

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

October 23, 2025

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

Dear Sir/Madam,

The undersigned members of the Food & Beverage Issue Alliance (FBIA) appreciate the opportunity to provide comments in response to the Food and Drug Administration's (FDA) and U.S. Department of Agriculture's (USDA) Request for Information (RFI) to develop a definition for "ultra-processed foods."

FBIA is comprised of forty-eight allied U.S. based food and beverage trade associations, representing various parts of the supply chain, from farmers and agricultural processors to manufacturers of packaged goods and retail establishments. FBIA, through collaboration with regulatory authorities, works to ensure that regulations and guidance are justified by verifiable, robust, peer reviewed, published science that is accessible through an open and transparent process.

The undersigned believe that defining the term "ultra-processed food" (UPF), or any similar term, is not supported by the existing scientific evidence or by a consensus in the scientific community and would distract from the primary determinant of healthfulness—the nutrient composition of foods in the context of the total diet. An evidence and science-based food classification system that seeks to define as broad a class of foods as implicated by a term that includes "processing," and which may have legally binding implications, cannot be usefully established without sufficient evidence and a scientific consensus on the approach. Accordingly, the Agencies should, prior to defining a classification system, prioritize research to inform the development of such an evidence and science-based food classification system.

The term "ultra-processed food" is not an accurate or appropriate term and risks villainizing processing, when in fact processing serves many beneficial purposes in ensuring a safe, nutritious, and abundant food supply. Given the unsettled state of the science and lack of consensus on classification systems for food products, it is premature for the Agencies to craft a term which can meaningfully be employed to improve the health of the American people.

The public policy implications are further exacerbated by the use of the term “ultra”—meaning extreme—designed to specifically identify certain processing techniques as excessive or improper, while conflating the production of food with the ingredients in that finished product. From this perspective, any “UPF” definition that incorporates specific ingredient content is misleading on its face. Further muddying the waters, undefined terms, such as “hyper palatability,” add to consumer and policy confusion by using language that is driven by advocacy and not the underlying science and available evidence.

Therefore, the undersigned do not support a definition of “UPF” and instead recommend that any effort for a science-based approach to food classification proceeds cautiously and is guided by principles developed by the Institute for the Advancement of Food and Nutrition Sciences (IAFNS). However, should the Agencies proceed with establishing a “UPF” definition, the undersigned respectfully urge that it be promulgated through the formal notice-and-comment rulemaking process, consistent with the Administrative Procedure Act (APA). Further, given the prospect of evolving research and understanding on the issue, the Agencies should incorporate a mechanism to permit the public to petition for revisions to the definition at any time, and for the timely review of any such petition by clearly defined standards. The undersigned respectfully submit the following comments.

1. The unsettled state of scientific research suggests that it is premature to establish a regulatory definition of “ultra-processed foods.”

Any regulatory definition of “UPF” or a related term must be useful to regulators and the public they serve by meaningfully distinguishing between foods based on variables that are of consequence to human health. The RFI recognizes as much and notes the importance of improving nutrition as a public health intervention to improve the health of Americans.

The undersigned share the Agencies’ laudable goals for the improvement of public health. However, a fundamental scientific and statistical principle is that causality cannot be inferred from association, and the scientific research on “UPF” has not established a causal link between the broad “UPF” terminology and health outcomes. The undersigned believe that current science indicates that nutrient composition is the primary determinant of the healthfulness and appropriateness of food in the diet and that, in many cases, processing techniques can improve the healthfulness and the safety of the food.

FDA’s announced plans to develop a partnership with NIH through the “NIH-FDA Nutrition Regulatory Science Program” is an acknowledgment of the need for more research in the field.¹

¹ FDA and NIH Announce Innovative Joint Nutrition Regulatory Science Program (May 9, 2025). <https://www.fda.gov/news-events/press-announcements/fda-and-nih-announce-innovative-joint-nutrition-regulatory-science-program>.

USDA has also acknowledged the unsettled state of the science and the need for additional research. For example, the Agency convened a two-day interdisciplinary panel in March 2023 to discuss the data gaps in the primarily observational studies conducted on “UPF” and to identify where more causal, mechanistic, and methodological research could advance the understanding of the associations between “UPF” and health outcomes.² Major themes of discussion during the panel and topics for further research were summarized in a research roadmap. The roadmap references the need for more research on foundational questions and issues, including a need to “improve objectivity in classifying foods as ‘ultra-processed’” and flagging as a research question whether outcomes associated with “UPF” intake are dependent on diet quality.³ The following year, USDA released a systemic review of “UPF” research,⁴ with the goal of determining whether there is a “relationship between consumption of dietary patterns with varying amounts of ‘ultra-processed foods’ and growth, body composition, and risk of obesity?” Its review encompassed five different sub-populations: (1) infants and young children up to 24 months, (2) children and adolescents, (3) adults and older adults, (4) individuals during pregnancy, and (5) individuals during postpartum. For three of the five groups (group #s 1, 4, and 5), the report concluded that there was insufficient evidence to draw any conclusion based on the reviewed evidence, while only associations based on “limited” grade evidence between “UPF” and adiposity and risk of being overweight could be drawn.

Conclusive answers to the fundamental questions regarding “UPF” remain uncertain, and there is a continued need for more research on correlations with healthfulness, a position which is widely shared by other organizations. For example, the UK’s Scientific Advisory Committee on Nutrition (SACN) recently published an update to an earlier position statement on processed foods and health which evaluated recent research on “UPF” and found that the available evidence “remains almost exclusively observational” and that methodological issues, including the failure to adjust for other variables like socioeconomic status, remain.⁵ Similarly, the French National Agency of Food Safety, Environment and Work (ANSES) recently concluded that in

² USDA, *Developing a Research Roadmap about Processed Foods, Food Processing, and Human Health in the Context of the US Food System*. <https://www.nal.usda.gov/research-tools/food-safety-research-projects/developing-research-roadmap-about-processed-foods-food-processing-and-human-health-context-us-food>.

³ O’Connor et al., *Perspective: A Research Roadmap about Ultra-Processed Foods and Human Health for the United States Food System: Proceedings from an Interdisciplinary, Multi-Stakeholder Workshop*, 14(6) *Perspective* P1255-1269, Figure 4 (Sept. 13, 2023). <https://advances.nutrition.org/article/S2161-8313%2823%2901378-9/fulltext>.

⁴ Stanford et al., *Dietary Patterns with Ultra-Processed Foods and Growth, Body Composition, and Risk of Obesity: A Systematic Review*, USDA Nutrition Evidence Systematic Review (Nov. 2024). <https://www.ncbi.nlm.nih.gov/books/NBK611035/>.

⁵ Processed foods and health: SACN’s rapid evidence update summary (Apr. 2, 2025). <https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update/processed-foods-and-health-sacns-rapid-evidence-update-summary>.

general it is too early to draw conclusions regarding “UPFs” and that more studies are required, as well as analysis of all risk factors including socio-economic, habits of consumptions, etc.⁶

A term and corresponding definition that is not carefully considered in consultation with experts in relevant disciplines risks undermining commonly understood definitions used in other fields and could result in terminology that is confusing at best, and misleading at worst, to consumers. A failure to ground any term and definition in current science would also encourage divergence of terms and definitions at the state level, which could further confuse and/or mislead consumers. The RFI’s summary of proposed state “UPF” laws demonstrates that there is a current risk of a state-by-state patchwork of regulation, which if enacted, will pose a significant challenge to industry and potentially create confusion for consumers.⁷

2. Any definition of “UPF” and/or related regulatory action requires notice and comment rulemaking.

The undersigned appreciate the Agencies’ request for public input through this RFI. The issues are complex, requiring information and expertise from many disciplines, including the food manufacturing industry, and information gathered from this process is likely to be helpful to the Agencies as they consider means to improve the nutrition and public health of the American population.

However, it remains unclear how any definition for “UPFs” developed from this information collection would be used by the U.S. Government. We respectfully request that the Agencies, in the interest of transparency and public policy, provide detailed information as to the ultimate use of such a definition, the authority under which it would be published, and an opportunity for public comment.

If the information collected in this RFI is intended to directly impact food and nutrition policy or leads to the promulgation of regulations adopting a food classification or a definition of “ultra-processed food” or some similar term, the Agencies should, and are legally required to, issue such binding regulations through notice and comment rulemaking. This follows from the Administrative Procedure Act’s (APA) notice and comment rulemaking requirements when issuing “legislative rules.”

A “rule” is defined in part as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or

⁶ Anses Opinion No. 2022-SA-0155 on the characterisation and assessment of the impact on health of the consumption of so-called ultra-processed foods. <https://www.anses.fr/fr/system/files/NUT2022-SA-0155.pdf>.

⁷ For example, some states such as Florida have proposed to define “UPFs” as those foods containing certain listed ingredients, other states such as California have proposed to define the term in part based on the presence of certain functional additives, and yet others such as Massachusetts have proposed to define the term by reference to certain processing steps.

policy . . .”⁸ Defining a food classification system, including the term “ultra-processed food” or any similar term, would be a “rule” because it would have immediate applicability to the food industry, as well as the public more generally, and would be intended to implement FDA’s authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and USDA’s authority under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), Egg Products Inspection Act (EPIA), and other applicable statutes. Furthermore, because any such rule would create an entirely new binding framework, it would have the “force and effect of law,” and therefore is appropriately considered legislative in nature.⁹

In summary, to the extent that developing a food classification framework is determined to be necessary, the Agencies are required to do so through notice and comment rulemaking procedures mandated by the APA for legislative rules. This is especially important in the present case due to the wide range of expertise and information that would be needed for such an endeavor, as well as the broad implications for public health and the food supply.

With respect to process, the Agencies should also carefully assess and balance the costs and benefits of any agency action. Indeed, this is particularly important if the Agencies’ proposals would require costly changes to labeling. As some Administration officials have made public statements referring to ultra-processed food labeling, in addition to the previous comments¹⁰ submitted on behalf of FBIA member organizations, the undersigned organizations submit that any front-of-pack label rule should evaluate whether the expected benefits outweigh the expected costs. FBIA and its member organizations commissioned a retrospective economic analysis on FDA’s 1993 series of rules requiring specified food nutrition labels.¹¹

In its analysis, FDA claimed the rule would reduce cases and premature deaths from cardiovascular disease and certain cancers, leading to very substantial benefits. In today’s dollars, FDA predicted the rule had a present value gain of \$7.9 billion, or an annualized benefit of nearly \$750 million at a seven percent discount rate.

The retrospective analysis found that there is no direct evidence that FDA’s 1993 food nutrition labeling rules produce the substantial health benefits FDA claimed at the time. Many researchers have concluded that labels alone are insufficient to change consumers’ behavior in the short-term and especially the longer-term necessary for health gains to occur. Even if there

⁸ 5 U.S.C. § 551.

⁹ U.S. Dep’t of Justice, Attorney General’s Manual on the Administrative Procedure Act 30 n.3 (1947).

¹⁰ Comment from Undersigned Members of the Food & Beverage Issue Alliance to Docket No. FDA-2024-N-2910 for “Food Labeling: Front-of-Package Nutrition Information.” <https://www.regulations.gov/comment/FDA-2024-N-2910-13112>.

¹¹ See Attached *Retrospective Evaluation of the U.S. Food and Drug Administration’s (FDA) Benefit-Cost Analysis (BCA) for the 1993 Final Nutrition Labeling Rule* (Apr. 2025).

are a small number of benefits to a few highly motivated individuals, these benefits are likely to be almost completely offset by consumers' costs that FDA did not acknowledge in 1993.

FDA continues to use this model with new data and with different claimed health benefits. However, FDA has failed to acknowledge that several links in its assumed causal relationship are broken or highly attenuated. Should an ultra-processed food label be considered, FDA should apply today's best available scientific information and revise its social benefit methodology.

3. Nutritional composition is the primary factor for determining the appropriateness of a food in the diet. Defining “ultra-processed foods” using terms and factors other than processing terms is misleading and misaligned.

The undersigned believe that the current science indicates that dietary healthfulness is primarily determined by the nutrition composition of that food. As discussed above, scientific research in the field is ongoing, and existing studies are inadequate to establish causal relationships of the breadth and scale implicated by the proposed terminology. The primacy of nutritional composition is supported by actions from both FDA and USDA, including the recently revised rule for using the term “healthy” on food labels, as well as the Dietary Guidelines for Americans.

Under the new “healthy” rule, use of the term “healthy” depends on (1) whether the food contains a specified amount of a “food group equivalent” and (2) the amount of added sugars, sodium, and saturated fat in the food.¹² The FDA's approach to the “healthy” rule reflects an appropriate, evidence based effort to constructively support the labeling and identification of foods in a manner that can help consumers identify healthful food choices. Processing and ingredients are not considered in this definition. The Dietary Guidelines for Americans are based on similar principles, emphasizing the need to consume nutrient-dense foods and beverages and limit added sugars, saturated fat, and sodium.¹³

The term “ultra-processed food” is used to describe foods with characteristics that are not based on processing, including the use of specific ingredients and combinations of ingredients. Untethered to the established meaning of processing, the term has been used to describe a wide variety of divergent foods and is used to invoke an emotional response rather than inform consumers about the healthfulness of a food. Any definition or food classification framework that is not based in science and on criteria that can be practically applied would create confusion and discourage innovation in food processing.

¹² 21 CFR § 101.65(d).

¹³ USDA, *Dietary Guidelines for Americans 2020-2025 Executive Summary*.

https://www.dietaryguidelines.gov/sites/default/files/2020-12/DGA_2020-2025_ExecutiveSummary_English.pdf.

4. Food processing serves beneficial purposes and is a key reason that the current safe and nutritious food supply exists.

Food processing serves many beneficial purposes, including increasing access to affordable food, improving food safety and nutrition, reducing food waste, and helping consumers navigate dietary preferences and intolerances.

a. Processed food contributes to affordability and accessibility.

Many Americans live in low-income areas with low access to food. According to USDA, approximately 18.8 million people (6.1 percent of the U.S. population) live in an area with limited access to a food store, based on a proximity measure of 1 mile for urban populations and 10 miles for rural populations.¹⁴ Lack of transportation and limited resources can also impact the availability of farm-fresh food. Processing—and the related supply chain—allow for the year-round availability of foods that would otherwise not be available, ranging from citrus products to coffee and other staples of the diet that are part of a complicated supply chain.

Many processed foods are affordable and convenient, save time, and when purchased with nutrition guidelines in mind, can be part of a healthy and balanced diet. FDA's efforts to improve the healthfulness of the food supply, including through the healthy rule, are important aids for consumers seeking healthy options. Processed foods meet consumers' real-world needs, and the convenience and time savings they offer are among the reasons people choose them.

b. Many foods are processed to improve safety.

Processing and the development of modern food safety systems and transportation infrastructure has allowed for not only the variety of foods available, but also the safe storage, distribution, and consistent availability of safe and nutritious food.

Drawing a line to determine the scope of “ultra” processes casts aside technological advances that are critical to health and safety. Municipal water processing can use technologies that include reverse-osmosis filtration, ultraviolet light, and ozone to ensure safe water. None of these technologies are “simple” or used in the home kitchen, but they are critical to providing one of the most basic and essential elements to life in a safe manner. Some, such as pasteurization, high pressure processing (HPP), and fermentation are key to preventing the growth of harmful microorganisms and are even required in some instances. For example, milk intended for human consumption and entering interstate commerce must be pasteurized, and juice must be processed to reduce foodborne pathogens, either through pasteurization or through other effective methods such as HPP. HPP involves using high pressures, with or

¹⁴ Rhone et al., *Low-Income and Low-Foodstore-Access Census Tracts, 2015-19*, USDA Economic Research Service at 14 (June 2022). <https://www.ers.usda.gov/publications/pub-details?pubid=104157>.

without the use of thermal energy, for a small exposure time.¹⁵ HPP can be used to ensure safe fruit juices and other foods without impacting bioactive compounds and aromas. These techniques are both highly effective at reducing pathogens and have a minimal effect on the nutritional and qualitative properties of the food. As a testament to the effectiveness of pasteurization, milk caused less than 1 percent of reported foodborne illness in 2015, down from approximately 25 percent in 1938, when pasteurization was less common.¹⁶ However, a recent trend of consuming raw milk has led to several outbreaks of *Salmonella*, *E. coli*, and *Campylobacter* infections.¹⁷ Processing can also eliminate other toxins, such as mycotoxins and metals through the polishing of grains.¹⁸

Additionally, as specific ingredients have been considered for inclusion in the definition of “UPFs,” it is important to point out that preservatives and antimicrobial ingredients play a critical role in maintaining shelf life and food safety in a range of food products. In addition to safety, many ingredients make nutritious and nutrient dense foods palatable to consumers, helping to provide taste and texture that encourage the consumption of nutritious food options.

c. Food processing can help reduce food waste.

Over one-third of the available food in the U.S. goes uneaten due to loss or waste, which amounted to approximately 133 billion pounds of food in 2010.¹⁹ Processing food and the use of ingredients or food additives with an intended function in the finished food can help to mitigate food waste by extending shelf life, encouraging consumption, and more efficiently using raw ingredients and whole plants. For example, freezing is a long-used natural physical process that has been optimized in commercial food processing system through technologies like high pressure freezing and Individual Quick Freezing (IQF), allowing for rapid freezing of food, thereby extending shelf-life, while also maintaining comparable nutrient levels in the frozen foods. Furthermore, processing allows for the beneficial use of agricultural byproducts to produce food for humans and animals.

¹⁵ Roji Waghmare, *High pressure processing of fruit beverages: A recent trend*, 2 Food and Humanity 100232 (May 2024). <https://www.sciencedirect.com/science/article/abs/pii/S2949824424000077>.

¹⁶ John A. Lucey, *Raw Milk Consumption: Risks and Benefits*, 50(4) Nutr. Today 189-193 (June 27, 2015). <https://pmc.ncbi.nlm.nih.gov/articles/PMC4890836/>.

¹⁷ Weinstein et al., *Outbreak of Salmonella Typhimurium Infections Linked to Commercially Distributed Raw Milk – California and Four Other States, September 2023–March 2024*, 74(27) Weekly 433-438 (July 24, 2025). <https://www.cdc.gov/mmwr/volumes/74/wr/mm7427a1.htm>; Forrest Saunders, *‘It’s Crestfallen’: Experts alarmed by raw milk illnesses in Florida*, Fox 4 Southwest Florida (Aug. 6, 2025). <https://www.fox4now.com/news/state/21-people-in-florida-sick-after-consuming-raw-milk-including-6-children>.

¹⁸ Albuquerque et al., *Processed Food: Nutrition, Safety, and Public Health*, 19(24) Int. J. Environ. Res. Public Health 16410 (Dec. 7, 2022). <https://pmc.ncbi.nlm.nih.gov/articles/PMC9778909/>.

¹⁹ USDA, *Food Loss and Waste*. <https://www.usda.gov/food-loss-and-waste>.

d. Processed foods can be an important contribution to a healthy dietary pattern.

The extent to which a food is processed does not in and of itself accurately portray the contributions the food can make to an overall healthy dietary pattern. Processed foods can significantly contribute to daily micronutrient intakes, including dietary fiber, calcium, potassium, vitamin D, iron, folate, and vitamin B12.²⁰ The inclusion of nutrient-dense processed foods, as well as foods with reduced or low/no content of nutrients, can help consumers meet food guidance recommendations.

A range of fortified processed foods are critical sources of underconsumed nutrients, such as thiamin, folate, and iodine, calcium, potassium and vitamin D.²¹ FDA has recognized the importance of fortification of processed foods in its food additive regulations²² and standards of identity.²³ FDA's fortification policy ensures that nutrient additions are made in a rational way based on evidenced need in the US population. Fermentation can also help enhance the nutritional content of food by increasing bioavailable protein and B vitamins while reducing substances such as phytates and tannins.²⁴ Interesterification has played a key role in reducing the consumption of trans fatty acids across America and the globe. In fact, the World Health Organization (WHO), which is driving a global campaign to eliminate partially hydrogenated oils (PHOs) from the food supply, has identified the use of interesterification as one of the existing technical solutions for PHO replacement.²⁵ Furthermore, ultrafiltration has been used to increase protein content while decreasing sugars, including lactose in milk.²⁶

e. Processed foods can help consumers navigate personal dietary preferences and intolerances, as well as meet special dietary needs.

Many processed foods provide more choices for consumers with limited dietary options, such as food allergies and intolerances, religious preferences, or general dietary preferences. This

²⁰ Weaver et al., *Processed foods: contributions to nutrition*, 99(6) Am. J. Clin. Nutr. 1525-42 (June 2014). <https://pubmed.ncbi.nlm.nih.gov/24760975/>.

²¹ Estell et al., *Fortification of grain foods and NOVA: the potential for altered nutrient intakes while avoiding ultra-processed foods*, 61 European J. Nutr. 935 (Oct. 19, 2021). <https://pubmed.ncbi.nlm.nih.gov/34668030/>; Weaver et al., *Processed foods: contributions to nutrition*, 99(6) Am J Clin Nutr. 1525-42 (June 2014). <https://pubmed.ncbi.nlm.nih.gov/24760975/>.

²² See e.g., 21 CFR § 172.345 – Folic acid.

²³ See e.g., 21 CFR § 137.350 – Enriched Rice; 21 CFR § 137.165 – Enriched Flour.

²⁴ Institute of Food Technologists, *Food Science and Technology Solutions to Improve Food and Nutrition Security: Sustainable Production of Nutritious Foods Through Processing Technology*, at 16. [ift_spi_white-paper_processed-foods_1023.pdf](#).

²⁵ REPLACE trans fat: an action package to eliminate industrially produced trans-fatty acids. Module 2: Promote. How-to guide for determining the best replacement oils and interventions to promote their use. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO.

²⁶ Institute of Food Technologists, *Food Science and Technology Solutions to Improve Food and Nutrition Security: Sustainable Production of Nutritious Foods Through Processing Technology*, at 16. [ift_spi_white-paper_processed-foods_1023.pdf](#).

includes, among others, foods like gluten free options for consumers who have celiac disease, plant-based options or dairy milk that has been treated with lactase enzyme to make it tolerable by lactose-intolerant individuals, and alternative proteins. For those with special dietary needs that require specific medical foods or formulas, processed foods are often the best option to meet these needs.

5. IAFNS principles for generating processing and formulation-based food classification systems should be considered.

The development of terminology such as “UPF” should follow, not lead, the development of research to support evidence-based food classification systems. To the extent that the Agencies believe that the development of a food classification framework, including a definition of “UPF” or related terms, is warranted, the Agencies should do so cautiously and with consideration to the nine “principles for science-based food classification systems focused on processing and formulation” proposed by the Institute for the Advancement of Food and Nutrition Sciences (IAFNS). The IAFNS working group drafted the principles to address specific issues identified with the various existing food classification systems. Certain principles are expanded upon here.²⁷

A key component of the first principle—“documentation and definitions that allow for reproducibility, rigor, and transparency should be provided”—is that “definitions should be objective, measurable, and grounded in scientific consensus.” At present, the plain meaning of the term “ultra-processed food” addresses only the processing of the food, and yet, discussion of “UPF” is typically much broader and considers, for example, the addition of certain food ingredients (e.g., salt) and food additives with a technical function.

The undersigned respectfully note that the RFI requests information regarding the impact of the addition of ingredients on the characterization of a food as “ultra-processed” (*see* question 2). Although the addition of food ingredients and food additives with technical functions and their impacts on human health are relevant to the dialogue and research on food and nutrition policy, these aspects can be considered through FDA’s existing ingredient safety framework and its recently established post-market assessment program. FDA and USDA must be careful to use the terms as they are understood in the food science community, and other relevant disciplines, and to distinguish between the different concepts of processing (the manufacturing steps) and formulation (the composition of the finished food product). Most fundamentally, given the current state of the literature, it is unlikely that there exists sufficient consensus to establish a universal definition of “UPF.”

²⁷ A complete list of principles can be found at 9 Principles for Science-Based Food Classification Systems Focused on Processing and Formulation - IAFNS. <https://iafns.org/9-principles/>.

The third principle states that “associations without robust causal evidence should be considered preliminary.” Adherence to this principle requires further research to demonstrate causality. As noted above, current research is largely observational and is insufficient to establish causal relationships between characteristics attributed to “UPF” and negative health outcomes.

Adherence to the fourth and fifth IAFNS principles requires consideration of the impact of processing steps and formulation, respectively, “on final composition and structure of the food terms of a putative effect on a health-related endpoint.” These principles underscore the importance of not conflating food processing with food formulation. Also, food processing is complex and depends on many variables and the same types of processing can have multiple effects in the same food and different effects, or different degrees of effect, in different foods. FDA and USDA should account for the complexity of food manufacturing and potential data limitations and should be careful not to overgeneralize conclusions based on limited information which may not apply to all foods or manufacturing conditions.

6. Conclusion

Food processing is vital to the American food supply and can provide a wide range of benefits from increased safety and improved nutrition to convenience and affordability. Processed foods, when consumed with evidence-based dietary recommendations in mind, are part of a healthy and balanced diet. Current research does not support a shift away from dietary recommendations based on nutritional composition in the context of the total diet and any effort to develop a food classification system, including defining “ultra-processed foods” or any similar term, will be challenged by the complexity of food processing and formulation and the limitations of the current research. The term “ultra-processed food” is fundamentally flawed and conflates processing with formulation. Regulatory efforts in this area should proceed cautiously, with input from all stakeholders, consideration of expert advice, including the principles developed by IAFNS, and through the notice and comment procedures mandated by the APA.

The undersigned FBIA signatories respectfully submit the above comments and look forward to continued engagement with the Agencies on the issues.

Sincerely,

1. American Bakers Association
2. American Frozen Food Institute
3. American Peanut Shellers Association
4. The Association for Dressings & Sauces
5. Calorie Control Council

6. Corn Refiners Association
7. Edible Oil Producers Association
8. Enzyme Technical Association
9. Independent Bakers Association
10. International Dairy Foods Association
11. International Food Additives Council
12. National Pasta Association
13. National Seasoning Manufacturers Association
14. North American Millers' Association
15. Peanut and Tree Nut Processors Association
16. Refrigerated Foods Association
17. SNAC International
18. SNI Global