beyond ultra-processed: considering the future role of food processing in human health. *Proceedings of the Nutrition Society*, 82(3), 406-418. <https://doi.org/10.1017/S0029665123003014>.

Gibney, M.J. (2019). Ultra-processed foods: definitions and policy issues. *Current Developments in Nutrition*, 3(2), nzy077. <https://doi.org/10.1093/cdn/nzy077>.

Hess, J.M., Comeau, M.E., Casperson, S., Slavin, J.L., Johnson, G.H., Messina, M., Raatz, S., Scheett, A.J., Bodensteiner, A., & Palmer, D.G. (2023). Dietary guidelines meet NOVA: developing a menu for a healthy dietary pattern using ultra-processed foods. *The Journal of Nutrition*, 153(8), 2472-2481. <https://doi.org/10.1016/j.tjnut.2023.06.028>.

Juul, F., Vaidean, G., & Parekh, N. (2021). Ultra-processed foods and cardiovascular diseases: potential mechanisms of action. *Advances in Nutrition*, 12(5), 1673-1680. <https://doi.org/10.1093/advances/nmab049>.

Marino, M., Puppo, F., Del Bo', C., Vinelli, V., Riso, P., Porrini, M., & Martini, D. (2021). A systematic review of worldwide consumption of ultra-processed foods: findings and criticisms. *Nutrients*, 13(8), 2778. <https://doi.org/10.3390/nu13082778>.

Martinez-Perez, C., San-Cristobal, R., Guallar-Castillon, P., Martínez-González, M.Á., Salas-Salvadó, J., Corella, D., Castañer, O., Martinez, J.A., Alonso-Gómez, Á.M., Wärnberg, J., et al. (2021). Use of different food classification systems to assess the association between ultra-processed food consumption and cardiometabolic health in an elderly population with metabolic syndrome (PREDIMED-Plus Cohort). *Nutrients*, 13(7), 2471. <https://doi.org/10.3390/nu13072471>.

Medin, A.C., Gulowsen, S.R., Groufh-Jacobsen, S., Berget, I., Grini, I.S., & Varela, P. (2025). Definitions of ultra-processed foods beyond NOVA: a systematic review and evaluation. *Food & Nutrition Research*, 69. <https://doi.org/10.29219/fnr.v69.12217>.

Monteiro, C.A., Levy, R.B., Claro, R.M., Castro, I.R.R.D., & Cannon, G. (2010). A new classification of foods based on the extent and purpose of their processing. *Cadernos de saude publica*, 26(11), 2039-2049. <https://doi.org/10.1590/S0102-311X2010001100005>.

Poti, J.M., Braga, B., & Qin, B. (2017). Ultra-processed food intake and obesity: what really matters for health—processing or nutrient content?. *Current Obesity Reports*, 6(4), 420–431. <https://doi.org/10.1007/s13679-017-0285-4>.

Trumbo, P.R., Bleiweiss-Sande, R., Campbell, J.K., Decker, E., Drewnowski, A., Erdman, J.W., Ferruzzi, M.G., Forde, C.G., Gibney, M.J., Hess, J.M., Klurfeld, D.M., Latulippe, M.E., O’Conner, L.E., Reimers, K.J., Rolls, B.J., Schulz, J., Weaver, C., & Yu, L. (2024). Toward a science-based classification of processed foods to support meaningful research and effective health policies. *Frontiers in Nutrition*, 11, 1389601. <https://doi.org/10.3389/fnut.2024.1389601>.

Valicente, V.M., Peng, C.M., Pacheco, K.N., Lin, L., Kielb, E.I., Dawoodani, E., Abdollahi, A., & Mattes, R.D. (2023). Ultraprocessed foods and obesity risk: a critical review of reported mechanisms. *Advances in Nutrition*, 14(4), 718-738. <https://doi.org/10.1016/j.advnut.2023.04.006>.

Weaver, C.M, Dwyer, J., Fulgoni, V.L, King, J.C, Leveille G.A, MacDonald, R.S, Ordovas J., Schnakenberg, D. (2014) Processed foods: contributions to nutrition. *The American Journal of Clinical Nutrition*, 99(6), 1525-1542. <https://doi.org/10.3945/ajcn.114.089284>.

Zhang, Y., & Giovannucci, E. L. (2022). Ultra-processed foods and health: a comprehensive review. *Critical Reviews in Food Science and Nutrition*, 63(31), 10836–10848. <https://doi.org/10.1080/10408398.2022.2084359>

Expert Reports from Independent Bodies

Dietary Guidelines for Americans. (2025). *Scientific Report of the 2025 Dietary Guidelines Advisory Committee*. <https://www.dietaryguidelines.gov/2025-advisory-committee-report>.

Nordic Nutrition Recommendations. (2023). *Ultra-processed foods (UPFs)*. <https://pub.norden.org/nord2023-003/ultra-processed-foods.html>.

Science Advisory Committee on Nutrition. (2025). *Independent report: Processed foods and health: SACN's rapid evidence update summary*. <https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update/processed-foods-and-health-sacns-rapid-evidence-update-summary>.

The French Agency for Food, Environmental and Occupational Health & Safety. (2024). *Opinion of the French Agency on Food, Environmental and Occupational Health and Safety on Characterising and Assessing the Health Impacts on Consuming “Ultra Processed” Foods*. <https://www.anses.fr/sites/default/files/NUT2022-SA-0155-EN.pdf>.