October 22, 2025

Submitted electronically via Regulations.gov

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

Re: Ultra-Processed Foods; Request for Information; Docket No. FDA-2025-N-1793 (July 25, 2025)

Dear Sir or Madam:

The Consumer Brands Association (Consumer Brands) champions the industry whose products Americans depend on every day. We represent more than 2,000 iconic brands spanning cleaning and personal care to food and beverage products. Beyond our presence in almost every home, the consumer packaged goods (CPG) industry is the largest domestic manufacturing segment by workforce, supporting more than 22 million American jobs and contributing $2.5 trillion in economic impact.

As relevant to the topic at hand, Consumer Brands represents companies that make a wide variety of packaged foods, including processed food and beverage products, with a portfolio that is inclusive of individual and mixed food items, as well as main dishes and meals, which are affordable, accessible, convenient, and at times, medically necessary for consumers. Our companies remain committed to introducing new and novel products and reformulating existing products to meet the demands of consumers, aligning with existing nutritional frameworks and ensuring ingredients are backed by robust scientific evidence relevant to the field of nutrition and dietetics.

Consumer Brands values the opportunity to provide comments on the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) (collectively the "Agencies") joint Request for Information (RFI) seeking "data and information to help develop a uniform definition of "ultra-processed" foods ("UPF" or "UPFs" for human food products in the

U.S. food supply.")[1] We appreciate in advance the Agencies' consideration of industry's perspectives.

Overview

Nutrient-dense foods should be the focus of dietary patterns and meeting food group needs.[2] We maintain that as the Agencies work to address diet-related chronic disease, the emphasis must be on science and consumer education on nutrient-dense foods, grounded in nutrients to encourage and nutrients to limit and food groups to encourage.[3] Definitions of "ultra-processed" foods often involve the "use of certain ingredients and substances (such as emulsifiers, bulking agents, or thickeners), industrial processing technologies, as well as sophisticated packaging, that result in a palatable and appealing product"[4] rather than the nutrient composition of foods and food groups within an evidence based dietary pattern.[5] While the associations between "ultra-processed" foods (UPFs) and chronic disease, mostly from observational studies, have drawn attention as a theoretical panacea to chronic disease, there is not a known direct or sufficiently explained scientific mechanism to explain the associations with obesity risk.[6] The prevailing NOVA definition of UPF is not principled, does not consider nutrient composition and patterns of food intake within portion size and energy density, and is over-inclusive. For example, the classification of "UPF" under the NOVA system could group together beef jerky, whole grain bread, pickles, canned tomato products, candy bars, high fiber cereal, guacamole, frozen healthy meals, ice cream, and countless other foods. To suggest that all of these foods contribute equally and negatively to a healthy eating pattern because of processing or formulation has no biological plausibility.[7] "The result is that NOVA is more a random collection of foods deemed less healthy on an undefined scale than a system with any common mechanism and basis for clear guidance."[8] A broad UPF definition will likely misclassify nutrient-dense foods, mislead consumers, derail innovation, and lead to enforcement confusion. It will likely also negatively impact people's access to safe, affordable foods. Accordingly, Consumer

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[1] Ultra-Processed Foods; Request for Information, 90 Fed. Reg. 35,305 (July 25, 2025).
[2] U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025*. 9th Edition. December 2020. Available at DietaryGuidelines.gov.
[3] *id.*
[4] Ultra-Processed Foods; Request for Information, 90 Fed. Reg. 35,305 at 35306 (July 25, 2025
[5] Valicente, V. M., Peng, C.-H., Pacheco, K. N., Lin, L., Kielb, E. I., Dawoodani, E., Abdollahi, A., & Mattes, R. D. (2023). *Ultraprocessed foods and obesity risk: A critical review of reported mechanisms*. *Advances in Nutrition, 14*(4), 718-738. https://doi.org/10.1016/j.advnut.2023.04.006
[6] *Id.*
[7] Sadler, C. R., Grassby, T., & Hart, K. (2021). Processed food classification: Conceptual confusion over key terms. *International Journal of Food Sciences and Nutrition, 72*(5), 659–667 https://doi.org/10.1080/09637486.2020.1792861.
[8] Valicente, V. M., Peng, C.-H., Pacheco, K. N., Lin, L., Kielb, E. I., Dawoodani, E., Abdollahi, A., & Mattes, R. D. (2023). *Ultraprocessed foods and obesity risk: A critical review of reported mechanisms*. *Advances in Nutrition, 14*(4) at 728. https://doi.org/10.1016/j.advnut.2023.04.006

Brands firmly believes that based on current science, the term “ultra-processed” food is unsuitable for definition.

A single definition cannot account for both food processing and ingredients or accurately "bundle” these concepts adequately while also considering nutritional impact. We are particularly concerned that the term “ultra-processed” is not grounded in rigorous objective peer-reviewed scientific research with reproducible results regarding any effect of processing or ingredient effect on the overall outcomes of food formulation, nutritional value, consumption, and health. Processing plays a fundamental and essential role in assuring access to safe, affordable, and nutritious foods across the U.S. food supply. Ingredients are essential for the safety, stability, palatability, and accessibility of food.[9] The identity or presence of individual ingredients should not determine classification of particular foods. Application of the term “ultra-processed” to describe foods, a term that has been used to demonize foods regardless of their nutrient density and utility, risks deterring consumers from selecting a wide range of affordable nutrient-dense foods, including foods with beneficial nutrients and food groups to encourage, many of which are recommended by evidence based dietary recommendations. The dietary pattern should continue to be emphasized as a whole “rather than individual nutrients, foods, or foods in isolation.”[10] Food classification systems and their associated criteria should encourage the food industry to innovate and reformulate against a clearly articulated and implementable set of guidelines.

Here, scientific research must take the lead; only if there is causal connection between certain types of foods and health outcomes, should the Agencies consider appropriate rulemaking in alignment with the President’s Executive Order on “Restoring Gold Standard Science.”[11] As shown by the first step in USDA’s Research Roadmap about Ultra-Processed Foods and Human Health,[12] there is a significant amount of research needed on methods and measures to categorize foods based on food processing, formulation and the interaction of the two. This work needs to take place before any “definition” can be established or is needed. Further,

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[9] Martin Michel et al., *Benefits and Challenges of Food Processing in the Context of Food Systems, Value Chains and Sustainable Development Goals*, 153 Trends Food Sci. & Tech**.** 104703 (2024), https://doi.org/10.1016/j.tifs.2024.104703

[10] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov.

[11] *Restoring Gold Standard Science*, Executive Order 14303 of May 23, 2025 — published in the *Federal Register* (Vol. 90, No. 102, pp. 22601–22606).

[12] O’Connor, Lauren E., 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*, vol. 14, no. 6, 2023, pp. 1255–1269. https://doi.org/10.1016/j.advnut.2023.09.005

authoritative international bodies like the Nordic Council of Ministers[13] and Scientific Advisory Committee on Nutrition (SACN)[14] have indicated that concerns that have been suggested with "ultra-processed" foods may be addressed by existing evidence-based nutritional science and dietary guidelines. The Agencies should consider further consumer education and scientific research on a better understanding of current models of consumption of nutrients to limit and nutrients to encourage and how these levels correlate to the U.S. food supply, its existing regulatory framework on processing, and consumer education before embarking on a quest to establish a definition. If the Agencies move forward with a definition of "ultra-processed" for regulatory purposes, the Agencies must do so through notice and comment rulemaking to allow for a fulsome administrative record consistent with the Administrative Procedures Act and considering input from relevant stakeholders. We maintain that as the Agencies work to address diet-related chronic disease, the emphasis must be on consumer education on nutrient-dense foods, grounded in food groups, nutrients to encourage and nutrients to limit in the context of the total diet. Any categorization of food should acknowledge the following:

As a grounding principle, America's food supply is safe. Food safety and protecting the integrity of the food supply are the number one priority of the makers of America's food and beverage products. Nutrient density should be the focus of dietary patterns and meeting food group needs. If the Agencies proceed with efforts to categorize food , the following principles form a basis for engagement:

(1) <u>Processing plays a critical role in ensuring food safety and supporting convenience and accessibility for American consumers.</u>

- Food processing transforms raw agricultural products into high-quality, safe consumables, extending the shelf life of foods, maintaining safety and nutritional value, guarding against food waste, and enabling innovation.
- Any categorization of foods or similar efforts should account for how processed foods are important for all Americans, and can help meet many different, individual needs regardless of physical condition, economic status, or cultural preferences.

(2) <u>Any categorization of food based on processing must be science-based, truthful, and not misleading.</u>

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[13] Nordic Council of Ministers, *Nordic Nutrition Recommendations 2023: Integrating Environmental Aspects*, Nordisk Ministerråd, 2023:003 (2023), available at https://www.norden.org/en/publication/nordic-nutrition-recommendations-2023.

[14] SACN statement on processed foods and health - summary report - GOV.UK

- The foundation for nutrition policy, ingredient vetting, and product labeling must be robust scientific evidence relevant to the field of nutrition and dietetics. Similarly, efforts to define food based on processing must be grounded in rigorous, reproducible, and transparent classifications that consider the effect on target health endpoints in humans.
- To ensure efforts concerning labeling, naming and categorization of food groups and dietary practices are truthful and not misleading or deceptive, they must be: grounded in rigorous scientific support; validated for causal connections of consumption; and have documented evidence of metabolic processes and evidence-based outcomes in humans.
- Efforts to categorize foods or recommend changes in policy must accurately reflect nutritional science with transparent and actionable information for consumers to inform dietary patterns.

(3) <u>Nutrients to encourage and nutrients to limit should be the basis of nutrition policy, rather than focusing on individual ingredients.</u>

- Recommendations or updates to existing food policy should focus on nutrients to encourage, nutrients to limit, and holistic consumer education on dietary patterns and lifestyle factors.
- This effort and collaboration should not demonize categories of food nor disenfranchise consumer access or preferences, and any updates should be based on robust scientific evidence.
- Any food categorization scheme should identify a clear purpose and metrics for determining the end results.
- Existing consumer transparency tools like SmartLabel[15] and Facts up Front[16] provide product information beyond the nutritional facts label. These tools complement existing regulatory frameworks and can easily be adapted to new guidance, regulatory updates and consumer education focuses by federal agencies.

In our comments that follow, we discuss the scientific and regulatory concerns with defining the concept of “ultra-processed food,” while also suggesting potential steps the Agencies could take to enhance consumer education and conduct robust scientific research in the areas of nutrition science and food formulation. We maintain that as the Agencies work to address diet-related chronic disease, the emphasis must be on consumer education on nutrient-dense foods,

[15] https://smartlabel.org/
[16] https://consumerbrandsassociation.org/facts-up-front/

grounded in food groups and nutrients to encourage and nutrients to limit in the context of the total diet.

Discussion

The term "ultra-processed food" is not suitable for definition because it fails to differentiate based on nutrient content, lacks a scientific basis to isolate particular ingredients or processing steps, and its use would result in significant unintended consequences.

The term "ultra-processed food" and similar concepts are not suitable for definition by FDA and USDA. The Agencies should not develop a definition for a categorization of food based on processing and ingredients and should not use the term "ultra-processed" in these efforts until and if an objective approach can be established through extensive scientific research that follows principles. The principles must acknowledge: 1) Processing plays a critical role in ensuring food safety and supporting convenience and accessibility for American consumers; 2) Any categorization of food based on processing must be science-based, truthful, and not misleading; 3) Nutrients to encourage and nutrients to limit should be the basis of nutrition policy, rather than focusing on individual ingredients. Proceeding with a definition absent these crucial steps would be arbitrary and capricious because the science fails to support an appropriate definition of the term.

The term "ultra-processed food" is inherently prone to multiple conflicting categorizations, with each classification system having its own internal contradictions and inconsistencies. As an example, NOVA's purported "ultra-processed" definition could capture as much 50%-70% of the food supply, overtly casting the food supply in a negative and unsubstantiated categorization.[17] Given the current environment, where researchers and consumers[18] alike do not understand and cannot agree on the meaning of the term or how it is applied, and states are seeking to define the term in conflicting ways, it is imperative for FDA and USDA to undertake a thoughtful and deliberative process when wading into the debate, rather than getting ahead of the science. **It is crucial to ensure that any regulatory action is grounded in a robust, science-based approach to enhance consumer understanding and promote nutritious dietary practices with an emphasis on nutrient-dense foods (regardless of level of processing) as the foundation of a healthy dietary pattern.**

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[17] Renée Johnson & Alexandria K. Mickler, *UltraProcessed Foods (UPF): Background and Policy Issues*, CRS In Focus IF12826 (Nov. 22, 2024), available at https://www.congress.gov/crs-product/IF12826

[18] Araújo TP, de Moraes MM, Afonso C, Santos C, Rodrigues SSP. Food Processing: Comparison of Different Food Classification Systems. Nutrients. 2022 Feb 9;14(4):7

Below, we discuss the scientific and policy rationale supporting our position that the term "ultra-processed food" and similar concepts are not suitable for the Agencies to define.

1. **Processing-Based Food Classification Schemes, By Ignoring Nutrient Content, are Inconsistent with Well-Established Nutrition Science and Should Not be the Basis for Food Classification or Dietary Recommendations.**

As previewed above, a significant fault of models purporting to characterize food based on processing, is that they completely neglect nutrient content, including macronutrients and micronutrients, nutrient density, and meeting food group needs with nutrient-dense foods within calorie limits and limiting added sugars, sodium, and saturated fats.[19] This approach contradicts established nutrition science, which bases dietary recommendations on macronutrients, micronutrients, and limiting nutrients like added sugar, saturated fat, and sodium for optimal energy intake and balanced food groups.[20] Such models risk impacting healthy dietary patterns containing nutrient-dense food sources in adequate amounts, which is fundamental for health maintenance and disease prevention at all stages of life.[21] This runs contrary to well-established nutrition science, which is founded on the role of nutrients. Importantly, whether a food has undergone varying levels of processing is not determinative of negative nutritional value and, by extension, how a food fits into an overall healthy dietary pattern.

Beyond these points, there is no causal evidence linking "ultra-processed foods" or any of the ingredients or processes highlighted in the definitions of this term, to adverse health outcomes. The Systematic Review Protocol developed with USDA methods resulted in a conclusion from the Dietary Guidelines Advisory Committee that highlighted the lack of reliable intervention studies and characterized as "limited" the evidence linking growth, body composition, and risk of obesity with "ultra-processed foods."[22] The "limited evidence" categorization indicates a small body of research with significant limitations, such as serious issues with study design, exposure misclassification, or poorly characterized assessments of dietary components. This is important

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[19] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov

[20] *Id.*

[21] Espinosa-Salas S, Gonzalez-Arias M. Nutrition: Macronutrient Intake, Imbalances, and Interventions. [Updated 2023 Aug 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK594226/

[22] Stanford, F. C., Taylor, C., Hoelscher, D. M., Anderson, C. A. M., Booth, S., Deierlein, A., Fung, T., Gardner, C., Giovannucci, E., Raynor, H., Talegawkar, S., Tobias, D., English, L. K., Higgins, M., Callahan, E., Raghavan, R., Reigh, N., Butera, G., Terry, N., & Obbagy, J. (2024, November). *Dietary Patterns with Ultra-Processed Foods and Growth, Body Composition, and Risk of Obesity: A Systematic Review.* U.S. Department of Agriculture, Food and Nutrition Service, Center for Nutrition Policy and Promotion, Nutrition Evidence Systematic Review. https://doi.org/10.52570/NESR.DGAC2025.SR11

because without such evidence it is unclear how researchers or the Agencies would have confidence that any definition is accurate.

Numerous scientific and health authorities have raised concern about the validity of classifying foods as "ultra-processed," including the UK Scientific Advisory Committee on Nutrition[23], and Nordic Nutrition Recommendations (NNR).[24]The Scientific Advisory Committee on Nutrition (SACN) in the UK performed a literature review and considered "ultra-processed" foods and found that it is "unclear to what extent observed associations between (ultra-) processed foods and adverse health outcomes are explained by established nutritional relationships between nutritional factors and health outcomes on which SACN has undertaken robust risk assessments."[25] Further, "observed associations between higher consumption of (ultra-) processed foods and adverse health outcomes are concerning – however, the limitations in the NOVA classification system, the potential for confounding, and the possibility that the observed adverse associations with (ultra-) processed foods are covered by existing UK dietary recommendations mean that the evidence to date needs to be treated with caution."[26] These findings echo those made by the NNR 2023 that are discussed further below. In 2025, the SACN performed an updated literature review on ultra-processed studies and made recommendations to the government to address processing within the existing UK nutritional framework. This includes implementing the existing guidelines, considering whether messaging on processing improves dietary intakes, monitoring intake of individual additives, and requiring information on additives and processing methods to be publicized.[27]

In addition to the U.S. Dietary Guidelines Advisory Committee and the SACN, the NNR Committee also *found the scientific basis for an "ultra-processed foods" definition to be lacking and its use to be unnecessary in a dietary system based on nutrients and food groups to encourage and limit*. The NNR provides dietary guidelines for one of the healthiest populations in the world which, like the U.S. Dietary Guidelines are based on nutrients and food groups to encourage and to limit, found that the NOVA classification system of foods includes many food products which are not associated with any apparent adverse health effect.[28] Further, the "NNR

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[23] https://www.gov.uk/government/publications/processed-foods-and-health-sacns-rapid-evidence-update
[24] Nordic Council of Ministers, *Nordic Nutrition Recommendations 2023: Prevention of Diet-Related Chronic Diseases* (2023), p. 103. https://www.norden.org/en/publication/nordic-nutrition-recommendations-2023
[25] Scientific Advisory Committee on Nutrition (SACN)**.** (2023). *SACN statement on processed foods and health – summary report*. Department of Health and Social Care, UK Government
[26] *id.*
[27] Scientific Advisory Committee on Nutrition. *Processed foods and health: SACN's rapid evidence update – summary*. Office for Health Improvement & Disparities. 2 April 2025. Accessed at Processed foods and health: SACN's rapid evidence update
[28] Nordic Council of Ministers, *Nordic Nutrition Recommendations 2023: Prevention of Diet-Related Chronic Diseases* (2023), p. 103. https://www.norden.org/en/publication/nordic-nutrition-recommendations-2023.

Committee's view is that the current categorization of foods as ultra-processed foods does not add to the already existing food classifications and recommendations in NNR2023 These [Food Based Dietary Guidelines] FBDGs and [Daily Reference Values] DRVs greatly overlap with many aspects of ultra-processed foods."[29]

2. The Agencies Should Not Demonize Safe and Nutritious Foods by Including Them in the Term "Ultra-Processed Foods"

As the RFI mentions, some foods that could be classified as "UPF" are known to have beneficial effects on health and are recommended as part of healthy dietary patterns."[30] The RFI goes on to note that, it is "important therefore to consider unintended consequences of an overly-inclusive definition of UPFs that could discourage intake of beneficial foods."[31] Consumer Brands wholeheartedly agrees with this concern noted in the RFI and believes that it is strong enough to weigh against the Agencies proceeding definition of "ultra-processed" foods.

Numerous nutritious foods, including those that are nutrient-dense and/or otherwise, contribute to balanced diets as well as foods that offer alternatives to macronutrients of concern, would be considered "ultra-processed" under the NOVA classification. These include foods that would qualify for a "healthy" nutrient content claim under FDA's recently revised criteria, which is intended to identify foods that are particularly useful as the foundation of a diet that is consistent with dietary recommendations. FDA explains in the final rule that use of the term "healthy,"[32] while voluntary, can augment consumer choice of nutrient-dense foods.[33] Examples include yogurt, wheat bread, fortified cereals, plant-based products, nut butters, dried fruits, marinated meat and poultry, and canned tomatoes, all of which provide nutrients to encourage.[34] A definition of "ultra-processed food" could conflict with the "healthy" nutrient content claim[35], cause consumer confusion, and threaten consumer access to "healthy" foods.

In fact, many processed foods are nutrient-dense, including yogurt, tofu, dried fruit, canned vegetables, dietary supplements such as protein powders and meal replacements shakes and bars, meat and poultry products, whole-grain breads, fortified cereals, plant-based meat alternatives, and nuts. Processing can further help with foods that meet particular medical needs such as infant formula, medical foods, and foods for those who have allergies. In particular, demonizing infant formula and medical foods could result in people not having access

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[29] *id.*
[30] Ultra-Processed Foods; Request for Information, 90 Fed. Reg. 35305 at 35306 (July 25, 2025)
[31] *id.*
[32] Food Labeling: Nutrient Content Claims; Definition of Term "Healthy," Final Rule, 89 Fed. Reg. 106064 (Dec. 27, 2024).
[33] *Id.*
[34] *id.*
[35] *id.*

to or undermining the importance of these lifesaving foods. Moreover, food processing affords a diverse array of nutrient-dense foods across a variety of health needs and cultural customs. For example, for people with allergies/intolerances, dietary or cultural preferences, processing provides options such as lactose-free milk, plant-based alternatives, gluten free products, etc. and ensures that these options not only exist but are nutritionally comparable alternatives for those who cannot consume standard versions. Without these innovations in processing, significant populations would be without lifesaving foods in some cases and have limited food options in other cases.

Any categorization or definition of food or food groups should be consistent with foundational nutritional science principles, focusing on encouraging overall balanced diets that consider portion size and moderation, including the intake of nutrient-dense foods and limiting nutrients of concern. Indeed, nutrient-based classification schemes are recognized as more appropriate tools than processing-based schemes to correlate the intake of certain foods, healthier eating patterns, and by extension, health outcomes.[36]

Processing enables innovation aimed at improving nutritional composition, such as fortification to increase beneficial nutrients or reformulation to reduce nutrients of concern to align with consumers' dietary and lifestyle needs. What is more, processing enables the creation and availability of low and no-calorie sweeteners which are helpful for managing blood sugar levels in diabetic patients and in people who want to maintain or reduce their caloric intake as part of a healthy dietary pattern. A recently published randomized controlled trial showed that sweeteners and sugar enhancers in a healthy diet can support weight loss maintenance and beneficial gut microbiota shifts in adults with overweight and obesity.[37] Food processing *methods*, such as pasteurization, fermentation, and thermal processing, play critical roles in controlling microbial and chemical hazards to ensure the delivery of safe foods. Additional methods provide for shelf-stability of products by removing moisture, reducing oxidation, and permeability to light. Methods also allow for innovation giving more and nutritious options to those whose dietary patterns are restricted. For example, extrusion allows for the creation of plant-based burgers and soy-based products which are protein-rich alternatives for those who do not consume meat or dairy.

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[36] Weaver CM, Dwyer J, Fulgoni VL 3rd, King JC, Leveille GA, MacDonald RS, Ordovas J, Schnakenberg D. Processed foods: contributions to nutrition. Am J Clin Nutr. 2014 Jun;99(6):1525-42. doi: 10.3945/ajcn.114.089284; Visioli, F., Marangoni, F., Fogliano, V., Del Rio, D., Martinez, J. A., Kuhnle, G., Buttriss, J., Da Costa Ribeiro, H., Bier, D., & Poli, A. (2022). The ultra-processed foods hypothesis: A product processed well beyond the basic ingredients in the package. Nutrition Research Reviews, 1–11. "https://doi.org/10.1017/S0954422422000112"https://doi.org/10.1017/S0954422422000112.

[37] Pang, M.D., Kjølbæk, L., Bastings, J.J.A.J. *et al.* Effect of sweeteners and sweetness enhancers on weight management and gut microbiota composition in individuals with overweight or obesity: the SWEET study. *Nat Metab* (2025). https://doi.org/10.1038/s42255-025-01381-z

Moreover, nutrition attributes that form the basis of overall diet quality have been shown to be linked to health outcomes[38] and as such, nutritional attributes that affect overall dietary profile should be the foundation of any regulatory characterization for food when the objective is to improve the health of Americans through better dietary patterns. In contrast, by focusing on inclusion of particular ingredients while neglecting nutrient content, the NOVA system and other similar "ultra-processed food" definitions fail to reflect basic nutrition science and fail to support consumers in achieving nutrient-dense dietary patterns.[39]

3. The Agencies Should Consider the Significant Unintended Consequences on Access to Safe and Sometimes Critical Foods Any Definition of "Ultra-Processed Foods" Would Generate

In addition to the lack of scientific basis for a definition of the term "ultra-processed food," creating such a definition would have significant unintended consequences from a policy perspective. Classifying foods as "ultra-processed" could discourage people from eating food that falls under the "Healthy" claim and other nutrient-dense foods that are included in the NOVA "ultra-processed" definition. Further, from the perspective of access, an "ultra-processed" definition could further food insecurity within America by limiting access to safe, nutritious, and affordable foods. In 2023, 13.5% of households were food insecure.[40] The levels of food insecurity varied by state, with the states of Texas, Oklahoma, Arkansas, Louisiana, Mississippi, South Carolina, and Kentucky showing food insecurity above the U.S. average.[41] HHS's Office of Disease Prevention and Health Promotion Healthy People 2030, Access to Foods that Support Healthy Dietary Patterns, found "a relationship between the inability to access foods that support healthy dietary patterns and negative health outcomes. Affordability also influences

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[38] Taylor RM, Haslam RL, Herbert J, Whatnall MC, Trijsburg L, de Vries JHM, Josefsson MS, Koochek A, Nowicka P, Neuman N, Clarke ED, Burrows TL, Collins CE. Diet quality and cardiovascular outcomes: A systematic review and meta-analysis of cohort studies. Nutr Diet. 2024 Feb;81(1):35-50. doi: 10.1111/1747-0080.12860. Epub 2023 Dec 21. PMID: 38129766; Boushey C, Ard J, Bazzano L, et al. Dietary Patterns and All-Cause Mortality: A Systematic Review [Internet]. Alexandria (VA): USDA Nutrition Evidence Systematic Review; 2020 Jul. Available from: https://www.ncbi.nlm.nih.gov/books/NBK578477

[39] *Processed food classification: Conceptualisation and challenges.Trends in Food Science & Technology, 112, 149–162.* https://doi.org/10.1016/j.tifs.2021.03.047

[40] Rabbitt, Matthew P., Melissa Reed-Jones, Leila J. Hales, and Margaret P. Burke. *Statistical Supplement to Household Food Security in the United States in 2023* (Report No. AP-124). U.S. Department of Agriculture, Economic Research Service, 2024.

[41] *Id.* and Food Security in the U.S. - Key Statistics & Graphics | Economic Research Service

access to foods that support healthy dietary patterns."[42] Research supporting the goals of Healthy People 2030 found that USDA's metrics of food insecurity mentioned above likely underestimate the prevalence of food insecurity as they do not consider the full impact of economic instability, the full extent of distance from a supermarket, and informational barriers.[43]

Food processing complements and supports farming and agricultural practices by transforming agricultural products such as grains, fruits, vegetables, and milk into food ingredients or "processed food" products. Further, processing is a critical component of food safety, shelf-life, nutrition, formulation of medical foods and foods that meet religious or moral dietary needs, sustainable eating practices, and innovation. Putting processing in a negative light could result in consumer confusion, fear or reduced use of processing steps that are critical to food access, safety, and more. Any definition or food classification system should reflect that food processing delivers a variety of benefits and processed foods are part of modern daily life in the United States.[44]

As mentioned above, processing allows food and beverage manufacturers to deliver safe products that are nutritious, affordable, and convenient, while also reducing food waste and supporting public health objectives. Processing gives food products longer shelf life, allowing food to be transported, stored, and available to consumers in ways to optimize food accessibility and equity. Meeting the nutritional needs in rural settings and urban communities, often at a disadvantage in the availability of safe, accessible and affordable food options is made possible through food processing.

Consumer Brands continues to urge the Agencies to consider the implications of a definition that would hinder a critical component of food production and manufacturing. Food processing is essential to the American diet and lifestyles to improve health equity and nutrition security, including food safety, affordability, accessibility, convenience, enjoyment, and the reduction of food waste.

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[42] Office of Disease Prevention and Health Promotion, Department of Health and Human Services, (n.d.). *Access to foods that support healthy dietary patterns — NWS-01*. Healthy People 2030. U.S. Department of Health and Human Services. https://health.gov/healthypeople/objectives-and-data/browse-objectives/nutrition-and-healthy-eating/access-foods-support-healthy-dietary-patterns-nws-01

[43] Sharareh N, Wallace AS. Applying a Health Access Framework to Understand and Address Food Insecurity. Healthcare (Basel). 2022 Feb 17;10(2):380. doi: 10.3390/healthcare10020380. PMID: 35206993; PMCID: PMC8872536.

[44] Hess JM, Comeau ME, Scheett, AJ, Bodensteiner A, Levine AS. Using less processed food to mimic a Standard American Diet does not improve nutrient value and may result in a shorter shelf life at a higher financial cost. *Curr Dev Nutr*. 2024 Oct 2;8(11):104471. doi:10.1016/j.cdnut.2024.104471. PMID: 39512845

Responses to FDA/USDA Requests for Information

While Consumer Brands is providing responses to the below questions as posed in the RFI, any reference to "ultra-processed foods," including any sources or terminology that attempt to categorize or define alleged "ultra-processed food," is undertaken solely for the purpose of responding to the questions in the RFI and is not an assertion of adoption or acceptance by Consumer Brands of any such categorization or any finding in any referenced source.

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.*

FDA and USDA should look to established and evidence-based principles of nutrition science as reflected in the *Dietary Guidelines for Americans*[45], support additional research on American dietary practices and diet quality, and make workable recommendations for dietary patterns grounded in rigorous science, rather than developing a definition for "ultra-processed" food or similar concepts prematurely ahead of scientific consensus. We recommend a more holistic focus on nutrient and food group content as part of recommended dietary practices.

The most widely recognized processing-based classification system, NOVA, was not developed for the U.S. food supply. Even the authors concede that the classification may not be appropriate for countries where processed foods make up the majority of the food supply.[46] Further, the term "ultra-processed food" was developed in the context of a specific classification scheme that presumes harm without scientific rigor, objectivity, or plausible biological mechanisms. Thus, the term is inherently biased and pejorative. Specifically, the term "ultra-processed food" was developed as part of the NOVA food classification system in 2009 by the Center for Epidemiological Studies in Health and Nutrition, School of Public Health, University of Sao Paulo.[47] The NOVA classification system groups foods according to the extent and purpose of industrial processing – principally through evaluating the inclusion of specific ingredients –

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[45] U.S. Department of Agriculture & U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025.* 9th Edition. December 2020. Available at DietaryGuidelines.gov.
[46]Baker, P., & Monteiro, C. (2025). Policies on ultra-processed diets: Feasible and urgent. *The Lancet Diabetes & Endocrinology*, *13*(8), 649–650. https://doi.org/10.1016/s2213-8587(25)00194-9
[47] Monteiro, C.A., "Nutrition and Health. The Issue Is Not Food, nor Nutrients, so Much as Processing." *Public Health Nutrition.* 2009; 12: 729–731. Accessed August 29, 2025. Available at https://doi.org/10.1017/S1368980009005291

across four categories.[48] The NOVA 4 category ("ultra-processed" foods) has become the source of significant debate about foods typically described as “Formulations of ingredients, mostly of exclusive industrial use, made by a series of industrial processes, many requiring sophisticated equipment and technology “ OR “Industrially manufactured food products made up of several ingredients (formulations) including sugar, oils, fats and salt (generally in combination and in higher amounts than in processed foods) and food substances of no or rare culinary use.“[49] Processing-based classification schemes like NOVA, have become the subject of significant debate and criticism, with researchers observing the many inherent flaws, contradictions, and inconsistencies in the framework and the outcomes produced with its application. These concerns about "ultra-processed” classification systems include:

- The term “ultra-processed food” is a misnomer, as processing-based schemes do not categorize foods merely by processing as the name suggests, but instead focus on the number and types of ingredients as determinative of a food’s healthfulness.[50]
- And yet there is a critical lack of evidence supporting that the ingredients that characterize a food as “ultra-processed” under the various proposed schemes, merit such characterization. Importantly, the proposed NOVA system lacks biological plausibility, meaning that there is no unifying factor or biological mechanism of action that would suggest that the broad NOVA 4 category – uniformly and across a wide range of different foods – is linked to health risks.[51]
- The differing treatment for home-cooked vs. packaged foods, which lacks a scientific basis[52] and ignores that home-cooked foods are nutritionally similar to packaged versions of the same food.
- The schemes lack clear, objective and precise criteria, and cannot be consistently applied, easily leading to misclassification, unreliable research results, and consumer confusion.

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[48] Monteiro, C.A., Cannon, G., Lawrence, M., Costa Louzada, M.L. and Pereira Machado, P. 2019. *Ultra-processed foods, diet quality, and health using the NOVA classification system*. Rome, FAO.
[49] O'Connor LE, Herrick KA, Papier K. Handle with care: challenges associated with ultra-processed foods research. Int J Epidemiol. 2024 Aug 14;53(5):dyae106. doi: 10.1093/ije/dyae106. Erratum in: Int J Epidemiol. 2024 Aug 14;53(5):dyae133. doi: 10.1093/ije/dyae133. PMID: 39191478; PMCID: PMC11349190, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11349190/
[50] Rodrigo Rodrigues Petrus, Paulo José do Amaral Sobral, Carmen Cecília Tadini, Cintia Bernardo Gonçalves, The NOVA classification system: A critical perspective in food science, Trends in Food Science & Technology, Volume 116,2021,Pages 603-608,ISSN 0924-2244, https://doi.org/10.1016/j.tifs.2021.08.010.
[51] Sadler, C.R., et al. (2021). *Processed food classification: conceptual confusion over key terms.* International Journal of Food Science & Nutrition,
[52] Pellegrini B, Strootman LX, Fryganas C, Martini D, Fogliano V. “Home-made vs industry-made: Nutrient composition and content of potentially harmful compounds of different food products.” Curr Res Food Sci. 2024 Dec 15;10:100958. Accessed 8/29/25. Available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11730957/

For example, research shows that even nutrition experts cannot consistently classify foods to one of the four NOVA categories. [53]

- NOVA ignores that international bodies have found that the current dietary guidelines based on nutrient density may already explain what is being found in "ultra-processed" food research, and the need for better education on the current guidelines.

Other systems have been developed to attempt to address shortcomings with NOVA or particular features of the system. These include Siga,[18] IFPRI,[54] and UNC.[55] The UNC system adds additional categories to the NOVA system to help consumers distinguish between "ultra-processed" and processed foods when preparing them in the home.[56] This system leads to consumers characterizing some foods tagged as "ultra-processed" under NOVA as "processed" under UNC, but the system does not account for nutrients within the products identified.[57] IFPRI breaks down the categorization of foods based on processing into three groups instead of four, unprocessed, partially (primary) processed foods, and highly-processed foods, but this system does not accurately address processing levels as one of its flaws.[58] For example, although the Siga system does consider some nutrients, added salt, sugar, and fat, it does not consider overall nutrient density, given that it is designed for food profiles of France, and should not be applied to the United States. However, all the aforementioned systems are fundamentally flawed and therefore not suitable to be applied regulatory policy in the United States.

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[53] 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 Sept; 76(9): 1245-53 (Of the 231 foods evaluated by 159 French food and nutrition specialists, only 4 foods were assigned to the same NOVA group by all the evaluators, and most of the foods in both lists were placed in two, three, or even four NOVA groups. The authors concluded, "Although assignments were more consistent for some foods than others, overall consistency among evaluators was low, even when ingredient information was available. These results suggest current NOVA criteria do not allow for robust and functional food assignments.").

[54] Asfaw A. Does consumption of processed foods explain disparities in the body weight of individuals? The case of Guatemala. Health Econ. 2011;20:184–195. doi: 10.1002/hec.1579.

[55] Bleiweiss-Sande R. Bailey BP, Sacheck J, Goldberg JP. Addressing challenges with the categorization of foods processed at home: a pilot methodology to inform consumer-facing guidance. Nutrients 2020; 12(u) 2373. Doi 10.3390/nu12082373

[56] [56] TBleiweiss-Sande, R., Bailey, C. P., Sacheck, J., & Goldberg, J. P. (2020). Addressing Challenges with the Categorization of Foods Processed at Home: A Pilot Methodology to Inform Consumer-Facing Guidance. *Nutrients*, *12*(8), 2373. https://doi.org/10.3390/nu12082373

[57] *Id.*

[58] Yrjo H Roos, Food processing levels and processed food intake classification, Future Foods, 10.1016/j.fufo.2025.100751, 12, (100751), (2025).

The differing schemes reflect a significant lack of consensus on which aspects of a food determine its level of processing.[59] Moreover, inconsistent interpretation by researchers within existing classification systems demonstrates a lack of consensus of what purportedly-defined terms mean.[60] This lack of consensus affects the assessment, comparison, and interpretation of studies related to various classifications and certain measurements of nutrients and ingredients.[61]

Also, the term "ultra-processed" is disingenuous to describe the NOVA categorization system and other similar systems because it does not divide foods according to processing.[62] "Food processing may be classified, for example, in nominal categories according to the type of processing involved, such as physical operations and microbial, biochemical and chemical processes[63] "Although, classification typically divides the objects of classification to groups which may or may not be known prior to classification the NOVA categories have no common processing variable for the grouping of processed foods.[64]

Further, NOVA adds little to existing food-based dietary guidelines and nutrient-profiling systems' ability to identify healthy foods and diets.[65] The many disadvantages of NOVA is its lack of consideration of nutrient density and similar classification schemes are discussed in more detail in our comments, above, on page 3-7. These disadvantages include:

1) The NOVA system fails to include the principle that nutrients and food groups to encourage and nutrients to limit in the context of the total diet should be the basis of nutrition policy;
2) The NOVA system ignores that processing plays a critical role in ensuring food safety and supporting convenience and accessibility for American consumers;
3) The NOVA definition lacks a scientific basis; and

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[59] Sadler, C.R., Grassby, T., Hart, K., Raats, M., Sokolović, M., & Timotjevic, L. Processed food classification: Conceptualisation and challenges. Trends in Food Science & Technology. 2021 Apr; 112: 149-62.
[60] Braesco, V., Souchon, I., Sauvant, P. *et al.* Ultra-processed foods: how functional is the NOVA system?. *Eur J Clin Nutr* 76, 1245–1253 (2022). https://doi.org/10.1038/s41430-022-01099-1
[61] Gibney, M. Ultra-processed foods in public health nutrition: The unanswered questions. Br J Nutr. 2022 Dec 14; 1-4.
[62] Yrjo H Roos, Food processing levels and processed food intake classification, Future Foods, 10.1016/j.fufo.2025.100751, 12, (100751), (2025).
[63] *Id.* citing G. Saravacos, A.E. Kostaropoulos, Handbook of Food Processing Equipment (2nd Ed.), Springer Science+Business Media, New York (2016), p. 775.
[64] A.D. Gordon Classification (2nd ed.), Chapman and Hall, Boca Raton, FL (1999)
[65] Scientific Advisory Committee on Nutrition (SACN)**.** (2023). *SACN statement on processed foods and health – summary report*. Department of Health and Social Care, UK Government and Nordic Council of Ministers, *Nordic Nutrition Recommendations 2023: Prevention of Diet-Related Chronic Diseases* (2023), p. 103. https://www.norden.org/en/publication/nordic-nutrition-recommendations-2023

4) The NOVA classification is overbroad and "demonizes" healthy and medically necessary foods.

Consumer Brands' position is that current science supports a nutrient based framework for setting policy. However, Consumer Brands also acknowledges keen interest in studying food's impact on health based on processing and formulation. As further research in that area progresses, any ensuing categorization of food should consider a stepwise approach. The multi-tiered set of principles developed by the Institute for the Advancement of Food and Nutrition Sciences (IAFNS)[66] working group and an independent writing team to guide the development and application of a food classification system.[67] The nine guiding principles follow.

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.
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.

Rather than seeking to develop a definition for "ultra-processed foods,"[68] Consumer Brands

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[66] https://iafns.org/publication/toward-a-science-based-classification-of-processed-foods-to-support-meaningful-research-and-effective-health-policies/
[67] Institute for the Advancement of Food and Nutrition Sciences Bernstein, Brown, Freeman, Estevez, Hess, Hubert, and Latulippe Concept Paper: Perspective: Guiding Principles for Science-Based Food Classification Systems Focused on Processing and Formulation, July 23. 2025, doi: 10.20944/preprints202507.1896.v1.
[68]Institute for the Advancement of Food and Nutrition Sciences Bernstein, Brown, Freeman, Estevez, Hess, Hubert, and Latulippe Concept Paper: Perspective: Guiding Principles for Science-Based Food Classification Systems Focused on Processing and Formulation, July 23. 2025, doi: 10.20944/preprints202507.1896.v1.

recommends that the Agencies pursue the steps discussed in our response to Question 6 of the RFI below, which include doing more scientific research on dietary consumption patterns of nutrients to encourage and nutrients to limit, conducting additional consumer education and outreach, sharing SmartLabel and Facts up Front as existing, readily available tools for consumer education, and using the current *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives* (June 2014).[69] Further, as discussed in our response to question 5 of the RFI, nutrient-based and food group-based approaches to evaluating the role of a food in a healthy dietary pattern, are more appropriate and scientifically founded than proposed models based on processing or individual ingredients.

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

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

    b. *Ingredients that appear toward the end of an ingredient list may contribute minimally to the overall composition and weight of a finished food (for example, ingredients may sometimes be listed as containing 2% or less by weight of the finished food (21 CFR 101.4(a)(2)). What types of these less prominent ingredients (e.g., ingredients that may share a similar composition, function, or purpose) might be used to characterize a food as ultra-processed? Further, ingredients that function as flavorings are either natural flavors or artificial flavors; colorings are either certified (for instance, "FD&C Red No. 40") or non-certified (for instance, "colored with beet juice") (21 CFR 101.22). Should these various types of flavors and colors be considered separately when characterizing a food as ultra-processed? Please provide supporting data and explain your rationale in your response.*

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[69] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-assessing-effects-significant-manufacturing-process-changes-including-emerging

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

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

There is no scientific basis that would support classifying foods "ultra-processed" based solely on the inclusion of individual ingredients, whether by type or the amount present. Many multi-ingredient foods play a role in helping consumers obtain healthy dietary patterns and many ingredients added to foods have beneficial effects.[70] Notably, "additives are ingredients, and do not indicate a level of processing" of the food.[71] As discussed elsewhere in these comments, to the extent the Agencies determine there is a need for a definition of "ultra-processed foods," it should be based on the food's nutritional content in the context of the total diet, not on the presence, number, or amount of a particular ingredient or ingredients. Evidence has shown that food composition, rather than the level of processing, can impact nutrient intake. For instance, a proof-of-concept study was designed to determine the feasibility of building a menu that aligns with recommendations for a healthy dietary pattern from the 2020 DGA and includes ≥80% kcal from "UPF" as defined by NOVA.[72] Further underscoring the inapplicability and flaws of NOVA's focus points on industrially manufactured ingredients in determining the healthfulness of food, the study's results showed that healthy dietary patterns can include most of their energy from UPF, still receive a high diet quality score, and contain adequate amounts of most macro- and micronutrients.[73] Specifically, the Healthy Eating Index-2015 score was 86 out of a possible 100 points, showing that meals comprised of "ultra-processed" foods can be nutrient-dense and be part of a recommended dietary pattern. This menu provided adequate amounts of all macronutrients and micronutrients except vitamin D, vitamin E, and choline.[74] Since this is just one menu and consumers are eating foods that are not "ultra-processed,"[75] as a part of dietary

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[70] See for example, Olson, R.; Gavin-Smith, B.; Ferraboschi, C.; Kraemer, K. Food Fortification: The Advantages, Disadvantages and Lessons from *Sight and Life* Programs. *Nutrients* 2021, *13*, 1118. https://doi.org/10.3390/nu13041118

[71] Trumbo et al. 2024. Toward a science-based classification of processed foods to support meaningful research and effective health policies. Food Pol and Econ. https://www.frontiersin.org/journals/nutrition/articles/10.3389/fnut.2024.1389601/full.

[72] 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.

[73] *Id.*

[74] *Id.*

[75] https://www.cdc.gov/nchs/data/databriefs/db536.pdf

patterns, consumers would be able to get Vitamin, D, Vitamin E, and choline through other nutrient dense foods that are a part of evidence based dietary guidelines.

Many foods with multiple ingredients contribute to food group consumption and can be a factor in healthy dietary patterns. For example, yogurt mixed with fruit or frozen vegetables with sauce are foods that could meet the FDA's recently established "healthy" definition. The presence of ingredients such as added colors, stabilizers, preservatives, or emulsifiers does not diminish from a food's potential role in a healthy diet and therefore should not result in it being classified as "ultra-processed." Rather, the presence of these ingredients makes healthy foods more palatable to consume and can ensure food product stability and safety for ultimate consumption. There is lack of clear evidence demonstrating that the inclusion of a food additive or ingredients with limited to negligible nutritional values added for technical purposes (e.g., an emulsifier, preservative, sweetener, or a fruit juice concentrate, etc.) changes how a food is metabolized or the role of the food in the diet. Additionally, some ingredients which may have cosmetic or structural functions in food may make up less than 2% of the total weight of the finished product, as reflected within the ingredient statement on the label, should not devalue the overall nutritional value of a food.

Ingredients developed through food processing can serve a variety of benefits as consumers seek to build healthy dietary patterns, including with support by the Agencies in certain cases. For instance, the addition of low- and no-calorie sweeteners, when substituted for nutritive sweeteners, can reduce added sugar and calorie intake, which are critical public health goals. [76] Similarly, salt substitutes can help reduce sodium consumption and are associated with reduced cardiovascular risk; to the extent that they have been acknowledged by FDA in its sodium reduction targets.[77] Specifically, FDA issued voluntary sodium reduction targets in 2021 and manufacturers rose to the challenge. In fact, a former FDA Deputy Commissioner of Human Foods observed that reducing sodium in the food supply has the potential to be one of the most important public health initiatives in a generation.[78] As of 2022, 40% of food categories already

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[76] Association of Low- and No-Calorie Sweetened Beverages as a Replacement for Sugar-Sweetened Beverages With Body Weight and Cardiometabolic Risk: A Systematic Review and Meta-analysis – PubMed, https://pubmed.ncbi.nlm.nih.gov/35285920/; See also High-intensity sweeteners are used in small amounts to provide sweetness without significant calories. They can help with managing calorie intake and may be beneficial for individuals trying to reduce their intake of added sugars."
U.S. Food & Drug Administration. (2021). Additional Information about High-Intensity Sweeteners Permitted for Use in Food in the United States.
https://www.fda.gov/food/food-additives-petitions/additional-information-about-high-intensity-sweeteners-permitted-use-food-united-states

[77] FDA recently announced in its Spring 2025 Unified Agenda that it intends to finalize a rule that allows salt substitutes to be used in place of sodium chloride in standardized foods.

[78] https://www.fda.gov/news-events/press-announcements/fda-announces-milestone-sodium-reduction-efforts-issues-draft-guidance-lower-target-levels-certain#:~:text=The%20U.S.%20Food%20and%20Drug%20Administration%20(FDA),of%20the%20targets%20have%20already%20been%20reached

had less sodium and new Phase II sodium targets were issued in 2024.[79] The sodium targets along with the "healthy rule" and other nutrition initiatives were a part of FDA's nutrient-based strategy to address chronic disease.[80] FDA should assess and share the evidence-based data from additional years of these recently launched efforts to address chronic disease before alternative approach focused on establishing a definition for "ultra-processed" food that is lacking in a scientifically evidenced basis.

Additionally, there is ample evidence that the presence of certain added micronutrients in foods can play a critical role in helping consumers achieve healthy dietary patterns. This highlights the importance of transparent information for consumers and reinforces the broader need for investing in consumer education around food. For example, vitamins and minerals may be added to a food to replace those lost during processing (such as those lost with milk during heat processing) or to prevent disease (e.g., folic acid). Enzymes can make dairy products lactose free, providing a good source of calcium and protein to consumers who might not otherwise be able to consume those products. Furthermore, a range of ingredients, such as fibers isolated from plants (e.g., psyllium from Plantago ovata, oat fiber from rolled oats, inulin from chicory root, and wheat bran from whole grain wheat), as well as protein concentrates and isolates, fortify and enhance the nutritional quality of food, contributing to public health goals.

Other ingredients may not play a nutritive role but provide variety, enjoyment, and enhance taste and should not be described as merely as "cosmetic" or impact a food's classification. Some of these ingredients are important to food safety, reducing food waste, and making food more nutrient dense. Antimicrobial agents kill off bacteria that are the cause of foodborne illness and disease, making food safer. For example, ingredients and processes (*e.g.,* antimicrobials, pasteurization) used to ensure food safety is maintained and enhanced in foods are critical and should not be demonized. Also important are the ingredients that can extend shelf life, accessibility, and thereby reduce food waste. Additionally, stabilizers and emulsifiers can impact how a food appears to a consumer, and thus acceptability. Similarly, flavorings and colors do not affect the nutritional value of a product and should not impact a food's classification. For example, emulsifiers are critical in bridging the gap between removal of FD&C synthetic colors and replacing them with natural color alternatives because they improve the solubility, stability, and uniformity of natural pigments. By dispersing fat- and water-soluble colors evenly across different foods, emulsifiers help natural colors achieve the vibrancy, consistency, and shelf stability that consumers expect.[81] Being these functions, operationally, processing allows consumers to stock up, take advantage of sales, keep extra supply of products, and avail themselves of extended shelf life of the products in the home.

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[79] Id.

[80] Id.

[81] See Henao-Ardila A, Quintanilla-Carvajal MX, Moreno FL. Emulsification and stabilisation technologies used for the inclusion of lipophilic functional ingredients in food systems. Heliyon. 2024 May 29;10(11):e32150. doi: 10.1016/j.heliyon.2024.e32150. PMID: 38873677; PMCID: PMC11170136.

Although there is no scientific consensus regarding certain types of ingredients, amounts, or location in the ingredient statement and how those impact dietary outcomes, there is ample evidence supporting nutrient density as a driver of dietary health. Therefore, rather than focus on ingredients as determinative of the level of processing for foods, the Agencies should continue to emphasize the nutritional composition of foods and educate consumers on how they can achieve healthy dietary patterns by portion size, moderation, and consuming nutrient-dense foods.

As the Agencies consider whether and how to define "ultra-processed foods," the Agencies should bear in mind that existing evidence-based authorities provide for addressing any evidence-based safety concerns. Any ingredient must be authorized[82] as safe for its intended use and at intended use levels and are subject to existing post-market review pathways and enforcement mechanisms, including FDA's Post-Market Chemical Review Program,[83] to ensure the continued safe use of ingredients in the food supply. To the extent the Agencies have concerns regarding the safety of a particular substance used in foods, the Agencies should use existing pathways to address those concerns and should not use a definition of "ultra-processed foods" to do so. Absence of this stepwise approach and proceeding with a definition that is unsupported by science could undermine consumer confidence in the food supply and the Agencies' oversight of it.

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

    a. *Processing a food through physical means may include cutting, extracting juice by an application of force, heating, freezing, extrusion, and other physical manipulations. What physical processes might be used to characterize a food as*

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[82] 21 U.S.C. § 348 (FD&C Act § 409); See also Federal Meat Inspection Act (FMIA) 21 U.S.C. §§ 601–695; Poultry Products Inspection Act (PPIA) – 21 U.S.C. §§ 451–472; https://www.fsis.usda.gov/policy/fsis-directives/7120.1; Egg Products Inspection Act (EPIA) – 21 U.S.C. §§ 1031–1056

[83] See https://www.fda.gov/food/hfp-constituent-updates/fda-update-post-market-assessment-chemicals-food-supply-0

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

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

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

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

As with ingredients, there is insufficient scientific evidence demonstrating that the type of "level of processing" a food undergoes causes negative health outcomes. There is strong and substantial evidence that food processing practices improve food safety and provide tangle benefits to consumers; pasteurization and thermal processing all serve critical functions to eliminate pathogens, etc. Moreover, there is insufficient evidence establishing that the processing techniques implemented at a commercial scale in food manufacturing facilities produce foods that are metabolized differently than foods processed by consumers in their home kitchens. Food processing is not a proxy for a food's health impact and applying it as a broad uniform construct results in an overly broad, meaningless food classification.[84]

Processing methods include activities such as baking, boiling, canning, cooking, cooling, cutting, distilling, drying, extracting juice, freezing, grinding, mixing, pasteurizing, peeling, washing, and many others.[85] Processing has been used throughout history to promote food safety and to preserve the quality of food. Further, processing enables the transformation of raw materials into foods that are safer, more stable, and more accessible - while also preserving and/or enhancing nutritional value and extending shelf life. Processing also makes food palatable, accessible, and convenient. For example, cheesemaking was a way of preserving milk prior to pasteurization and refrigeration. Similarly, classic techniques such as dried and fermentation of meat products, canning and/or freezing fruits and vegetables, baking bread (using yeast and fermentation), pickling, and distilling vinegar have all been used for centuries to produce safe foods and extend their shelf life. Peeling, cutting, and baking, frying, or roasting are common steps used to make certain vegetables edible, for example. These processing

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[84] 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. doi: 10.1038/s41430-022-01099-1. Epub 2022 Mar 21. PMID: 35314769; PMCID: PMC9436773.
[85] 21 C.F.R. 117.3.

steps, whether physical, biological, or chemical, all have been (and continue to be) used by consumers to ensure access to foods beyond the growing or production season. And today, these processes are used by food manufacturers to provide consumers with access to nutritious, safe, affordable foods, regardless of the time of year or where the consumer lives. What is more, processed food provides families with access to nutritious foods that offer time-saving convenience -- this is critical with work schedules and parents balancing work with their children's frequent school, athletic, and other activities.[86]

Where this processing takes place should not determine whether a food is considered "ultra-processed." A food is not "ultra-processed" simply because the ingredients are mixed and the product is baked in a food manufacturing facility rather than in a consumer's home.[87] Because there is no scientific basis to distinguish among foods based on the type of processing they receive or where it occurs, the Agencies should not focus on whether certain processing methods contribute to a food being considered "ultra-processed." Instead, the Agencies should continue to use food groups and nutrient content when assessing the role of a food in a healthy dietary pattern.

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

As discussed at length on pages 3-7 of these comments, there are significant shortcomings with the term "ultra-processed." First, nutrients and food groups to encourage and nutrients to limit in the context of the total diet should be the basis of nutrition policy yet the term "ultra processed" seemingly sets these inputs aside; second, casting nutrient dense foods in a negative light including in being contradiction to the FDA "healthy" definition; third, the term ignores the well-recognized role processing plays a critical role in ensuring food safety and supporting convenience and accessibility for American consumers; fourth, the term incorrectly ignores that international bodies have determined that current dietary guidelines cover concerns raised by "ultra-processed food" research through focus on nutrient density and food groups; fifth, the term does not consider the need for better consumer education on the current guidelines as an important part of nutrition policy; and sixth, the term lacks a scientific basis; and the term "demonizes" healthy foods in a manner that will discourage consumption of nutrient dense food. Thus, the term "ultra-processed" is not suitable for definition and the existing, relied upon

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[86] Coveney, J., & Santich, B. (2015).*Food, bodies and families: Towards a sociology of family food practices. Health Sociology Review, 24(2), 131–145.* https://doi.org/10.1080/14461242.2015.1032331 Costa, A. I. A., Dekker, M., & Jongen, W. M. F. (2001). *Quality function deployment in the food industry: A review. Trends in Food Science & Technology, 12(9),* 306–314. https://doi.org/10.1016/S0924-2244(01)00059-9

[87] The NOVA classification system: A critical perspective in food science, Trends in Food Science & Technology, Volume 116,2021,Pages 603-608,ISSN 0924-2244, https://doi.org/10.1016/j.tifs.2021.08.010.

constructs of “ultra-processed” impermissibly run counter to science-supported nutrition policy while presenting negative consequences for consumers.

Adopting an overly broad and subjective classification of foods risks upending the U.S. food supply with no reasonable path forward. **If the Agencies seek to articulate concerns with American diet quality, they should instead focus on food groups and nutrients to limit and encourage, while emphasizing the inherent safety of ingredients approved for use in the U.S. food supply. By classifying vast quantities of food using a term that could be used to broadly associate them with health risks, without an appropriate scientific basis and without distinguishing between nutrient content, use of the term “ultra-processed” would lead to flawed dietary guidance and would confuse and mislead consumers without helping them to construct healthier diets.** Drawing upon prior historical examples of oversimplified nutrition advice, such as low-fat recommendations,[88] the public health community has learned that negatively indexing certain foods with no clear view of how consumers and the economy will react, is likely to cause more harm than good.

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

    a. *In considering nutritional attributes (such as information presented on the Nutrition Facts label), to what extent, if any, and how, should nutritional composition or the presence of certain nutrients be incorporated in a definition of UPFs? Please provide supporting data and explain your rationale in your response.*
    b. *What other attributes, such as energy density or palatability, might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response. If relevant to your answer, please also provide suggestions on how these attributes can be measured and/or potentially be incorporated into a definition of UPFs, if they are not readily apparent on the food labeling.*

Consumer Brands maintains that the term “ultra-processed” is not suitable for definition by USDA or FDA. We maintain that as the Agencies work to address diet-related chronic disease, the emphasis must be on consumer education on nutrient-dense foods, grounded in food groups and nutrients to encourage and nutrients to limit as well as portion sizes. To the extent the Agencies do attempt to define “ultra-processed foods,” any definition must be grounded in a robust, science-based approach to enhance consumer understanding and promote nutritious

[88] Reedy, Julia, "How the U.S. Low-Fat Diet Recommendations of 1977 Contributed to the Declining Health of Americans" (2016). Honors Scholar Theses. 490.

dietary practices with an emphasis on nutrient-dense foods (regardless of the level of processing) as the foundation of a healthy dietary pattern.

As noted above, a significant fault of many of the current models purporting to characterize food based on processing is that they completely neglect nutrient content, including macronutrients and micronutrients. This runs contrary to well-established nutrition science. Importantly, whether a food has undergone varying levels of processing is not definitive of its overall nutritional impact and, by extension, how it fits into an overall dietary pattern.

Any categorization or definition of food should be consistent with foundational nutritional science principles by focusing on encouraging nutrient-dense foods, treatment of nutrients to limit, and ensuring parity with evidence-based dietary guidance. Indeed, nutrient-based classification schemes are recognized as more appropriate tools than processing-based schemes to correlate the intake of certain foods with health outcomes[89] Moreover, nutrition attributes that form the basis of overall diet quality have been shown to be causally linked to health outcomes, and as such, nutritional attributes (rather than the presence of particular ingredients) that affect overall dietary profile should be the foundation of any regulatory characterization for food where the objective is to improve the health of Americans through better dietary patterns.[90]

Instead of prematurely establishing a definition for "ultra-processed" food or similar concepts, FDA and USDA should focus their efforts on consumer behavior and adoption of dietary patterns and guidance established by consensus-based science recommendations. The 2020-2025 *Dietary Guidelines* note that "A healthy dietary pattern consists of nutrient-dense forms of food and beverages across all food groups, in recommended amounts, and within calorie limits."[91] Further, researchers found that it is possible to eat within UK Eatwell guidelines on an "ultra-processed" diet.[92] Participants in a randomized controlled trial who ate an "ultra-processed" food diet that conformed to UK Eatwell guidelines lost weight over a period of eight weeks. Although the participants in the group that ate a minimally processed diet lost more

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[89] Weaver CM, Dwyer J, Fulgoni VL 3rd, King JC, Leveille GA, MacDonald RS, Ordovas J, Schnakenberg D. Processed foods: contributions to nutrition. Am J Clin Nutr. 2014 Jun;99(6):1525-42. doi: 10.3945/ajcn.114.089284. Epub 2014 Apr 23. PMID: 24760975; PMCID: PMC6410904, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC6410904; Visioli, F., Marangoni, F., Fogliano, V., Del Rio, D., Martinez, J. A., Kuhnle, G., Buttriss, J., Da Costa Ribeiro, H., Bier, D., & Poli, A. (2022). The ultra-processed foods hypothesis: A product processed well beyond the basic ingredients in the package. Nutrition Research Reviews, 1–11. https://doi.org/10.1017/S0954422422000112

[90] See USDA & HHS, *Dietary Guidelines for Americans, 2020–2025* (2020); 2020 DGAC Scientific Report, Part D (USDA/HHS 2020); Food Labeling: Nutrient Content Claims; Definition of Term "Healthy", 87 Fed. Reg. 59,168, 59,171–59,173 (FDA Sept. 29, 2022 Wu, Q., Gao, Z. J., Yu, X. & Wang, P. Dietary regulation in health and disease. *Signal Transduct. Target. Ther.* 7, 252 (2022).

[91] Dietary Guidelines for Americans 2020-2025, Executive Summary x.

[92] Dicken, S.J., Jassil, F.C., Brown, A. *et al.* Ultra-processed 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

weight, there were benefits for those eating the "ultra-processed" food.[93]Consumer Brands urges that more education should be provided to consumers on nutrition education within the context of dietary patterns. Specifically, the Agencies should continue to educate consumers on how to incorporate nutrient-dense processed foods into healthy dietary patterns, including through use of the Nutrition Facts panel, Facts Up Front, and SmartLabel so that consumers can work to meet food group consumption targets. Consumer Brands urges the Agencies to use nutrition composition in the context of an overall balanced diet as the foundation for any policy or research, rather than trying to define a term that is scientifically unsound.

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 Term "Ultra-Processed Food" and Similar Concepts Are Not Suitable for Definition

For the reasons discussed above, the term "ultra-processed food" is not suitable for definition. Any effort to do so would be getting ahead of the science, which simply does not support the use of processing-based classification schemes. To ensure transparency and uphold the integrity of the regulatory process, any further work concerning food processing and formulation and its potential health impacts should proceed through the notice-and-comment process. This approach appropriately reflects the complexity and significance of the underlying scientific and technical issues at play. **As part of this deliberative process, the Agencies must consider consumer understanding and education, as well as the potential for inconsistency with existing regulations and policies.** As discussed above, it would be misleading and confusing to characterize foods as "UPF" when those same foods are encouraged under federal evidence based dietary guidance or recognized as "healthy" under FDA's nutrient content claim definition. Likewise, the Agencies must consider authorized health claims, which recognize the role of certain nutrients and food substances in reducing the risk of certain chronic diseases. Characterizing a food as "ultra-processed" when it is eligible for an authorized health claim would be conflicting and inaccurate. As another example of the potential for inconsistency, USDA's FSIS has authorized "natural" claims where a food contains no synthetic ingredients and has been subject to minimal processing.[94] It would be misleading and confusing for a food

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[93] *id.*

[94] For instance, USDA defines "natural" to mean a "product containing no artificial ingredient or added color and is only minimally processed. Minimal processing means that the product was processed in a

to be considered both “minimally” and “ultra-” processed. The strong potential for such inconsistencies illustrates why a nutrient-based approach is more appropriate to evaluate the role of foods in a healthy dietary pattern, also considering food group contributions and other factors such as portion size.

To Address Diet-Related Chronic Disease, the Agencies Should Conduct Scientific Research and Advance Consumer Education

Rather than seeking to develop a definition for “ultra-processed foods,” FDA and USDA can partner to conduct additional research and advance consumer education around dietary patterns. Such research should be undertaken as part of a coordinated whole-of-government approach. In taking this stepwise approach, scientists would be able to explore the relationship between nutrients, modes of consumption, and processing.

Should the Agencies look at processing more closely, they should consider IAFNS Principles for Classification Focused on Processing noted on page 17 as well as the systems they already have in place for assessing the safety and utility of processing. In FDA’s *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives,*[95] the Agency describes considerations to determine significant manufacturing processing change or the safety or regulatory status of the food, including ones subject to food additive or GRAS determinations. An assessment of the safety of a food substance involves information about its safety and functionality. The identity of the food includes the manufacturing process as well as its chemical name, chemical formula, source, quantitative composition, impurities and contaminants, and physical and chemical properties and specifications. Importantly, the guidance notes that changes to the physical and chemical properties of a food substance can influence its technical effect in food and can influence the nutritional or toxicological properties. This approach emphasizes the need to look at each food as a whole and independently. The Guidance is further reflective of the existing, science-based recognition by the Agencies of the regulatory framework for processing and the role it plays to provide consumers with safe food.

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manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term natural (such as "no artificial ingredients; minimally processed"). https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/meat-and-poultry-labeling-terms

[95] U.S. Food & Drug Admin., *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives* (June 2014), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-assessing-effects-significant-manufacturing-process-changes-including-emerging.

Consumer Education: Consumer Brands encourages the Agencies to pursue consumer education efforts that reinforce the importance of constructing a diet that is mindful of nutrients of public health concern, food groups and nutrients to encourage, and nutrients to limit within established daily values, aligning with food group equivalents without demonizing entire food categories to avoid. The foundation for federal nutrition policy aimed at ensuring healthy dietary patterns and reducing chronic disease should be educating consumers that most of their caloric intake should come from foods that contain a high concentration of vitamins, minerals, fiber, and other vital nutrients such as protein.[96] This could also include actionable education on nutrients to limit. Conversely, grounding efforts merely in foods (or even ingredients) to avoid — when indeed food categorization terms such as those contemplated by the RFI would cause avoidance of nutrient dense foods — misses the mark in reducing chronic disease.

Industry has invested in consumer education tools such as Facts up Front[97] and SmartLabel that help to promote a diet that is nutrient-dense and in alignment with the evidence based dietary guidelines. Facts up Front is a voluntary industry-led labeling initiative that summarizes important nutrition information from the Nutrition Facts label in a simple and easy-to-use format on the front of food and beverage packages. The industry has worked in partnership with the FDA for over a decade to improve the accessibility of critical nutrition facts, promoting nutrition literacy and helping consumers achieve their unique dietary goals.

The SmartLabel digital platform, implemented by national brands and retailers in major grocery categories, provides consumers with access to more detailed product information than could ever fit on a package. It is fast and easy to use, with a consistent display across participating brands allowing fulsome information on nutrients. Industry will continue to promote Facts up Front and SmartLabel as tools to educate consumers on how to achieve a nutrient-dense diet. Consumer Brands welcomes partnership opportunities with the Agencies to support consumer education on these useful tools.

The Agency Should Prioritize the Following Principles When Taking Steps to Improve the Diet Quality and Health of Americans

As a grounding principle, America's food supply is safe. Food safety and protecting the integrity of the food supply is the number one priority of the makers of America's food and beverage products. Nutrient-dense foods should be the focus of dietary patterns and meeting food group needs with nutrient-dense foods. The Agencies should reexamine *existing* definitions that currently guide dietary advice to consumers before establishing a new system or creating new categorizations of food. We urge that, for the Agencies to proceed with any efforts to categorize food based on processing, the following principles form a basis for engagement:

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[96] Dietary Guidelines for Americans, 2020-2025 at 93.
[97] https://consumerbrandsassociation.org/facts-up-front/

(1) Processing plays a critical role in ensuring food safety and supporting convenience and accessibility for American consumers.

- Food processing transforms raw agricultural products into high-quality safe consumables, extending the shelf life of foods, maintaining safety and nutritional value, guarding against food waste, and enabling innovation.
- Any categorization of foods or similar efforts should account for how processed foods are important for all Americans, and can help meet many different, individual needs regardless of physical condition, economic status, or cultural preferences.

(2) Any categorization of food based on processing must be science-based, truthful, and not misleading.

- The foundation for nutrition policy and product labeling must be robust scientific evidence relevant to the field of nutrition and dietetics. Similarly, efforts to define food, based on processing, must be grounded in rigorous, reproducible, and transparent classifications that consider the effect on target health endpoints in humans.
- To ensure efforts concerning labeling, naming, and categorization of food groups and dietary practices are truthful and not misleading or deceptive, they must be: grounded in rigorous scientific support; validated for causal connections of consumption; and have documented evidence of metabolic processes and evidence-based outcomes in humans.
- Efforts to categorize foods or recommend changes in policy must accurately reflect nutritional science with transparent and actionable information for consumers to inform dietary patterns.

(3) Nutrients to encourage and nutrients to limit should be the basis of nutrition policy, rather than focusing on individual ingredients.

- Recommendations or updates to existing food policy should focus on nutrients to encourage, nutrients to limit, and holistic consumer education on dietary patterns and lifestyle factors.
- This effort and collaboration should not demonize categories of food nor disenfranchise consumer access or preferences, and any updates should be based on robust scientific evidence.
- Any food categorization scheme should identify a clear purpose and metrics for determining the end results.
- Existing consumer transparency tools like SmartLabel and Facts Up Front provide product information beyond the nutritional facts label. These tools complement existing regulatory frameworks and can easily be adapted to new guidance, regulatory updates, and consumer education focuses by federal agencies.

* * *

Conclusion

In closing, Consumer Brands believes a coordinated, strategic approach to establishing nutrition policies is crucial to achieving the federal government's goals of reducing diet-related chronic diseases and empowering consumers to make healthier choices more easily. Importantly, we believe all nutrition policies should be grounded in clear and convincing scientific evidence that provides truthful, non-misleading information to consumers. Robust engagement with stakeholders is a must. Consumer Brands strongly encourages the FDA and USDA to prioritize transparency in its consideration of the topics raised in the RFI and establish more open engagement with stakeholders on its related regulatory activities.

Consumer Brands represents companies that make a wide variety of packaged processed food and beverage products which are affordable, accessible, and convenient. The private and public sectors are both committed to providing safe and nutritious foods for consumers to advance public health and reduce food waste and loss. Consumer Brands thanks FDA and USDA for the opportunity to submit comments on this important topic, and we look forward to continued dialogue with the Agencies. Please do not hesitate to contact us to provide further information in support of our comments.

Sincerely,

Joseph Aquilina Lauren Berkowitz

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