



October 23, 2025

Submitted via regulations.gov

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

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

Dear Sir or Madam,

The American Frozen Food Institute (AFFI) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) and U.S. Department of Agriculture's (USDA) joint Request for Information on Ultra-processed Foods. From manufacturers to distributors to suppliers and packagers, AFFI is proud to represent publicly traded and family-owned companies who help produce frozen foods and beverages for today's food service and retail marketplace and serve as economic pillars within their communities. Throughout the U.S., frozen food sales at retail reached \$85 billion in the last year, and the industry accounts for 670,000 U.S. jobs.

AFFI appreciates that FDA and USDA are interested in collecting data and evidence regarding so-called "ultra-processed foods" ("UPFs") and utilizing comments from stakeholders to better understand classification systems, needed research, and additional information to explore prior to a federal regulatory approach or definition. We recognize that this effort is intended to address concerns about how consumer food choices and dietary intake impact non-communicable diseases within the U.S. population. We agree with the agencies that a federal focus on improving nutrition is an important public health intervention to address diet-related disease and commend the agencies for their continued focus on supporting American consumers in making healthy dietary choices. As the trade association representing the frozen food industry, we share these public health goals and are committed to policies and programs that help consumers make food and dietary choices that best fit their family's needs while ensuring food options are nutritious and accessible. Frozen foods play a critical role in supporting healthy eating patterns by offering safe, affordable, and convenient access to a variety of nutrient-dense options, ranging from single-ingredient vegetables and fruits to complete, portion-controlled meals.

In past comments to the agencies and the Dietary Guidelines Advisory Committee, we have noted the complexity, inconsistency, and lack of processing focus as it

relates to the term “ultra-processed food” and research pertaining to “UPFs.”^{1, 2} Research seeking to understand the impact of food processing has unsuccessfully linked consumption of “UPFs” to a variety of health outcomes. These studies have largely been observational in design and the few randomized controlled trials that exist have limitations in sample size, generalizability, and comparative diet design, as reviewed below. Furthermore, the categorization methods used in this research have primarily focused on addition of ingredients and food formulation as a proxy for processing and the research has failed to identify and explore mechanisms for observed associations.

For these reasons, AFFI maintains that the lack of scientific agreement and evidence indicates that establishment of any regulatory definition to inform policy is premature and futile at this time. AFFI recommends that hypothesis-driven research on food processing and formulation should be guided by clearly defined, consensus objectives grounded in current nutrition and food-science evidence; use U.S.-relevant, measurable exposure definitions, and prioritize mechanistic and causal designs over purely associative analyses. In that vein, targeted federal investment in the research questions outlined in USDA’s Research Roadmap on “ultra-processed foods” and human health is appropriate.³ Until further mechanistic evidence is available, we recommend that policy and education continue to focus on nutrient density, which in contrast to processing-based models, represents a robust, evidence-based framework that has clear impact on health outcomes. We address these and other comments in more detail below. We have organized our comments by responding to the questions listed in the RFI. For ease of review, we first repeat the question in bold italics, followed by AFFI’s response.

AFFI Response to Request for Information Questions:

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?

As an initial matter, AFFI maintains that classifying foods based on the level of processing or presence of specific ingredients is an inappropriate approach to FDA’s and USDA’s ultimate public health goals because it oversimplifies the complex differences in foods that extend beyond just how the food was processed. Proposed

¹ American Frozen Food Institute. Comments on Docket No. HHS-OASH-2022-0021 September 28, 2023. Available at: https://downloads.regulations.gov/HHS-OASH-2022-0021-0532/attachment_1.pdf.

² American Frozen Food Institute. Comments on Docket No. HHS-OASH-2024-0017. February 10, 2025. Available at: https://downloads.regulations.gov/HHS-OASH-2024-0017-9043/attachment_1.pdf.

³ O’Connor L, Higgins K, Smiljanec K, 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. *Advances in Nutrition*. 2023; 14(6): 1255-1269.

processing or ingredient-based classification systems categorize foods in a way that often does not align with established dietary recommendations, and reliance on such proposed models would result in nutrition policy that is confusing and counterproductive to the overall goal of improving health outcomes for Americans. Accordingly, such classification systems should not inform a regulatory definition.

An evaluation of the existing classification systems that have been proposed globally demonstrates the significant challenges and disadvantages of classifying foods using a processing or ingredient-based scheme. We address some of the meaningful weaknesses of these classification systems in greater detail below.⁴

i. Processing and ingredient based classification systems are the subject of significant scientific debate and criticism.

First, and critically, processing and ingredient-based classification systems are the subject of significant debate, and the science behind these systems is far from settled. As will be discussed in greater detail below, researchers have identified significant flaws when evaluating and attempting to apply these classification systems. For example, researchers have conducted numerous studies in recent years to evaluate the proposed NOVA system, with published results highlighting concerns that range from the unwieldiness of the system to its “lack of biological plausibility” and scientific basis.^{5,6,7} For example, in a 2023 review of proposed processing-based classification systems, food, nutrition, and children’s health researchers concluded that “the NOVA system suffers from a lack of biological plausibility so the assertion that ultra-processed foods are intrinsically unhealthy is largely unproven, and needs

⁴ AFFI is aware of many proposed processing or ingredient based classification models that are of relevance to this Request for Information, including the EPIC and Siga models, but focus our discussion in these comments on the NOVA classification for two reasons. First, the NOVA system is the most widely cited proposed model of relevance to this inquiry. Second, the key aspects of the NOVA model are shared in other proposed systems, so a discussion of the NOVA model can apply to processing and ingredient based classification models more broadly. By way of background, the NOVA system was developed by Brazilian researchers in 2009 and categorizes foods and beverages into four groups. Group 1, unprocessed or minimally processed foods, includes edible parts of plants or animals as well as natural foods altered by processes such as removal of inedible parts, drying, crushing, grinding, fractioning, filtering, roasting, boiling, pasteurization, refrigeration, freezing, placing in containers, vacuum packaging, or non-alcoholic fermentation. Group 2, processed culinary ingredients, are substances obtained directly from Group 1 foods or from nature by processes such as pressing, refining, grinding, milling, and spray drying. Group 3, processed foods, are “relatively simple” products made by adding sugar, oil, salt, or other Group 2 substances to Group 1 foods, including by various preservation and cooking methods. Group 4, “ultra-processed food and drink products,” are defined as “industrial formulations” made up of several ingredients including sugar, oils, fats, and salt and food substances of no or rare culinary use, manufactured through the use of industrial processes such as extrusion, molding, and pre-processing for frying. See, Monteiro, Carlos & Cannon, Geoffrey & Levy, Renata & Moubarac, Jean-Claude & Jaime, Patricia & al, Ana. (2016). NOVA. The star shines bright. Position paper 2. World Nutrition. 7. 28-38.

⁵ See, e.g., Braesco V, Souchon I, Sauvant P, Haurigné T, Maillot M, Féart C, Darmon N. Ultra-processed foods: how functional is the NOVA system? Eur J Clin Nutr. 2022 Sep;76(9):1245-1253 (“These results suggest current NOVA criteria do not allow for robust and functional food assignments.”).

⁶ See, e.g., A 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 (“In conclusion, the Nova classification adds little to existing nutrient profiling systems; characterizes several healthy, nutrient-dense foods as unhealthy; and is counterproductive to solve the major global food production challenges.”).

⁷ See, e.g., Forde CG. Beyond ultra-processed: considering the future role of food processing in human health. *Proceedings of the Nutrition Society*. 2023;82(3):406-418 (“There is now a growing acceptance that the NOVA system is not fit for purpose if it is to be applied to guide public health strategies or provide population-level dietary guidance.”).

further examination and elaboration.”⁸ Similarly, in a 2017 article in the American Journal of Clinical Nutrition, researchers reviewing the NOVA system found that, “[o]n 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.”⁹

In sum, there is extensive published literature criticizing fundamental aspects of these classification systems, and this fact alone demonstrates that there has yet to be scientific consensus in this area and the adoption of any classification system or definition is premature and inappropriate at this time.

ii. Processing and ingredient-based classification systems are inconsistent and cannot be consistently interpreted or applied to distinguish between foods.

Critical analysis of processing and ingredient-based classification systems shows that such systems are internally inconsistent and difficult to apply, in part because they focus on narrow, subjective, and ambiguous criteria. Studies have shown that even nutrition specialists have a difficult time consistently distinguishing foods using these proposed classification systems. For example, Braesco et al. (2022) found that when nutrition specialists were tasked with assigning 231 different foods to one of the four NOVA groups, the results were so inconsistent that only 4 of the 231 foods were assigned to the same NOVA group by all of the evaluators, and most foods were assigned to two, three, or even four groups.¹⁰ In some instances, the same food was assigned to all four NOVA groups. The authors concluded that “overall consistency among evaluators was low, even when ingredient information was available,” suggesting that the proposed NOVA criteria “do not allow for robust and functional food assignments.”¹¹

NOVA also builds in arbitrary distinctions, such as distinctions between home cooking or canning processes and industrial food preparation involving these same processes, as well as distinctions based on the number of ingredients or the presence of a single ingredient in a food. For example, the researchers who developed the proposed NOVA system state that “common attributes of ultra-processed products are hyper-palatability, sophisticated and attractive packaging, multi-media and other aggressive marketing to children and adolescents, health claims, high profitability, and branding and ownership by transnational corporations,” characteristics that arbitrarily distinguish largescale food production from home cooking but bear no relationship to the nutritional quality of the food.¹² As another example, the researchers explain that “the practical way to identify if a product is ultra-processed

⁸ 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.

⁹ 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.

¹⁰ Braesco V, Souchon I, Sauviant P, Haurogné T, Maillot M, Féart C, Darmon N. Ultra-processed foods: how functional is the NOVA system? *Eur J Clin Nutr*. 2022 Sep;76(9):1245-1253 at 1247.

¹¹ *Id.* at 1245.

¹² Monteiro, Carlos & Cannon, Geoffrey & Levy, Renata & Moubarac, Jean-Claude & Jaime, Patricia & al, Ana. (2016). NOVA. The star shines bright. Position paper 2. *World Nutrition*. 7. 28-38 at 33.

is to check to see if its list of ingredients contains at least one item characteristic of the ultra-processed food group . . .”¹³ This suggests that the presence of a single ingredient would be sufficient to classify the food as “ultra-processed,” when there is no explanation proposed in the scientific literature for how the addition of a single ingredient on its own, particularly one authorized for use in foods in the U.S., could cause a food to be characterized as being linked to health concerns.

iii. Processing and ingredient-based classification systems ignore aspects of well-established nutrition science, such as nutrient density and portion size.

Processing and ingredient-based classification systems ignore two key characteristics of well-established nutrition science: nutrient composition, as well as other factors such as food group content and portion size. Nutrient density is an essential component of a healthy dietary pattern that has long been recognized as key drivers of health outcomes. In the Scientific Report of the 2025 Dietary Guidelines Advisory Committee, the committee highlights the importance of nutrient-dense food and beverage choices, stating “the importance of nutrient-dense food and beverage choices is underscored by the limited modifications or flexibilities that can be introduced without introducing nutritional gaps.”¹⁴ The 2020 – 2025 Dietary Guidelines for Americans (DGA) similarly highlights the importance of choosing nutrient-dense foods when building a healthy dietary pattern, and advises consumers to “pay attention to portion size.”¹⁵ Frozen foods support portion control through single serve meals and the ability to cook only what is needed with over half of consumers citing portion size as a reason for purchasing frozen foods.¹⁶

Neither nutrient density nor other important considerations like food group composition and portion size are accounted for in processing and ingredient-based classification schemes, rendering such systems substantially limited in their ability to adequately distinguish foods from a health outcome perspective.

iv. There is a critical lack of causal evidence linking processing or ingredients to any health-related outcomes.

Crucially, there has been no causal evidence in the scientific literature linking processing or the inclusion of certain ingredients to health-related outcomes. Studies alleging to link “ultra-processed foods” to negative health outcomes tend to be observational or non-intervention studies that are not designed or statistically powered to demonstrate a causal connection.

¹³ Monteiro CA, Cannon G, Levy RB, Moubarac JC, Louzada ML, Rauber F, Khandpur N, Cediel G, Neri D, Martinez-Steele E, Baraldi LG, Jaime PC. Ultra-processed foods: what they are and how to identify them. *Public Health Nutr.* 2019 Apr;22(5):936-941 at 938.

¹⁴ U.S. Department of Health and Human Services and U.S. Department of Agriculture, Scientific Report of the 2025 Dietary Guidelines Advisory Committee, https://www.dietaryguidelines.gov/sites/default/files/2024-12/Scientific_Report_of_the_2025_Dietary_Guidelines_Advisory_Committee_508c.pdf.

¹⁵ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th Edition. December 2020.

¹⁶ Cardello, H., Ferry L., Freedman H. 2024. The Power of Portions. *Georgetown University*. Available at <https://msb.georgetown.edu/wp-content/uploads/2024/03/POWER-OF-PORZIONIsdigital-1.pdf>

For example, Whelan et al. (2024) characterizes these limitations when the authors conclude, “[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 and few were adjusted for the known dietary risk factors for those diseases.”¹⁷ Similarly, Poti et al. (2017) highlighted that “[l]ittle research has examined whether ultra-processed foods have effects on health independent of their nutrient content” and that the wide variability in the nutrient content of “ultra-processed food” suggests that “processing itself may not be a causal determinant of the nutritional quality of foods.”¹⁸ Furthermore, the Dietary Guidelines Advisory Committee has characterized the evidence on “ultra-processed food” and bodyweight as “limited,” the lowest grade of scientific evidence.¹⁹

Clinical trials that have sought to identify a causal link between processing and health-related outcomes are significantly limited in both the conclusions they are designed to draw and their ultimate findings. For example, Hall et al. (2019) was a randomized clinical trial in which weight-stable adults were given either “ultra-processed” or “unprocessed” diets for 2 weeks, followed by the alternate diet for two weeks.²⁰ The authors concluded that “ultra-processed diets cause excessive calorie intake and weight gain,” but importantly noted that the study was not designed to identify the *cause* of the observed differences in energy intake, and “[m]any of the potential negative effects of ultra-processed foods have been hypothesized to relate to their elevated sugar, fat, and sodium content while being low in protein and fiber.” Other researchers have further identified fundamental limitations of the trial, including its short duration and its failure to adjust for the role of macronutrients and energy density in the findings.²¹ Similarly, in Hamano et al. (2024), the authors concluded that “consumption of UPFs causes significant weight gain,” but the study itself was an open-label, randomized, crossover study involving only 9 individuals, all of whom were overweight Japanese males, and the intervention period was only one week.²² Here, the authors themselves noted that “the long-term consequences of

¹⁷ Whelan, K., Bancel, 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).

¹⁸ 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.

¹⁹ U.S. Department of Health and Human Services and U.S. Department of Agriculture, Scientific Report of the 2025 Dietary Guidelines Advisory Committee, https://www.dietaryguidelines.gov/sites/default/files/2024-12/Scientific_Report_of_the_2025_Dietary_Guidelines_Advisory_Committee_508c.pdf.

²⁰ Hall KD, Ayuketah A, Brychta R, Cai H, Cassimatis T, Chen KY, Chung ST, Costa E, Courville A, Darcey V, Fletcher LA, Forde CG, Gharib AM, Guo J, Howard R, Joseph PV, McGehee S, Ouwerkerk R, Raisinger K, Rozga I, Stagliano M, Walter M, Walter PJ, Yang S, Zhou M. Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake. *Cell Metab*. 2019 Jul 2;30(1):67-77.e3. doi: 10.1016/j.cmet.2019.05.008. Epub 2019 May 16. Erratum in: *Cell Metab*. 2019 Jul 2;30(1):226.

²¹ 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 (“The study, 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.”)

²² Hamano, S., Sawada, M., Aihara, M., Sakurai, Y., Sekine, R., Usami, S., Kubota, N., & Yamauchi, T. (2024). Ultra-processed foods cause weight gain and increased energy intake associated with reduced chewing frequency:

consistent UPF consumption could not be elucidated.”²³ Dicken et al. (2025) further illustrates the centrality of nutrient targets and energy balance. In the eight-week feeding study, participants followed diets that met national dietary-guidance criteria but differed in “ultra-processed” versus minimally processed foods. Both diets produced weight loss and favorable shifts in cardiometabolic biomarkers, consistent with consensus that guideline-concordant, nutrient-dense patterns improve risk factors.²⁴ The minimally processed arm achieved greater weight reduction; however, participants on the ultra-processed arm consumed more total energy and the two diets were not matched for energy density.²⁵ Given the substantial evidence linking energy density and caloric intake to weight change, the between diet difference is more likely explained by higher energy intake, not by “processing” status. Taken together, these trials reinforce the policy point advanced in our comments: when nutrient composition, energy density, and portion size are held constant the incremental, processing-specific effect on outcomes is uncertain, whereas nutrient- and energy-focused levers have clear, reproducible impacts. In sum, we are not aware of any randomized, placebo-controlled intervention study that has identified a statistically significant causal connection between a food’s level of processing or formulation and negative health outcomes. The lack of rigorous, replicable science identifying this causal connection is a critical flaw in any system that seeks to classify a food’s value based on processing or ingredients.

- v. There is no unifying factor or biological mechanism of action that would suggest that the category of “ultra-processed foods” is linked to health risks.

Relatedly, scientists have yet to identify any unifying factor or biological mechanism of action that would suggest that the category of “ultra-processed foods” can be linked to negative health outcomes. Accordingly, it would be inappropriate to classify foods based on the level of processing, when there is no established science demonstrating that processing itself can plausibly impact human health.^{26,27}

For example, in Zhang & Giovannucci (2022), the authors suggest that the possible effects of nutrient displacement, factors that influence adiposity, and processing may contribute to the mechanisms underlying the associations between “ultra-processed

A randomized, open-label, crossover study. *Diabetes, Obesity and Metabolism*, 26(11), 5431–5443. <https://doi.org/10.1111/dom.15922>.

²³ *Id.*

²⁴ Dicken, S.J., Jassil, F.C., Brown, A. *et al.* Ultraprocessed or minimally processed diets following healthy dietary guidelines on weight and cardiometabolic health: a randomized, crossover trial. *Nat Med* (2025). <https://doi.org/10.1038/s41591-025-03842-0>.

²⁵ Dicken, S.J., Jassil, F.C., Brown A. *et al.* Supplementary information: Ultraprocedssed or minimally processed diets following healthy dietary guidelines on weight and cardiometabolic health: a randomized, crossover trial. *Nat Med* (2025). <https://doi.org/10.1038/s41591-025-03842-0>.

²⁶ See *id.* (“To establish causality, studies in humans should demonstrate plausible physiologic mechanisms using reliable proxy biomarkers for health risks, including RCTs as a critical level of evidence. UPF has been defined as ready-to-eat, industrial, highly palatable creations that cause passive overconsumption and obesity. Arguably, this effect is determined more by other food characteristics than by processing per se.”).

²⁷ See Forde CG. Beyond ultra-processed: considering the future role of food processing in human health. *Proceedings of the Nutrition Society*. 2023;82(3):406-418 (“There has also been criticism of the subjective nature of definitions used to differentiate foods by their degree of processing, and there is currently a lack of empirical data to support a clear mechanism by which highly processed foods promote greater energy intakes.”).

foods” and health outcomes, but ultimately conclude that “the uncertainties and complexities in putative mechanisms,” among other factors, “highlight the need for future high-quality epidemiologic and mechanistic investigations on this topic.”²⁸

In sum, the lack of a scientific consensus on the mechanism of action by which the level of processing of a specific food would contribute to negative health outcomes further demonstrates the shortcomings of any proposed classification system that distinguishes foods based on processing.

- vi. Classifying foods based on processing and/or ingredients alone ignores the critical role processing plays in delivering safe and accessible foods for Americans.

Finally, a focus on processing or ingredients as the key factors in characterizing a food’s health value fails to take into consideration the critical role processing plays in enabling Americans to build healthy dietary patterns in the first place. As will be discussed in further detail below, food processing helps ensure food safety, improves shelf-life, reduces food waste, and promotes the ability to conveniently and affordably incorporate healthful products into a busy lifestyle. In short, processing allows consumers to access nutrient-dense foods year-round at an appropriate price point. These important factors, which certainly contribute to overall health outcomes, are wholly excluded in proposed ingredient- and processing-based classification schemes.

2c. 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?

AFFI believes that the inclusion of or relative amount of any particular ingredient should not be used as criteria to classify foods or determine whether a food is characterized as “ultra-processed.” Ingredients added to food undergo extensive review by qualified food safety and toxicology experts and are supported with publicly available data through the Generally Recognized as Safe (GRAS) process or through FDA’s Food Additive Petition or Color Additive Petition processes.²⁹ These reviews explicitly consider exposure and intended levels of use, determine acceptable daily intake, and when approving an additive, may set maximum use levels or require manufacturers to limit use to the amount necessary to achieve the intended technical effect.

Where concerns emerge with specific ingredients already used in foods, FDA’s post-market assessment of authorized substances is designed to reassess certain ingredients when new information is made available or safety is questioned through petitions or notifications. This is the appropriate pathway for addressing specific

²⁸ Zhang Y, Giovannucci EL. Ultra-processed foods and health: a comprehensive review. *Crit Rev Food Sci Nutr*. 2022;63(31):10836-10848.

²⁹ Food and Drug Administration. 2025. *Food Chemical Safety*, available at: <https://www.fda.gov/food/food-ingredients-packaging/food-chemical-safety>.

ingredient concerns and thus characterizing a food as “ultra-processed” because it contains an allowed ingredient at an allowed amount would conflict with and undermine the risk-based regulatory system already in place. AFFI is concerned that a definition or classification scheme that relies on labeled ingredients rather than physiological relevance, would elevate a labeling convention into a health proxy, something existing regulations never intended. Furthermore, anchoring a definition of “ultra-processed foods” to ingredients that FDA already allows as safe for specified uses risks eroding consumer trust in FDA’s science and risk-based oversight. Credibility is better maintained by aligning any definitions or policy approaches with existing risk assessment and nutrient-density frameworks.

As mentioned throughout AFFI’s comments, federal nutrition policy has consistently oriented consumers toward nutrient content, food groups, and overall dietary patterns as focuses for dietary health.³⁰ The weight of science supports nutrient density and energy density as primary drivers of diet-related risk and noncommunicable disease outcomes. By contrast, scientific consensus has not been reached as it relates to broad ingredient categories, ingredient amount, or label order as indicators of level of processing or drivers of dietary health outcomes. Elevating ingredient inclusion or proportions as a determination of processing level or healthfulness would divert attention from the factors that most meaningfully influence dietary health and risks confusing consumers. Accordingly, AFFI recommends that federal policy continue to emphasize nutrient density, encouragement of under consumed food groups, and consideration of energy density as the most appropriate, science-based dietary health focus.

3a. 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?

AFFI appreciates the agencies’ interest in better understanding the role that processing plays across the food supply. Physical processing, including peeling, chopping, blending, shaping, cooking, or freezing, occurs along a continuum in both home kitchens and commercial facilities. These processing steps make foods safe to eat, preserve quality, improve palatability and convenience, and help consumers access balanced meals. When these established techniques are performed at scale in a regulated manufacturing environment, the underlying effect on the food is the same as when performed at home; scale alone does not transform routine physical processing into “ultra-processing.” It would be inappropriate and confusing to classify packaged foods as “ultra-processed” based solely on the presence of common, long-established physical processes that are equally used at home. Moreover, current

³⁰ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans*, 2020-2025.9th Edition. December 2020.

research frameworks exploring “ultra-processed foods” generally group foods into broad categories based on ingredients rather than analyzing specific processing steps. As such, existing evidence relies heavily on ingredient proxies, which do not isolate the independent effect of a particular physical process on diet quality or health outcomes. Policy decisions based on the use of physical processes risks mischaracterizing many safe, nutrient-dense foods that help Americans meet dietary recommendations.

Freezing is a long-standing and natural physical process that has been used for centuries to preserve food. By controlling temperature, time, and air flow, water naturally present in cellular structures transitions into ice, thereby immobilizing water and preventing reaction kinetics.³¹ This process preserves the food by inhibiting spoilage microorganism growth and enzymatic activities that would otherwise degrade nutrients and quality. Modern freezing technology, including high pressure freezing and Individual Quick Freezing (IQF), enables rapid cooling of water into ice and can freeze food products within minutes. Commercial freezing is a scientifically advanced process that optimizes product preparation, such as peeling, cutting, and/or blanching, temperature, rate of air flow or pressure, and time to control ice crystal formation. Smaller ice crystals better maintain cellular structure compared to the slow, large ice crystal formation typical of home freezing. Freezing performed in a manufacturing facility safeguards nutritional value, especially for water-soluble micronutrients, and maintains overall product quality.³² Research demonstrates that packaged frozen fruits and vegetables generally have the same micronutrient levels compared to their fresh equivalents and may even surpass them following extended refrigerated storage.^{33, 34} For instance, studies have shown that frozen produce frequently matches or exceeds fresh produce in levels of L-ascorbic acid (vitamin C), trans- β -carotene (a source of vitamin A), and folate.³⁵ Freezing also supports nutrient retention because it enables produce to be harvested at peak ripeness and preserved within hours, maintaining optimal nutrient levels and ensuring long-term access to high-quality foods.

Freezing also advances food-waste prevention. Households are the largest source of food waste in the U.S.³⁶ In both retail and household settings, research consistently shows lower waste rates for frozen versus fresh counterparts because freezing

³¹ Attrey, D.P. 2017. Safety and quality of frozen foods. *Food Safety in the 21st Century* (pp. 527–539). Academic Press.

³² Parreño, W and Torres, M. 2016. Quality and safety of frozen vegetables. *Handbook of Frozen Food Processing and Packaging*. (pp. 378 – 410). CRC Press.

³³ Bouzari A., Holstege D., Barrett D.M. 2014. Mineral, fiber, and total phenolic retention in eight fruits and vegetables: A comparison of refrigerated and frozen storage. *Journal of Agricultural and Food Chemistry*, 63(3): 951 – 956.

³⁴ Bouzari A., Holstege D., Barrett D.M. 2014. Vitamin retention in eight fruits and vegetables: A comparison of refrigerated and frozen storage. *Journal of Agricultural and Food Chemistry*, 63(3): 957 – 962.

³⁵ Li L., Pegg R., Eitenmiller R., Chun J., Kerrihard A. 2017. Analyses of fresh, fresh-stored, and frozen fruits and vegetables. *Journal of Food Composition and Analysis*, 59:8-17.

³⁶ ReFED. 2023. Food Waste Monitor Insights Engine. Available at: https://insights-engine.refed.org/food-waste-monitor?break_by=sector&indicator=tons-surplus&view=detail&year=2023

extends shelf life, supports balanced portions, and reduces spoilage.³⁷ For instance, U.S. survey data likewise find that purchasing frozen foods and home-freezing fresh items are associated with lower household food waste.³⁸ Furthermore, frozen foods are critical tools for federal nutrition programs, such as the National School Lunch Program, by helping minimize waste in food preparation, promote nutrient density and alignment with nutrition standards, and keep produce on menus year-round. Penalizing frozen categories via a processing label would run directly against federal waste reduction goals and negatively impact federal feeding programs, while offering no demonstrated health benefit.

Research proposing to classify foods as “ultra-processed” has primarily emphasized formulation, ingredient addition, and additive purpose, rather than focusing on physical processing operations. In contrast, freezing is unrelated to formulation, as nothing is added to freeze the food. Freezing is a unique preservation technique for both single- and multi-ingredient foods that preserves the intrinsic nature of the food while sustaining food safety, cell structure, nutrient levels, and food quality.

5a. 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?

If and until any proposed U.S. based processing classification system is supported by sufficient scientific evidence and agreement, federal food and nutrition regulations, guidance documents, and statements should remain anchored in nutrient density and food-group contributions, not formulation or ingredients as a proxy for processing level. Nutrient based approaches operationalize longstanding evidence and resources on limiting saturated fat, added sugars, and sodium while promoting under-consumed food groups and balanced energy intake. The 2020 – 2025 Dietary Guidelines for Americans (DGA) base recommendations on nutrients, food groups, and overall dietary patterns, encouraging higher intake of fruits, vegetables, dairy, whole grains, and protein while managing nutrients overconsumed in the American diet.³⁹ The 2025 Dietary Guidelines Advisory Committee reaffirmed that consumption of nutrient dense foods and beverages is critical for a healthy lifestyle following extensive data analysis and food pattern modeling.⁴⁰ Yet, dietary intake data continues to show that consumption of vegetables, fruits, dairy, seafood, nuts, seeds,

³⁷ Groter H., Hao J., Just D., Kilauga E. Measurement of frozen versus fresh food waste at retail and consumer levels: A critical review and meta analysis. 2023. *Cornell SC Johnson College of Business*. Available at <https://ecommons.cornell.edu/server/api/core/bitstreams/54979bd6-8422-45c2-b943-b5ac8e619376/content>

³⁸ Xu L., Li R., Roe B. 2024. Frozen food purchasing and home freezing of fresh foods: associations with household food waste. *British Food Journal*, 126(12): 4260-4276.

³⁹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th Edition. December 2020.

⁴⁰ 2025 Dietary Guidelines Advisory Committee. 2024. *Scientific Report of the 2025 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and Secretary of Agriculture*. U.S. Department of Health and Human Services.

soy products, and whole grains falls short of recommendations. To address this, the United States already has durable, consumer-facing mechanisms. For example, the Nutrition Facts label provides standardized declarations and percent Daily Values and the recently finalized rule updating the definition of “healthy” reinforces the importance of meeting food-group targets while managing nutrients of concern. Building on these proven tools would be more effective, and more consistent with consumer understanding, than creating a new processing-based classification system that fails to account for nutrient thresholds and food groups.

Although AFFI maintains that there is an insufficient scientific basis to support any federal definition or processing classification construct, if this approach is pursued, nutritional attributes must be integrated. Notably, research that disaggregates “UPF” exposure by “UPF” subgroups, nutrient profiles, or overall diet quality consistently shows that observed risks are not uniform across all foods that are categorized as “UPF.” Instead, potential associations with health concerns tends to cluster in “UPF” categories with low nutrient density while “UPF” categories that are nutrient-dense or that contribute meaningfully to recommended food groups show neutral or more favorable associations. Similarly, diet-modeling work demonstrates that guideline-concordant diets are achievable even when many items are classified as “UPF,” so long as selections meet nutrient targets and food-group recommendations.⁴¹

A recently published randomized controlled trial assessed weight and cardiometabolic outcomes while eating a diet that meets dietary recommendations but is composed of minimally processed or “ultra-processed foods.” Following eight weeks of each diet, participants saw significant weight and body mass index reduction on both the minimally processed and “ultra-processed” diet.⁴² Similarly, studies that measure diet quality of diets with varying amounts of “UPFs” show that those who eat more “UPFs” have lower consumption of fruits and vegetables, whole grains, seafood, and significantly lower Healthy Eating Index scores.⁴³ This research reemphasizes that a diet following nutrient and food group recommendations continues to benefit dietary disease markers and health status. Thus, federal efforts should continue to better align American diets and educate consumers to follow the dietary guidelines. Without explicit consideration of nutrition and food-group contribution, operationalizing a processing definition would oversimplify complex dietary relationships and group products with very different whole-food content, processing methods, and nutritional profiles under a single, potentially pejorative term. A nutrient- and food-group-first

⁴¹ Julie M. Hess, Madeline E. Comeau, Shanon Casperson, Joanne L. Slavin, Guy H. Johnson, Mark Messina, Susan Raatz, Angela J. Scheett, Anne Bodensteiner, Daniel G. Palmer, Dietary Guidelines Meet NOVA: Developing a Menu for A Healthy Dietary Pattern Using Ultra-Processed Foods, *The Journal of Nutrition*, Volume 153, Issue 8, 2023, Pages 2472-2481, ISSN 0022-3166, <https://doi.org/10.1016/j.tjnut.2023.06.028>.

⁴² Dicken, S.J., Jassil, F.C., Brown, A. *et al.* Ultraprocessed or minimally processed diets following healthy dietary guidelines on weight and cardiometabolic health: a randomized, crossover trial. *Nat Med* (2025). <https://doi.org/10.1038/s41591-025-03842-0>.

⁴³ Liu j., Seele E., Li Y., Karageorgou D., Micha R., Monteiro C., Mozaffarian D. 2023. Consumption of ultra-processed foods and diet quality among U.S. children and adults. *American Journal of Preventative Medicine*, 62: 252 – 264.

framework, supported by ongoing consumer education, remains the most scientifically grounded and practical path to improve diet quality and reduce diet-related disease.

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?

As previously mentioned, AFFI believes that it is not appropriate to pursue a federal definition or processing classification scheme while existing evidence lacks in causality, generalizability, and consistency. In short, the concept of “ultra-processed foods” is not supported from a scientific standpoint to serve as a regulatory classification. The agencies stated in the Request for Information that “[t]here is a clear need for a uniform definition of UPFs to allow for consistency in research and policy.” However, the lack of a scientific consensus on the connection between a food’s processing or formulation and potential health outcomes demonstrates that the agency is premature in seeking to develop a regulatory definition. As discussed above, the scientific evidence on the biological impact of processing is extremely limited and continuously evolving. Accordingly, AFFI contends that the agencies should let the science drive and allow further research and scientific consensus to inform any definition of “ultra-processed foods” as well as any efforts to better educate consumers on the role of foods in a healthy diet, not the other way around.

If the agencies proceed with any “UPF” construct, AFFI urges clear guardrails to avoid unintended consequences on federal nutrition programs, food supply chain stability, and food access. A processing definition should not be used to determine eligibility of a food item or compliance in the Supplemental Nutrition Assistance Program (SNAP), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), or National School Lunch and School Breakfast Programs. These are critical nutrition safety nets for vulnerable populations and access would be unnecessarily restricted if foods were limited in these programs due to processing, formulation or inclusion of certain permitted ingredients. Doing so would arbitrarily exclude many safe options that are aligned with the dietary guidelines, including many frozen fruits, vegetables, and prepared meals, complicate procurement, raise costs, increase waste, and reduce access to affordable, culturally appropriate foods without a demonstrable public health benefit. Similarly, any federal procurement requirements should remain grounded in nutrient benchmarks, sourcing location requirements, or program specific operational needs and the agencies should conduct program-level impact analyses focused on cost, access, equity, and food waste implications before proposing or adopting a definition or classification method. These safeguards ensure

that well-functioning, nutrient-based federal programs are not unintentionally destabilized by efforts to label foods based on level of processing.

To that end, AFFI supports research on formulation and/or processing related to health outcomes so long as the research uses a principled approach to classify foods, such as that developed by The Institute for the Advancement of Food and Nutrition Sciences (IAFNS) expert working group. The purpose of the project was to evaluate existing classification methods, analyze food processing related research, and establish agreed upon scientific criteria and methodological principles to classify foods based on formulation and processing. This working group was cross functional in nature, including food technologists, toxicologists, public health experts, and regulatory professionals in government, industry, and academia.⁴⁴ The group developed nine principles to guide future research and assist in refining how food classification systems incorporate processing and formulation.⁴⁵

These principles outline that definitions for food processing must be objective, quantitatively measurable, and should not misclassify or co-opt terms from other disciplines. Similarly, research that includes processing or formulation classification should focus on food properties and health related endpoints that are measurable, such as food texture, nutrient loss, contaminant formation, or formulation and prioritize study designs capable of testing mechanisms and causality rather than relying primarily on observational associations.⁴⁶ To enable this, dietary assessment methods must capture and code foods in ways that reliably reflect processing, formulation, or other systems of classification. If a relevant U.S. based classification system is developed, and mechanistic and causal evidence supports the need for a federal policy approach, any resulting definition or policy must integrate regular updates as nutrition and food science evolve and new evidence emerges.

Applied to existing proposed classification methods, the commonly used NOVA framework does not satisfy these IAFNS principles. As discussed above, NOVA relies largely on qualitative descriptors and ingredient list analysis rather than on measurable processing operations or product properties. This leads to inconsistent and sometimes incorrect classification of familiar foods and blurs the line between “processing” and “formulation.” Such features limit reproducibility and weaken the framework’s suitability for studies that seek causal or mechanistic evidence which is precisely the type of evidence the IAFNS principles prioritize.⁴⁷ Similarly, when NOVA is used as the exposure in nutrition studies, the resulting associations often reflect

⁴⁴ 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>.

⁴⁵ Institute for the Advancement of Food and Nutrition Sciences. 2025. 9 Principles for science-based food classification systems focused on processing and formulation. Available at: <https://iafns.org/9-principles/>.

⁴⁶ *Id.*

⁴⁷ Petrus R., Sobral P., Tadini C., Goncalves C. 2021. The NOVA classification system: A critical perspective in food science. *Trends in Food Science & Technology*, 116:603-608.

the heterogeneity of the foods grouped together rather than the independent effect of “processing” itself. A recent critical review reports that risk signals tend to cluster in specific product types while other NOVA-designated items can be neutral or even favorable depending on nutrient composition, a factor the classification method does not incorporate.⁴⁸ The review also notes methodological issues common to NOVA-based research, such that this research utilizes inappropriate dietary assessment tools that do not assess processing level, suffers from misclassification of food, and overlooks quantifiable properties like texture or matrix impacts. Thus, this reinforces the need for research into classification tools that are measurable, transparent, and relevant in the U.S. context.

For the reasons discussed in this comment, AFFI maintains that there is currently a lack of sufficient and conclusive scientific evidence to define a group of foods based on processing and/or formulation. If, however, the agencies nonetheless pursue such a definition despite the lack of scientific support, the definition should follow the current regulatory nutrition framework relating nutrient density to health outcomes. In the event the agencies are inclined to pursue a definition to be used more broadly, particularly for policy use, they should do so through notice-and-comment rulemaking consistent with the Administrative Procedure Act. As the agencies are aware, defining “UPF,” even if only for research and policy purposes, could impact nearly the entire food and beverage industry and a large portion of foods and beverages on the market. A definition could also potentially have far-reaching implications, including informing regulatory approaches to these foods in other jurisdictions. Because of the importance and wide-ranging impacts of this issue, FDA and USDA should follow a notice-and-comment rulemaking process should they decide to develop a definition to ensure that all stakeholders and interested parties have the opportunity to formally comment on the record.

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The American Frozen Food Institute greatly appreciates the opportunity to provide comment on the joint Request for Information on Ultra-processed Foods. Please do not hesitate to contact us if we can provide further information.

Respectfully submitted,



Jennifer Norka, MPH
Senior Director of Scientific and Regulatory Affairs

⁴⁸ Chun J. & Louie Y. 2025. Are all ultra-processed foods bad? A critical review of the NOVA classification system. *Proceedings of the Nutrition Society*. doi:10.1017/S0029665125100645.