October 22, 2025

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

**RE: FDA-2025-N-1973-0001: Ultra-Processed Foods; Request for Information**

To Whom it May Concern:

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3 million jobs that generate $198 billion in wages and $779 billion in overall economic impact. IDFA's diverse membership ranges from multinational organizations to single-plant companies, from dairy manufacturers and cooperatives to food retailers and suppliers, all on the cutting edge of innovation and sustainable business practices. Together, they represent most of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. Delicious, safe and nutritious, dairy foods offer unparalleled health and consumer benefits to people of all ages.

## Executive Summary

**IDFA does not support the establishment of a regulatory definition for "ultra-processed foods" ("UPF") at this time based on the following:**

- Robust scientific evidence demonstrates a connection between nutrition and health, specifically showing that healthy dietary patterns based on nutrient rich foods can help people achieve and maintain good health and reduce the risk of chronic diseases throughout all life stages.

- Available science **does not**, however, support processing alone as the basis for determining whether a food is nutritious or contributing to chronic disease. The nutrient profile of a food, within the context of the total diet, should be the primary consideration for dietary recommendations and developing policies to reduce food related chronic disease.
- Government programs and initiatives to improve nutrition and promote long term health already exist and should be leveraged to improve population health and health behaviors. A definition for "UPF" is not necessary to accomplish such goals. Focusing instead on processing could distract consumers from identifying nutritious foods because foods commonly undergo processing to improve the nutrition, taste, palatability, shelf-life and safety of foods and thus support healthy lifestyles. For example, raw milk has been pasteurized for decades in the U.S. to mitigate the hazard of pathogens in milk and dairy products, to prevent illnesses and deaths in vulnerable populations; the process of pasteurizing foods and similar processing steps to mitigate food safety hazards has no place in defining "UPF" foods.
- While an agreed upon "UPF" framework may be useful to facilitate research and study designs that promote consistency in science and the generation of results that can be compared, IDFA urges the FDA and USDA to let research and scientific consensus drive the development of any potential classification system for "UPF" foods and to ensure the classification system is based on well-founded and widely accepted scientific research that establishes a clear basis for categorizing foods in a particular way.
- Additional research to identify and fill knowledge gaps will be necessary before establishing any "UPF" framework specifically for research purposes. Such research must be conducted according to standards for high quality science, consider consumer comprehension and avoid unintended consequences, such as discouraging the consumption of nutrient rich foods like dairy.
- If the federal government decides to move forward with developing a regulatory definition for "UPF", it must do so through notice and comment rulemaking as required by the Administrative Procedures Act.

## I. Dairy products are key components of a healthy diet and important for reducing the prevalence of food-related chronic disease.

Dairy is a key component of nutritious eating patterns for Americans of all ages. Milk and dairy foods provide 13 essential nutrients, including three nutrients of public health

concern that are under-consumed (calcium, potassium, vitamin D). The preponderance of evidence confirms that dairy is a key component of healthy eating patterns associated with better health outcomes, including reduced risk of Type 2 diabetes and hypertension; and provides better growth outcomes for children.[1] The complete dairy matrix has been linked to a variety of health and nutritional benefits.[2]

However, 90% of Americans do not meet Dietary Guidelines for American (DGA) recommendations for the consumption of dairy products[3], which means they are missing important nutrients and a key contributor to healthy diets. Nutrition policies should not intentionally or inadvertently discourage the consumption of nutrient rich[4], yet under-consumed, food groups such as dairy.

As stated above, nutrient rich and processed foods are not mutually exclusive. To deliver nutritious foods to consumers of all socio economic backgrounds living in varied communities across the country, dairy companies use a variety of processing methods to: make foods familiar to Americans (culturing to make yogurt), ensure food safety (pasteurization), enhance nutritional value (fortification with vitamin D), meet consumer's dietary needs (treatment with lactase enzyme to remove lactose), and extend shelf life to reduce food waste.[5] Many of these methods of food processing have been used for hundreds or thousands of years and others were developed in the past century as a means of protecting public health through food safety practices, and are essential to creating safe, nutritious foods that consumers know and love.

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[1] U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th ed. Washington, DC: USDA and HHS; Dec 2020. Available from: https://www.dietaryguidelines.gov/

[2] Mulet-Cabero AI, Torres-Gonzalez M, Geurts J, Rosales A, Farhang B, Marmonier C, Ulleberg EK, Hocking E, Neiderer I, Gandolfi I, Anderson L, Brader L, Vermaak M, Cameron M, Myrup Christensen M, Haryono R, Peters S. The Dairy Matrix: Its Importance, Definition, and Current Application in the Context of Nutrition and Health. *Nutrients.* 2024 Aug 31;16(17):2908. doi: 10.3390/nu16172908. PMID: 39275224; PMCID: PMC11397276.

[3] U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th ed. Washington, DC: USDA and HHS; Dec 2020. Available from: https://www.dietaryguidelines.gov/

[4] Throughout these comments, the term "nutrient rich" will refer to the Nutrient Rich Food Index, a "formal metric of nutrient density that has been …validated with respect to a healthy diet. The NRF index is based on 9 nutrients to encourage (protein, fiber, vitamins A, C and E, calcium, iron, potassium, magnesium) and 3 nutrients to limit (saturated fat, added sugar and sodium."
Drewnowski A. Defining nutrient density: development and validation of the nutrient rich foods index. *J Am Coll Nutr.* 2009 Aug;28(4):421S-426S. doi: 10.1080/07315724.2009.10718106. PMID: 20368382.

[5] International Dairy Federation. *Benefits of processing in dairy* (Factsheet of the IDF N° 37/2024) [Internet]. Brussels: IDF; 2024 [cited 2025 Oct 15]. Available from: https://doi.org/10.56169/GXKI8437

## II. Defining "Ultra-processed Foods" is Premature and Not Based in Science.

IDFA does not believe the federal government (FDA and/or USDA) should establish a definition for "UPF" until it is clear how the definition will be used to, as stated in the RFI, inform "research and policymaking." These are two very broad categories of activities. We do agree that more research is needed to determine if defining "UPF" is necessary to inform policies intended to reduce food related chronic disease. It is difficult for industry to provide complete comments on a definition for "UPF" without clarity on its scientific and regulatory applications. For example, a definition for "UPF" applied to research has different implications and requires a different approach than a definition applied to labeling or nutrition assistance program policies.

While we can understand defining "UPF" to assist with framing needed research, IDFA believes it is inappropriate for FDA and USDA to set a regulatory definition for "ultra-processed foods" at this time based on the rationale below.

- **Experts have not established a causal link between a food's processing and potential health outcomes.**

Importantly, the research is not sufficiently robust, and experts have yet to reach consensus, nor have they identified a causal connection between a food's processing and potential health outcomes, independent of other key factors such as the food's nutrient density.

For example, researchers in a 2017 review observed that "[l]ittle research has examined whether "ultra-processed foods" have effects on health independent of their nutrient content" and that "processing itself may not be a causal determinant of the nutritional quality of foods," in part because of the wide variability in the nutrient content of foods some would classify as "UPFs."[6] Similarly, a 2024 scientific review noted that "[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."[7] The authors of a 2019 clinical trial in which adults consumed either "ultra-processed" or "unprocessed" diets, noted that the two diets were not controlled to be nutritionally

[6] 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. doi: 10.1007/s13679-017-0285-4.
[7] Whelan K, Bancil AS, Lindsay JO, et al. Ultra-processed foods and food additives in gut health and disease. *Nat Rev Gastroenterol Hepatol.* 2024;21:406-427. doi: 10.1038/s41575-024-00790-0.

equivalent and ultimately concluded that "[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" underscoring that the nutritional value of food is of more relevance than processing techniques.[8] Even the U.S. Dietary Guidelines Advisory Committee (DGAC), in its most recent scientific report, declined to make a recommendation regarding the consumption of "UPFs."[9]

The lack of empirical evidence causally linking the processing of a food to potential health outcomes independent of factors such as the food's nutrient density and portion size, nor scientific consensus on any biological mechanism of action by which this link could exist, demonstrates why a definition for "UPF" is premature at this time. Any definition, and regulatory action including policy making that uses that definition, must be based on consensus science. A sweeping definition that forms the basis of policy that is not based on science runs the risk of confusing consumers and undermining the federal government's public health goals by unnecessarily maligning foods that are safe, nutritious, affordable, accessible and contribute to an overall healthy dietary pattern.

- **USDA and FDA can achieve their goals of improving public health outcomes through consumer diets by bolstering existing regulatory frameworks that are based on scientifically proven nutrition science.**

Classifying foods based on the level of processing fails to consider other aspects of a food that science has routinely linked to potential health outcomes, such as nutrient content, moderate portion size, and food group composition. These factors are well-understood by experts to be connected to potential health outcomes and already serve as a throughline in federal nutrition policy. Accordingly, IDFA believes that bolstering existing regulatory frameworks based on these aspects of nutrition science would be a more effective method for achieving FDA and USDA public heath goals which include reducing food related chronic disease.

The lack of scientific consensus on the connection between a food's processing and potential health outcomes, as outlined above, contrasts significantly with the established

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[8] 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.

[9] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *Scientific Report of the 2025 Dietary Guidelines Advisory Committee* [Internet]. Washington, DC: USDA and HHS; 2024 Dec. Available from: https://www.dietaryguidelines.gov/sites/default/files/2024-12/Scientific_Report_of_the_2025_Dietary_Guidelines_Advisory_Committee_508c.pdf.

body of scientific research regarding dietary patterns that promote the consumption of nutrient rich foods. For example, the 2020 – 2025 DGA emphasizes the importance of choosing nutrient rich foods when building a healthy dietary pattern and limiting the intake of added sugar, sodium and saturated fat, with a focus on food group composition and portion size.[10] These well-established foundations of nutrition policy have already been incorporated into regulatory frameworks and IDFA recommends that these be further bolstered through education to empower Americans to build healthy dietary patterns. Other regulatory bodies have already reached this conclusion; for example, the Nordic Nutrition Recommendations Committee declined to establish specific recommendations on "ultra-processed foods" in 2023, stating that "the current categorization of foods as ultra-processed foods does not add to the already existing food classifications and recommendations."[11] Other health authorities agree, including the UK Scientific Advisory Committee on Nutrition, French Food Safety Authority, and German Nutrition Society.[12]

Examples of potential actions that could currently be undertaken to improve dietary intake and health outcomes, utilizing existing regulatory frameworks based on scientific consensus include:

- Educational efforts to ensure consumers understand the nutrition information required and already presented on the labels of packaged food and how to use this information to inform their purchasing choices, such as FDA's "Read the Label" program;[13]

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[10] U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th ed. Washington, DC: USDA and HHS; Dec 2020. Available from: https://www.dietaryguidelines.gov/

[11] Blomhoff R, Andersen R, Arnesen EK, Christensen JJ, Eneroth H, Erkkola M, Gudanaviciene I, Halldorsson TI, Høyer-Lund A, Lemming EW, Meltzer HM, Pitsi T, Schwab U, Siksna I, Thorsdottir I, Trolle E. *Nordic Nutrition Recommendations 2023* . Copenhagen: Nordic Council of Ministers; 2023. Available from: https://pub.norden.org/nord2023-003/nord2023-003.pdf

[13] Office for Health Improvement and Disparities. *Processed foods and health: SACN's rapid evidence update* [Internet]. London: GOV.UK; 2025 Apr 2 [cited 2025 Oct 15]. Available from: https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update
Anses. *Aliments dits ultratransformés : mieux comprendre leurs effets potentiels sur la santé* [Internet]. Maisons-Alfort: ANSES; 30 Jan 2025 [cited 2025 Oct 15]. Available from: https://www.anses.fr/fr/system/files/NUT2022-SA-0155.pdf
German Nutrition Society. *Proceedings of the German Nutrition Society: Abstractband zum 61. Wissenschaftlichen Kongress. Vol. 30* [Internet]. 2024 [cited 2025 Oct 15]. Available from: https://www.dge.de/fileadmin/dok/veranstaltungen/kongresse/wk61/DGE-Proc-Germ-Nutr-Soc-Vol-30-2024.pdf

[13] U.S. Food and Drug Administration. *Read the Label Youth Outreach Materials* [Internet]. Washington, DC: FDA; content current as of 03/05/2024 [cited 2025 Oct 09]. Available from: https://www.fda.gov/food/nutrition-facts-label/read-label-youth-outreach-materials

- Incorporating pragmatic factors such as dietary preference and the cost and preparation time for foods into dietary guidance, to make the recommendations more useful and applicable to consumers; and
- Educational and transparency initiatives to enhance consumer understanding of federal food regulatory frameworks for ensuring food and ingredient safety, including updating FDA's "Science and Our Food Supply" curriculum.[14]

IDFA believes strongly that building upon existing scientifically sound frameworks would be a more effective way of helping Americans move toward healthier dietary patterns that does not ignore the benefits of food processing which include food safety, accessibility, affordability, fortification and nutrient delivery, convenience, and taste.

- **Before a decision is made to define "UPF," a review of the existing science on "UPF" should be conducted and gaps/unanswered questions identified; then a framework for classifying and understanding "UPF" should be established to drive and align scientific research to address the gaps and questions; and finally, research should be conducted and the results used to gain an understanding of any connections between processing and health outcomes and to make a decision on whether a regulatory definition for "UPF" is needed to inform policymaking.**

As we indicate above, a body of science to support the need for a regulatory definition for "UPF" does not yet exist. If additional research is to be conducted, a consistent framework for classifying and understanding "UPF" may be needed so that studies and the results generated through them can be compared and build upon each other.

However, before this framework is established and agreed upon, issue landscaping of the science currently applicable to the topic of "UPF" must be conducted. The existing science and body of knowledge regarding "UPF" should be examined to better understand existing knowledge and identify knowledge gaps. Following this review, a framework for the purpose of aligning "UPF" research going forward to fill identified gaps and answer other scientific questions such as identifying potential causal links to health outcomes could be considered and established. Multiple assessments of the body of knowledge regarding

[14] U.S. Food and Drug Administration. *Science and Our Food Supply* [Internet]. Washington, DC: FDA; content current as of 08/12/2024 [cited 2025 Oct 09]. Available from: https://www.fda.gov/food/students-teachers/science-and-our-food-supply

"UPF" have identified significant research gaps including any potential links to chronic disease.[15, 16, 17]

Research undertaken should be rigorous and in line with tenets published by the National Institutes of Health (NIH) for gold standard science.[18] In addition, scientific research should include evaluations of the impact the proposed "UPF" definition would have on: a wide variety of food products including those that are nutrient rich and also described as an "UPF"; the availability of foods and beverages in the federal nutrition programs; and nutritionally at-risk individuals that rely on federal nutrition products and programs. In addition, when considering a "UPF" definition, the potential need for different approaches for certain foods, including medical foods, infant formulas, and nutrient rich "UPF" should be considered.

IDFA believes the guiding principles identified by the Institute for the Advancement of Food and Nutrition Science would be particularly useful in considering the science needed regarding "UPF" and classification systems which include:

1. Documentation and definitions that allow for reproducibility, rigor, and transparency should be provided.
2. Properties for which there is evidence of a biological link with a health-related endpoint should be used to differentiate foods.
3. Associations without robust causal evidence should be considered preliminary.
4. The impact that processing steps have on the final composition and structure of the food in terms of a putative effect on a health-related endpoint should be considered.
5. The impact of formulation on the final composition and structure of the food in terms of a putative effect on a health-related endpoint should be considered.
6. Systems should evolve over time to reflect advancements in science and changes in the food supply, with previous versions of a system being distinguishable from updated versions.

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[15]. Gibney MJ, Forde CG. Nutrition research challenges for processed food and health. *Nat Food*. 2022 Feb;3(2):104-109. doi: 10.1038/s43016-021-00457-9. Epub 2022 Feb 7. PMID: 37117956.

[16] Restructure Project. *Restructure Project* [Internet]. Wageningen, Netherlands: Wageningen University & Research; [cited 2025 Oct 15]. Available from: https://restructureproject.org/

[17] Trumbo PR, Bleiweiss-Sande R, Campbell JK, Decker E, Drewnowski A, Erdman JW, Ferruzzi MG, Forde CG, Gibney MJ, Hess JM, Klurfeld DM, Latulippe ME, O'Connor LE, Reimers KJ, Rolls BJ, Schulz J, Weaver C, Yu L. Toward a science-based classification of processed foods to support meaningful research and effective health policies. *Front Nutr.* 2024 Jul 3;11:1389601. doi: 10.3389/fnut.2024.1389601. PMID: 39055388; PMCID: PMC11271201.

[18] National Institutes of Health. *Leading in Gold Standard Science: An NIH Implementation Plan* [Internet]. Bethesda, MD: NIH; 22 August 2025 [cited 2025 Oct 09]. Available from: https://www.nih.gov/sites/default/files/2025-08/2025-gss.pdf

7. Current scientific evaluations from scientific bodies with relevant expertise should be consulted for each iteration.
8. The context(s) in which a system was validated should be considered in its application.
9. The probative value of a research question or proposed food classification system should be considered prior to engaging in analysis or development.

IDFA acknowledges that research has not been conducted to address existing knowledge gaps needed to support a regulatory definition of "UPF" in which case we urge the federal government to continue to make dietary recommendations based on the extensive body of existing science demonstrating the nutritional value of foods.

## III. <u>While IDFA Does Not Support a Regulatory Definition for "UPF" at This Time, Should the Federal Government Move Forward with a Regulatory Definition, It Must Be Grounded in Science and Established Through Notice and Comment Rulemaking in Compliance with the Administrative Procedures Act.</u>

If the federal government prematurely moves forward with a regulatory definition for "UPF", it must do so through notice and comment rulemaking in accordance with the Administrative Procedures Act (APA).[19] The APA requires "rules" that have the force of law and that implement, interpret or prescribe law or policy, to be issued via notice and comment rulemaking. A "UPF" definition would be a substantive policy that will be repurposed in regulatory programs and would be considered a rule that should undergo notice and comment rulemaking.

- **<u>A regulatory definition for "ultra-processed foods" must be grounded in science and measurable.</u>**

As stated above, a body of science does not yet exist to set a regulatory definition for "UPF," although this research could be conducted and it will evolve over time. Also, setting a regulatory definition for an issue like "UPF" that is so unsettled due to a lack of science is not only premature but unwise because once a regulatory definition is codified through rulemaking or established through guidance, it will be very difficult to amend or modify in a timely manner. However, if, at a future time, a body of science that is reproducible, representative of the population of interest, and reflective of significant scientific consensus of qualified experts and institutions is established, then we would understand the federal government determining if it is appropriate to establish a definition for "UPF."

[19] United States. *Administrative Procedure Act, 5 U.S.C. § 553 (2024)*.

Additionally, both the "UPF" definition and the criteria used as the basis for the definition such as nutritional content, should be measurable to facilitate evaluating policy changes informed by the definition against specific public health goals.[20] These measures or metrics would need to be analyzed carefully to ensure that they are applicable to multiple categories and types of foods and beverages, including a variety of food matrices.

IDFA urges the federal government to take into consideration that the body of science on "UPF" will continue to grow and evolve, as is natural for science. For example, a mechanism may be identified that associates an element of the "UPF" definition with a health outcome or a potential association may be disproved. As nutrition science advances, any definition of "UPF" may need to change.

## IV. Responses to Specific Questions

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

Existing processing- and ingredient-based classification systems that have been explored by researchers are flawed in ways that demonstrate that this type of classification is fundamentally unworkable and contrary to established science.[21,22, 23, 24,25]

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[20] Ahrné L, Chen H, Henry CJ, Kim HS, Schneeman B, Windhab EJ. Defining the role of processing in food classification systems—the IUFoST formulation & processing approach. *NPJ Sci Food*. 2025 Apr 23;9(1):56. doi: 10.1038/s41538-025-00395-x. PMID: 40268939; PMCID: PMC12019408.

[21] Office for Health Improvement and Disparities. *Processed foods and health: SACN's rapid evidence update* [Internet]. London: GOV.UK; 2025 Apr 2 [cited 2025 Oct 15]. Available from: https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update

[22] Blomhoff R, Andersen R, Arnesen EK, Christensen JJ, Eneroth H, Erkkola M, Gudanaviciene I, Halldorsson TI, Høyer-Lund A, Lemming EW, Meltzer HM, Pitsi T, Schwab U, Siksna I, Thorsdottir I, Trolle E. *Nordic Nutrition Recommendations 2023* . Copenhagen: Nordic Council of Ministers; 2023. Available from: https://pub.norden.org/nord2023-003/nord2023-003.pdf

[23] FoodDrinkEurope. *Scientific critique of 'ultra-processed foods' (UPFs) classifications* [Internet]. Brussels: FoodDrinkEurope; June 2025 [cited 2025 Sept 26]. Available from: https://www.fooddrinkeurope.eu/wp-content/uploads/2025/06/EXTERNAL-Scientific-critique-of-UPF-classifications-June-2025.pdf

[24] Bernstein J, Brown A, Burton-Freeman B, Estevez M, Hess J, Hubert P, Latulippe M. Perspective: Guiding principles for science-based food classification systems focused on processing and formulation. *Preprints*. 2025 [cited 2025 Oct 14];2025:202507.1896.v1. Available from: https://doi.org/10.20944/preprints202507.1896.v1

[25] Ahrné L, Chen H, Henry CJ, Kim HS, Schneeman B, Windhab EJ. Defining the role of processing in food classification systems—the IUFoST formulation & processing approach. *NPJ Sci Food*. 2025 Apr 23;9(1):56. doi: 10.1038/s41538-025-00395-x. PMID: 40268939; PMCID: PMC12019408.

For example, the Nova system, a proposed processing-based classification system developed by researchers in Brazil, has been broadly criticized as unwieldy, inconsistent,[26] and having a "lack of biological plausibility."[27] The authors of one study ultimately concluded that "overall consistency among evaluators was low, even when ingredient information was available" and that the Nova criteria "do not allow for robust and functional food assignments."[28] Additionally, as discussed above, the Nova scheme has been criticized for providing no additional information on the healthfulness of a food beyond which can be more reliably determined by evaluating the nutrient density of the food.[29]

Any effort by the federal government to explore a definition for "UPF" or a similar term, must ensure it is tailored to the U.S. food system, culture, and the unique characteristics and needs of U.S. consumers, including assuring food safety, accessibility, and affordability.

Rather than focus on processing, the federal government should look to established nutrition science, which focuses on nutrients and food groups to encourage, portion size, and the nutrient density of a food, when making recommendations to consumers on healthy dietary patterns.

Policymaking around "UPF," including any potential definition, will be complex and must consider a number of criteria and importantly must avoid unintended consequences, including exacerbating the under consumption of foods recommended by the DGAs.[30] Broad recommendations to discourage consumption of convenient, affordable, and shelf-stable foods could limit access to nutrient rich foods and foods that limit nutrients of

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[26] Astrup A, Monteiro CA. Does the concept of "ultra-processed foods" help inform dietary guidelines, beyond conventional classification systems? *Am J Clin Nutr.* 2022 Dec;116(6):1482-1488. doi: 10.1093/ajcn/nqac123. ("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.").

[27] Visioli F, Marangoni F, Fogliano V, et al. The ultra-processed foods hypothesis: a product processed well beyond the basic ingredients in the package. *Nutr Res Rev.* 2023;36(2):340-350. doi: 10.1017/S0954422423000176. ("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.").

[28] Braesco V, Souchon I, Sauvant 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.

[29] Drewnowski A, Gupta S, Darmon N**.** An overlap between "ultraprocessed" foods and the preexisting Nutrient Rich Foods Index? *Nutrition Today.* 2020;55(2):75-81. ("We conclude that the NOVA classification scheme adds little to the preexisting nutrient profiling models. The purported links between NOVA categories and health outcomes could have been obtained using preexisting [Nutrient Rich Food] nutrient density metrics.").

[30] Gibney MJ. Ultra-processed foods: definitions and policy issues. *Curr Dev Nutr.* 2018 Sep 14;3(2):nzy077. doi: 10.1093/cdn/nzy077. PMID: 30820487; PMCID: PMC6389637.

concern, thereby decreasing diet quality, and could also increase the risk of foodborne illness and exacerbate health disparities.

Nutritional recommendations should urge increased intake of nutrient rich dairy foods, which provide important nutrients but are under-consumed by Americans.[31] If a definition for "UPF" is set that focuses on non-nutritional parameters such as processing or specific ingredients for which there is no specific causal link to health outcomes, some dairy foods such as yogurt, flavored milk, cottage cheese and American cheese may be excluded from dietary recommendations. Regarding cottage cheese for example, it is a food that contributes toward an additional serving of the under consumed dairy group, provides significant levels of protein and other nutrients[32] while containing ingredients to maintain adequate shelf life, and that is processed through culturing. The federal government should avoid discouraging consumption of cottage cheese and other nutritious dairy products on the basis that they contain certain ingredients or are made using traditional processing methods common to dairy manufacturing. These foods serve an important role in healthy diets, providing key nutrients with a flavor that people enjoy, while also being safe and convenient.

***Question #2a. 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.***

***Question #2b: 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***

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[31] U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th ed. Washington, DC: USDA and HHS; Dec 2020. Available from: https://www.dietaryguidelines.gov/

[32] National Agricultural Library (US), United States Department of Agriculture**.** *FoodData Central: Cottage cheese, full fat, large or small curd* [Internet]. Beltsville, MD: USDA; [cited 2025 Oct 08]. Available from: https://fdc.nal.usda.gov/food-details/2346384/nutrients

***ultra-processed? Please provide supporting data and explain your rationale in your response.***

***Question #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? Please provide supporting data and explain your rationale in your response.***

**General Comments on RFI Questions #2a-#2c:**

- **Additives used in U.S. foods are regulated by the FDA to assure they are safe and any premature attempts defining "UPF" should not undermine well established federal regulatory oversight pathways for these substances added to food for specific intended uses.**

The RFI's questions regarding food ingredients are based on incorrect assumptions. To be clear, there are existing regulatory pathways and processes in place to ensure food and color additives and GRAS (Generally Recognized as Safe) substances are safe for their intended uses when incorporated into foods marketed in the U.S. These regulatory pathways include FDA premarket safety assessments for food and color additives and FDA reviews of voluntary industry GRAS notifications and regulatory requirements for industry GRAS determinations for GRAS substances; these longstanding pathways and requirements have been established through federal laws and/or regulations.

More specifically, the aforementioned regulatory pathways are implemented to assure the safety of food ingredients and include:

- **Food Additive Petitions:** FDA reviews pre-market food additive petitions that include toxicological data, exposure levels, and intended use provided by the petitioner to assess the safety of the additive. If the agency concludes after its review that the food additive is safe, it publishes a regulation specifying the additive's conditions of use, including the foods it can safely be used in and threshold amounts of use for the ingredient. FDA's regulatory framework for assessing the safety of food additives is documented in Section 409 of the Federal Food Drug and Cosmetic Act (FFDCA) and Title 21 of the Code of Regulations (CFR), Part 170.
- **Industry GRAS Determinations and Voluntary FDA Notifications:** Food ingredients can be classified as GRAS if shown to be safe through scientific evidence widely accepted among qualified experts (scientific procedures), or the substance has a substantial history of safe consumption in food. Today, most new GRAS ingredients are reviewed by FDA under its voluntary GRAS Notification process; FDA reviews the submitted manufacturer-collected safety data, including

toxicological studies and exposure data, agrees the substance is GRAS and safe for its intended use, and issues a letter to the entity that notified the agency indicating this or disagrees the substance is GRAS and issues a letter to the entity that notified the agency stating its concerns and questions. While GRAS substances do not require FDA notification or premarket approval, industry must conduct and document a robust safety review prior to marketing foods with a GRAS substance. Refer to Sections 201(s) and 409 of the FFDCA and 21 CFR 170.3 and 21 CFR 170.3.

- **Color Additive Petitions:** Color additives require an FDA premarket safety review and approval prior to their use in food. A subset of color additives requires an additional batch-by-batch FDA certification. FDA reviews color additive petitions submitted by manufacturers or sponsors that detail the safety of the substance and intended use; FDA evaluates the petition, and if deemed safe and approved, issues a regulation. All color additives must be approved and listed by the FDA before they can be used in food. Refer to Section 721 [379e(b)(5)(B)] of the FFDCA and 21 CFR Parts 70-82.

Importantly, the U.S. applies a risk-based approach to food and color additive and GRAS substance safety in which manufacturers or sponsors must demonstrate the additive presents a "reasonable certainty of no harm" to consumers. This is in contrast to the European Union's hazards-based approach to food additive safety that is based on the "precautionary principle," which means additives can be banned or restricted if there is any scientific uncertainty at all about their safety. Additionally, in the U.S. all additives to food are assessed to ensure there is a technological justification for their use at specific levels and for their safety at those proposed levels. In summary, all additives used in foods in the U.S. marketplace must present a reasonable certainty of no harm to consumers prior to their use and this approach has proven to be effective. IDFA urges the federal government to take care not to undermine the aforementioned federal regulatory frameworks established to assure the safe use of food ingredients in the U.S. during all its deliberations on "UPF".

Relatedly, IDFA supports FDA's routine monitoring for new gold standard science and other legitimate sources of information to assist the agency's efforts to prioritize its post market risk and safety assessments of food and color additives that have previously undergone a safety review by FDA and substances that have been deemed GRAS. We also appreciate the FDA reinvigorating its post market assessment activities for both intentionally and unintentionally added food chemicals and the implementation of a modernized and transparent process for prioritizing and conducting these assessments. We do, however, suggest that FDA provide a statement on its website that for food and color additives or

GRAS substances prioritized by the agency for post market assessment, these substances are safe pending the outcome of the agency's assessments. Furthermore, IDFA supports FDA's GRAS modernization efforts and specifically mandatory GRAS notifications and enhanced consumer transparency.

- **The use of specific ingredients alone should not cause a food to be classified as "UPF" given all ingredients used in foods sold in the U.S. marketplace have previously been determined by the FDA or the manufacturer/sponsor to be safe.**

Given the established regulatory pathways for assuring the safety of food ingredients in the U.S. and the post market processes in place to rereview/assess these ingredients if new gold standard science warrants such action, IDFA does not believe ingredients that have been preapproved by FDA for specific intended uses in the U.S. or ingredients that experts agree are GRAS should be the basis for classifying packaged foods as "UPF." It is inappropriate to focus on additives and ingredients to the detriment of nutritional considerations in any definition of "UPF" that may be used to make dietary recommendations.

- **Consumer focused education and transparency initiatives pertaining to food ingredients are needed.**

With regard to ingredients, IDFA believes enhanced ingredient transparency and consumer education on ingredients would be most beneficial to consumers to help inform their food purchasing decisions. We encourage clear labeling of ingredients and using common and usual names for ingredients that are understandable to consumers. We would also support government initiatives to educate consumers on the common names for ingredients, the functionalities and uses of ingredients in food and the benefits of food processing in the spirit of enhancing consumer transparency and building consumer trust.

**Comments on Specific RFI Questions on Ingredients**

***Question #2b:*** **....**

***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.***

There is no scientific basis for considering flavorings and colorings separately or collectively from other ingredients when characterizing a food as "UPF." Colorings and

flavorings have not been shown by the scientific community to directly contribute to food related chronic disease in the U.S. IDFA therefore does not support these specific ingredient categories as the basis for inclusion of foods under a definition for "UPF" regardless of whether they are natural or artificial flavors or certified or non-certified colors. All colorings and flavorings used in foods marketed in the U.S. have met FDA's safety standard of a reasonable certainty of no harm to consumers. Discriminatory language should not be applied to any ingredients or categories of ingredients that are used under their FDA approved conditions of intended use. The pre-market review and approval process drives the safety determination of the substance, regardless of how the colorings and flavorings are derived.

Each ingredient used in a food serves a purpose, from ensuring food safety to providing nutritional benefits or improving organoleptic properties such as texture, color, and taste. Flavors and colorings can increase consumer acceptance of dairy products which are an under-consumed food group for most Americans that can provide exceptional nutritional benefits to consumers. There is evidence, for example, that children who drink flavored milk drink more milk than children who do not drink flavored milk, ensuring they receive milk's 13 essential nutrients.[33] And while flavorings may include added sugars, as per the current DGAs, "a small amount of added sugars…can be added to nutrient-dense foods and beverages to help meet food group recommendations….".[34] While added sugar may be a nutrient to limit, it may also be useful as part of an overall diet to increase nutrient rich dairy intake.

***Question #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? Please provide supporting data and explain your rationale in your response.***

***Question #3b: 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.***

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[33] Fayet-Moore F. Effect of flavored milk vs plain milk on total milk intake and nutrient provision in children. Nutr Rev. 2016 Jan;74(1):1-17. doi: 10.1093/nutrit/nuv031. Epub 2015 Nov 3. PMID: 26534904.
[34] U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th ed. Washington, DC: USDA and HHS; Dec 2020. Available from: https://www.dietaryguidelines.gov/

***Question #3c: 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.***

***Question #3d: 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.***

As discussed above, the current body of science and evidence does not support the idea that the level of processing a food undergoes correlates in any way to health outcomes. IDFA therefore does not believe that processing alone should be considered as part of a definition of "UPF." Processing overall is already addressed in a number of regulations and government policies including in product standards of identity, and to further emphasize processing could discourage or limit consumer choice and food options that aid in creating a healthy and balanced dietary pattern.

Food processing complements and supports farming and agricultural practices by transforming raw agricultural products such as grains, fruits, vegetables and milk into nutritious food ingredients or "processed food" products.[35] Processing is required for many reasons ranging from simple size transformation, shelf stability, food safety, and enhancing nutritional quality to meeting special nutritional needs, efficiency, and flavor and cultural preferences. Furthermore, food processing serves many beneficial purposes, including increasing access to palatable food, reducing food waste, and helping consumers navigate dietary preferences and intolerances. Many of the processing methods in use today have been used for hundreds or thousands of years.

Take for example heating, a very common processing step. It can be used to make food safe by eliminating bacterial and viral pathogens as exemplified by the pasteurization of milk. Heating not only ensures safety; it also improves the shelf stability of food products and can also be used to improve the nutritional quality and bioavailability of nutrients in a food or change the taste or appearance of a food. It is thus important to understand not only what processing method is being used but what the processing method's use is meant to achieve in the given food. Additionally, many processing methods are used by consumers in their homes and a significant number of these are largely identical to the methods used in food manufacturing facilities, just on a different scale.

[35] Institute of Food Technologists. *Food Processing* [Internet]. Chicago, IL: IFT; [cited 2025 Oct 15]. Available from: https://www.ift.org/policy-and-advocacy/advocacy-toolkits/food-processing

Another challenge in classifying foods by processing is that not all processing steps are apparent to the policy makers setting policies regarding "UPF." Similar looking foods or ingredients can be made in different ways. Without actual knowledge of the specific processing steps used by a given food manufacturer for a given food product, there is a serious risk that two food products that are similar nutritionally or ingredient-wise, are classified as having the same level of processing when in fact they are processed quite differently. This lack of proprietary food processing knowledge by policymakers is a significant hurdle to accurately classifying products based on the level of processing and emphasizes the importance of relying on an established body of publicly-available science, such as that around healthy dietary patterns, to make nutritional recommendations.

Finally, there are already federal regulatory definitions for processing, including USDA definitions for "minimally processed" and "processed food item."[36] No part of a definition for "UPF" should conflict with these pre-existing definitions.

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

The term "ultra-processed food" is not a useful term for communicating nutritional recommendations to Americans. The term has been socialized through widespread use in a pejorative manner, despite the lack of an agreed upon definition and alignment within the scientific literature which is causing consumer confusion. An additional point of confusion with the term is that the existing categorization schemes for "UPF" including Nova are not based exclusively on processing. Therefore, the term is actually misleading, and it is important that any term is based on scientific data and very clearly understood by consumers.

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[36] ***"****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." (7 CFR 65.220)

***Question #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? Please provide supporting data and explain your rationale in your response.***

As stated above, nutritional attributes should be the primary consideration when making nutritional recommendations, reflecting the body of science that demonstrates the benefits of a diet built on nutrient rich foods and foods that limit the intake of nutrients of concern including added sugar, sodium, and saturated fat to prevent food related chronic disease. The Nutrient Rich Foods Index does consider the full nutrient profile of a food, including nutrients to encourage and nutrients to limit.[37] While the amount of nutrients to limit in foods is an important consideration, this should be balanced with the contribution of nutrients to encourage present in the food. For some foods, moderate levels of saturated fat, sodium or added sugar are accompanied by a variety of nutrients that should be encouraged in the overall diet, such as calcium, vitamin D, potassium and protein. All foods and the nutrients they provide must be considered as part of an overall diet to encourage consumers to choose healthier dietary patterns.

Nutrition policies, regulations, and recommendations already in place can help consumers make healthier choices and adopt healthier dietary patterns. We believe that additional efforts to better educate consumers on these policies, regulations, and recommendations would be far more impactful to public health and reducing food related chronic disease than introducing an unscientific definition for "UPF" which is pejorative and already causing widespread confusion. IDFA urges the federal government to focus its resources on educating consumers with the goal of enhancing their knowledge of nutrition and food and providing them with tools for behavior modification.

***Question #5b: 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.***

Any attribute that contributes to the categorization of a food must be supported by scientific evidence.

[37] Drewnowski A. Defining nutrient density: development and validation of the nutrient rich foods index. J Am Coll Nutr. 2009 Aug;28(4):421S-426S. doi: 10.1080/07315724.2009.10718106. PMID: 20368382.

Energy density and palatability have been proposed as two factors that may be related to "ultra-processed foods," however there is no research that confirms a mechanism tied to risk of chronic disease. This research should continue, so it can inform nutrition policies. However, other factors must be considered, including protein's effect on satiety.[38, 39, 40]

***Question #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?***

- **The definition for "UPF" must consider the nutritional contributions of foods in the context of a complete diet first and foremost.**

Before setting any definition for "UPF" or other similar term with the intention of making nutritional and dietary recommendations, the foremost consideration should be nutritional contributions of the food in the context of an overall diet, including meeting nutrient needs and consideration of nutrients to limit. No definition should change the overall nutritional recommendation that a healthy diet is based on nutrient rich foods and foods that limit nutrients of concern, and these foods should continue to be recommended, regardless of if or how they are processed or formulated.

Nutrient richness is a concept that must be maintained in nutritional and dietary recommendations. The Nutrient Rich Foods Index was developed to holistically consider the essential nutrients provided by foods, while balancing nutrients to limit and the calories in the food.[41]

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[38] Halton TL, Hu FB**.** The effects of high protein diets on thermogenesis, satiety and weight loss: a critical review. *J Am Coll Nutr.* 2004 Oct;23(5):373-385. doi: 10.1080/07315724.2004.10719381.

[39] Weigle DS, Breen PA, Matthys CC, Callahan HS, Meeuws KE, Burden VR, Purnell JQ. A high-protein diet induces sustained reductions in appetite, ad libitum caloric intake, and body weight despite compensatory changes in diurnal plasma leptin and ghrelin concentrations. *Am J Clin Nutr.* 2005 Jul;82(1):41-48. doi: 10.1093/ajcn.82.1.41. PMID: 16002798.

[40] Leidy HJ, Tang M, Armstrong CL, Martin CB, Campbell WW. The effects of consuming frequent, higher protein meals on appetite and satiety during weight loss in overweight/obese men. *Obesity (Silver Spring).* 2011 Apr;19(4):818-824. doi: 10.1038/oby.2010.203. Epub 2010 Sep 16. PMID: 20847729; PMCID: PMC4564867.

[41] Drewnowski A. Defining nutrient density: development and validation of the nutrient rich foods index. J Am Coll Nutr. 2009 Aug;28(4):421S-426S. doi: 10.1080/07315724.2009.10718106. PMID: 20368382.

While there is overlap between some systems of categorizing "UPFs" and limiting saturated fat, added sugar and sodium,[42] there is also the ability to meet nutrient requirements, including limits on saturated fat, added sugar and sodium while consuming a diet largely made up of foods categorized as "UPFs."[43] This underscores that the focus for nutritional recommendations needs to be foremost on the nutrient content of foods in the context of the total diet.

Due to the wide variety of foods available in the U.S. food supply and the wide variety of foods that can make up a healthy diet, it is unreasonable to assume that a uniform, "one size fits all" approach to a definition or categorization scheme for "UPF" would be equally applicable to all foods and beverages in the U.S. marketplace without unintended consequences including the potential for consumers to move away from certain nutrient dense foods that are also "UPF."

Any positions or changes to nutrition policy that could affect federal feeding programs including school meals, must be carefully considered to avoid unintended consequences, such as requiring foods that would be impractical for schools to source or prepare, or increasing costs to school meal programs which are often mandated to break even financially. Additionally, any new definition for "UPF" must not conflict or be misaligned with other existing policies including FDA's recently updated "healthy" claim such that it causes consumer confusion. Currently, an unflavored yogurt that meets the updated definition of "healthy" could contain stabilizers or dairy powders that would cause it to be classified as a "UPF" under certain categorization schemes discussed in the public media. In this example, the product qualifies to bear the FDA "healthy" claim yet may also be classified as a "UPF" which could be confusing to consumers trying to select healthier food options that will contribute to an overall healthy diet.

## Conclusion

IDFA believes that setting a regulatory definition for "UPF" is premature at this time given the inconsistent and inconclusive body of existing science regarding "UPF" and the absence of any correlation between the consumption of "UPF" and specific negative health outcomes. We understand that the FDA and USDA have already used the term "ultra-

[42] Drewnowski A, Gupta S, Darmon N. An overlap between "ultraprocessed" foods and the preexisting Nutrient Rich Foods Index? *Nutrition Today.* 2020;55(2):75-81. doi: 10.1097/NT.0000000000000400.
[43] Hess JM, Comeau ME, Casperson S, Slavin JL, Johnson GH, Messina M, Raatz S, Scheett AJ, Bodensteiner A, Palmer DG. Dietary Guidelines meet NOVA: developing a menu for a healthy dietary pattern using ultra-processed foods. *J Nutr.* 2023 Aug;153(8):2472-2481. doi: 10.1016/j.tjnut.2023.06.028. Epub 2023 Jun 24. PMID: 37356502.

processed foods" in communications prior to establishing an official definition[44], but caution that efforts to reduce the consumption of so-called "ultra-processed foods" without a robust body of science could inadvertently further reduce the consumption of nutrient rich products such as dairy products which are currently under-consumed foods that play an important role in healthy diets.

IDFA recommends that the federal government use existing governmental initiatives to encourage consumers to consume moderate portion sizes and construct a balanced diet that aligns with DGA dietary recommendations. These initiatives should remain the focus and continue until, or if, a body of science demonstrates a new approach is needed. If science does justify a regulatory definition for "UPF" in the future, the definition should be based on sound scientific evidence (e.g., peer-reviewed, replicable, representative of the population of interest, reflective of significant scientific consensus of qualified experts and institutions), defined through notice and comment rulemaking, carefully constructed to avoid unintended consequences such as reduced consumption of nutrient rich foods like dairy products, and be accompanied by robust consumer education.

Regards,

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[44] The MAHA assessment defines "UPFs" as "industrially processed products made with additives or ingredients not commonly used in home cooking." In August 2025, the Centers for Disease Control and Prevention published a data brief indicating that 55% of the foods consumed by Americans are purportedly "UPF", using the processing categories defined by Nova. The U.S. Department of Health and Human Services (HHS) is launching a national campaign, "Take Back Your Health," focused on the purported links between ultra-processed foods and increased diabetes risk. The U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) announced that the new Nutrition Regulatory Science Program will aim to answer multiple questions regarding "ultra-processed foods."