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

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

To Whom It May Concern:

The Corn Refiners Association (CRA) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) and U.S. Department of Agriculture's (USDA) joint Request for Information (RFI) on ultra-processed foods.[1] CRA is the national trade association representing the corn refining industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, starch, advanced bioproducts, corn oil, and feed products from corn components such as starch, oil, protein, and fiber.

CRA recognizes FDA and USDA's efforts to solicit data regarding "ultra-processed food" (UPF) and supports the agencies' mission to improve nutrition and reduce diet-related chronic diseases through evidence-based policy and public health initiatives. However, CRA and our members are concerned that based on the current body of scientific evidence, the term "ultra-processed food" is not suitable for a definition. The term is overly broad, risks misclassifying nutrient-dense foods as unhealthy, and lacks a scientific basis. Even among experts, there is significant disagreement on what constitutes a "ultra-processed food" and the potential relevance of such a category to dietary guidance. Moreover, researchers have identified no biological mechanism of action that would suggest what the "markers" or characteristic ingredients of an "ultra-processed food" might be, and accordingly whether it is appropriate to define this term and how it should be defined. Without robust scientific support, adopting a federal definition would outpace the current state of nutrition science, which does not support classification systems based on processing or ingredient composition, and would conflict with FDA and USDA's broader goals to promote healthy dietary patterns and protect public health.

[1] 90 Fed. Reg. 35305 (July 25, 2025).

However, if FDA and USDA disagree with this approach and choose to pursue a definition for "ultra-processed food" or similar terms, such efforts should be confined to narrow research settings. In particular, FDA could pose a definition as a hypothesis for purposes of a particular intervention study, which would need to be evaluated using the scientific process. Given the unsettled nature of the science surrounding "ultra-processed food," any initial hypothesized definition should not be used to inform public policy.

1. **The term "ultra-processed food" is unsuitable for a definition because it lacks a scientific basis and would discourage consumption of nutrient-dense foods.**

The term "ultra-processed food" is not suitable for a definition due to its lack of scientific basis. Evidence linking "ultra-processed food" consumption to health outcomes is derived almost entirely from observational studies, which are inherently limited in their ability to establish causal relationships and are prone to bias by confounding and reverse causality.[2] As Poti et al. (2017) observed, "[l]ittle research has examined whether ultra-processed foods have effects on health independent of their nutrient content" and the availability of ultra-processed foods with more favorable nutrient content (e.g., whole-grain packaged bread, unsweetened breakfast cereals) suggests that "processing itself may not be a causal determinant of the nutritional quality of foods."[3] More recent literature has cautioned that "[w]hile recent systematic reviews and meta-analyses linking UPFs to health outcomes have generated attention-grabbing headlines, […] a closer examination of the underlying research reveals critical gaps often overlooked in academic and public discussions."[4]

Few randomized, controlled, trials have demonstrated a link between "ultra-processed food" consumption and major health outcomes, and those that exist are too limited in design to support reliable conclusions. The frequently cited randomized controlled feeding trial by Hall et al. found that an "ultra-processed" diet caused increased energy intake and weight gain compared to an "unprocessed" food-based diet.[5] However, the researchers themselves acknowledged that the study did not explain "the *cause* of the observed differences in energy intake." The study has also been criticized because the "ultra-processed and unprocessed diets differed substantially in multiple characteristics beyond processing status alone," including energy density, added sugars and dietary fiber content, and palatability.[6] These differences, together with the small number of study participants, could readily explain the observed effects. Similar limitations were present in the more recent randomized controlled trial by Hamano et al., which likewise concluded that "consumption of UPFs causes significant weight gain."[7] That finding, however, was based on a sample of only nine

[2] Astrup, A, Monteiro, CA. Does the concept of "ultra-processed foods" help inform dietary guidelines, beyond conventional classification systems? NO. Am J Clin Nutr. (2022) 116:1489-1491.
[3] Poti JM, Braga B, Qin B. Ultra-processed Food Intake and Obesity: What Really Matters for Health-Processing or Nutrient Content? Curr Obes Rep. 2017 Dec;6(4):420-431.
[4] Louie JCY. Are all ultra-processed foods bad? A critical review of the NOVA classification system. Proceedings of the Nutrition Society. 2025:1-9.
[5] Hall, KD, Ayuketah, A, Brychta, R et al. Ultra-processed diets cause excess calorie intake and weight gain: an inpatient randomized controlled trial of ad libitum food intake. Cell Metab. 2019;30(1)67-77.e3. Erratum in: Cell Metab. 2020; 32(4):690.
[6] Louie, *supra*; Astrup, *supra*.
[7] Hamano, S., Sawada, M., Aihara, M., et al. Ultra-processed foods cause weight gain and increased energy intake associated with reduced chewing frequency: A randomized, open-label, crossover study. Diabetes, Obesity and Metabolism. 2024;26(11), 5431–5443.

participants, all overweight or obese Japanese males, over a one-week intervention period. As the authors themselves highlighted, "the long-term consequences of consistent UPF consumption could not be elucidated." These trials demonstrate that the limited clinical evidence available does not establish a causal relationship between "ultra-processed food" consumption and adverse health effects.

Critically, studies in this area have failed to control for differences in nutritional composition. A randomized, crossover trial by Dicken et al. published in August 2025 found that "minimally processed food" (MPF) diets resulted in greater weight loss compared to "ultra-processed food" diets.[8] The researchers noted, however, that "[i]n contrast with [their] hypothesis given the body of observational evidence linking UPF with weight gain," participants still lost weight on the "ultra-processed" diet. Moreover, the greater weight reductions on the MPF diet did not translate into significant improvements in most cardiometabolic risk factors. The only cardiometabolic marker that showed greater improvement on the MPF diet was triglycerides, whereas the "ultra-processed" diet led to reductions in several key cardiometabolic risk factors including heart rate, fasting glucose, and LDL cholesterol. The researchers also observed a significant order effect, meaning the order in which participants received the MPF and "ultra-processed" diets may have influenced outcomes and introduced bias. Further, and crucially, the authors comment that one potential mechanism explaining the results is energy density, as the "UPF diet" in the trial was more energy dense than the "MPF diet." These results highlight the lack of established causality between "ultra-processed food" and health outcomes.

Moreover, in the absence of robust scientific evidence, defining foods as "ultra-processed" could inadvertently discourage the consumption of nutrient-dense foods that make important contributions to dietary quality and are recommended by federal dietary guidelines. Many "processed" foods, including yogurts, high-fiber and whole-grain breads, plant-based meat and dairy alternatives, and fortified cereals containing HFCS and other refined corn products, contribute recommended food groups and essential nutrients such as fiber, vitamins, and minerals. Labeling these foods as "ultra-processed" would be contrary to federal dietary guidance, which could in turn mislead consumers and create confusion, directly conflicting with FDA and USDA's missions to promote public health and nutrition.

Labeling nutrient-dense foods as "ultra-processed" would also conflict with existing regulatory frameworks, such as FDA's updated "healthy" rule and standards for health-related claims. For example, while the "healthy" rule imposes limits on added sugars, it does not automatically disqualify foods that contain an ingredient contributing added sugars from bearing the "healthy" label. Similarly, foods containing added sugars or ingredients that proposed schemes would classify as making a food "ultra-processed," may still qualify for authorized health claims, which reflect FDA's determination that significant scientific agreement shows that a substance in the food has a relationship with a reduced risk of disease. These FDA frameworks reflect a science-based, holistic approach to evaluating foods that emphasizes overall nutrient density, dietary contribution, and broader eating patterns. Departing from this approach by labeling foods as "ultra-processed" based on specific ingredients such as added

[8] Dicken, SJ, Jassil, FC, Brown, A. et al. Ultraprocessed or minimally processed diets following healthy dietary guidelines on weight and cardiometabolic health: a randomized, crossover trial. Nat Med (2025). https://doi.org/10.1038/s41591-025-03842-0.

sugars or others would be inconsistent with existing regulatory policy and undermine the credibility of established nutrition labeling standards.

2. Existing processing-based classification systems such as Nova rely on ambiguous and inconsistent criteria that are unsupported by scientific evidence.

The lack of a scientific basis for the term "ultra-processed food" is underscored by the shortcomings of existing processing-based classification systems such as Nova, which have faced significant criticism. These systems rely on ambiguous, inconsistent, and flawed criteria that are not supported by scientific evidence and suffer from "a lack of biological plausibility."[9] Studies show that even food and nutrition specialists cannot consistently classify foods under the Nova system, meaning that such processing-based systems "do not currently allow foods to be unequivocally defined as ultra-processed."[10]

One of the central challenges to processing-based classification systems is the absence of consensus on what constitutes a "processed" food and how to distinguish between different degrees of processing.[11] A 2023 review of the Nova classification system noted that terms like "processing" and "ultra-processed" are subjective and poorly defined, as "no scientific, measurable or precise reference parameters exist for them" and "no independent, objectively measurable or precise reference parameters exist that account for the wide range of methods by which foods are processed."[12] For example, the Nova classification system arbitrarily distinguishes between the treatment of processing used for foods prepared at home versus foods that are industrially prepared, labeling the former as "less processed." However, processing methods that are used both at home and industrially, such as cooking, drying, and salting, can produce comparable effects on food regardless of the processing location, undermining the validity of this subjective distinction.[13]

Additionally, under processing-based classification systems, the mere addition of certain ingredients may be sufficient to classify the food as "ultra-processed."[14] This approach lacks scientific support, as it assumes without evidence that the presence of a single ingredient makes a food inherently harmful, ignoring the quantity and quality of the ingredient, its functional role (e.g., for preservation or food safety), and the overall nutritional profile of the food. Additionally, as highlighted in critiques of the Nova classification system, the mere presence of certain ingredients does not reliably predict adverse health effects.[15] CRA is concerned that, without robust scientific support, labeling individual

[9] Visioli F, Marangoni F, Fogliano V, et al. The ultra-processed foods hypothesis: a product processed well beyond the basic ingredients in the package. Nutrition Research Reviews. 2023;36(2):340-350; 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.
[10] 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.
[11] Sadler et al., *supra*.
[12] Visioli et al., *supra*.
[13] Monteiro CA, Cannon G, Moubarac JC et al. (2018). The UN decade of nutrition, the NOVA food classification and the trouble with ultra-processing. Public Health Nutr. 21, 5–17.
[14] Monteiro CA, Cannon G, Levy RB, et al. Ultra-processed foods: What they are and how to identify them. Public Health Nutr. 2019 Apr;22(5):936-941.
[15] *See, e.g.,* Astrup, *supra*; Gibney, MJ, Forde, CG, Mullally, D, & Gibney, ER. (2017). Ultra-processed foods in human health: A critical appraisal. Am J Clin Nutr. 106(3), 717–724.

ingredients as markers of "ultra-processed food" could drive costly reformulation decisions across the food industry without commensurate benefits to public health. Moreover, these reformulation efforts often require significant investment in research, development, and production processes, which could disproportionately burden small and mid-sized businesses.

Further, because processing-based schemes focus on ingredient inclusion rather than processing intensity, the term "ultra-processed food" is a misnomer; the classification purports to be processing-based when in fact the addition of a single ingredient can arbitrarily shift a food into the "ultra-processed" category.

3. Food processing is not inherently harmful to nutrition and health; to the contrary, it can offer essential benefits to food safety and quality.

Food processing in itself is not inherently harmful to nutrition or health outcomes and, to the contrary, plays a vital role in ensuring food quality and safety.[16] As noted by FDA and USDA in the RFI, processing extends shelf life, reduces spoilage, and makes nutritious foods more affordable. For example, published literature shows that high-fructose corn syrup (HFCS) – a processed ingredient – offers functional advantages over sucrose (sugar), by improving flavor, freshness, texture, and pourability, particularly in beverage products.[17] HFCS's efficiency and low cost also reduce manufacturing expenses and lower food prices for consumers.[18] And importantly, FDA has stated that there is no evidence of safety differences between HFCS and other sweeteners with similar glucose-fructose ratios, such as sucrose and honey.[19] There is also ample evidence that consumption of HFCS and sucrose elicit comparable effects on health, metabolism, and anthropometric markers. A randomized control trial comparing the metabolic effects of HFCS-55 (55% fructose) and sucrose found "no differences in the metabolic effects of HFCS and sucrose when compared at low, medium and high levels of consumption."[20] Another randomized crossover trial comparing the metabolic and health effects of consumption of honey, sucrose, and HFCS-55 found that daily intake of all three sweeteners "resulted in similar effects on measures of glycemia, lipid metabolism, and inflammation."[21] In this way, processing is a crucial role in the modern food supply, contributing not only to food safety and quality but also to public health protection.

[16] Monteiro et al. (2018), *supra* ("Food processing as such is not the issue").
[17] Moeller S, Fryhofer S, Osbahr AJ 3rd, Robinowitz CB. The effects of high fructose syrup. Am J Clin Nutr. (2009) 28:619–26.
[18] *See, e.g.,* White JS. Straight talk about high-fructose corn syrup: what it is and what it ain't. Am J Clin Nutr. (2008) 88(6):1716S-1721S.
[19] FDA, High Fructose Corn Syrup Questions and Answers (Jan. 1, 2018), available at: https://www.fda.gov/food/food-additives-petitions/high-fructose-corn-syrup-questions-and-answers.
[20] Yu Z, Lowndes J, Rippe J. High-fructose corn syrup and sucrose have equivalent effects on energy-regulating hormones at normal human consumption levels. Nutr Res Rev. (2013) 33:1043–52.
[21] Raatz SK, Johnson LK, Picklo MJ. Consumption of honey, sucrose, and high-fructose corn syrup produces similar metabolic effects in glucose-tolerant and-intolerant individuals. J Nutr. (2015) 145:2265–72.

4. **Processing-based classification systems, by ignoring the role of nutrient composition, are inconsistent with nutrition science and could misclassify nutrient-dense foods as "ultra-processed."**

Processing-based classification systems are inconsistent with established principles of nutrition science because they focus solely on processing while ignoring nutrient composition. This narrow approach oversimplifies the complex relationship between food and health, and contradicts longstanding dietary guidance, which emphasizes evaluating foods through a holistic lens that considers nutrient content and healthy dietary patterns as a whole.

By overlooking nutrient composition and overall dietary patterns, processing-based systems misclassify many nutrient-dense foods as "ultra-processed" simply because they contain specific ingredients. Indeed, FDA and USDA acknowledge in the RFI that some foods classified as "ultra-processed" "are known to have beneficial effects on health and are recommended as part of healthy dietary patterns."[22] Examples include nutrient-dense yogurts, high-fiber or whole-grain breads containing high-fructose corn syrup, low-carb breads made with refined corn products, and salad dressings and sauces that encourage consumers to eat more vegetables (e.g., in salads and stir fry). Because these products contain ingredients such as high-fructose corn syrup, refined corn, modified starches, and emulsifiers, a processing-based classification system could categorize them as "ultra-processed" – despite their contributions of beneficial food groups like dairy and whole grains, dietary fiber, essential micronutrients, and naturally occurring healthy fats and antioxidants. We urge FDA and USDA to maintain the longstanding and scientifically supported view that these ingredients do not negate a food's potential role in a healthy diet and should not automatically result in it being labeled "ultra-processed."

5. **Defining the term "ultra-processed food" would outpace the current state of nutrition science and risk misuse.**

As outlined above, the term "ultra-processed food" is unsuitable for definition. Absent robust scientific evidence, attempting to define it would be premature and outpace the current state of nutrition science, which does not support classification systems based solely on the degree of processing. However, if FDA and USDA propose a classification scheme or definition for "ultra-processed food" or similar terms, such efforts should be confined to narrow research settings due to the unsettled nature of the science, and should not be used to inform public policy. In particular, FDA could pose a definition as a hypothesis for research purposes only, which would need to be evaluated using the scientific process. In the event the agencies consider applying such a definition more broadly, they should do so through a formal notice-and-comment rulemaking process to ensure that the complex scientific and technical issues involved are fully considered and there is a meaningful opportunity for stakeholders to comment, consistent with the requirements of the Administrative Procedure Act. Food classifications need to be thoughtfully approached. It is recommended to use guiding principles to build consensus across a multidisciplinary team of stakeholders, such as food scientists, nutrition scientists, toxicologists, behavioral scientists, and public health experts, when creating classification systems.

[22] 90 Fed. Reg. 35305, 35307 (July 25, 2025); USDA and U.S. Department of Health & Human Services, *Dietary Guidelines for Americans, 2020*-2025, available at https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf.

Classifications also need to be objective, measurable, and validated for the American population.[23] Classifications that are not validated for the American population – like Nova – should be treated as exploratory and premature for use in the US.

In addition, CRA is concerned that a federal definition for "ultra-processed food" would likely result in the term being used in a derogatory and defamatory manner, unfairly maligning broad categories of nutrient-dense foods without scientific justification. Such an outcome would directly conflict with the agencies' focus on nutrient content and overall diet patterns as the foundation of dietary guidance.

Conclusion

For these reasons, we respectfully urge FDA and USDA not to adopt a definition of "ultra-processed food" at this time. Instead, the agencies should focus on encouraging research that focuses on the nutrient content of foods, their role in in overall dietary patterns, and their demonstrated impact on health outcomes. If the agencies disagree with this approach, and intend to move forward in exploring a definition of "ultra-processed," CRA urges the agencies to propose a definition that would be used only for investigation via scientific research, and that would be refined depending on the results of that research. Only by grounding policy in rigorous science can FDA and USDA advance their shared goals of promoting nutrition and public health without unintended negative consequences for consumers or industry.

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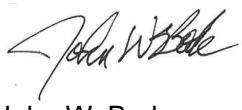
The Corn Refiners Association greatly appreciates the opportunity to provide comments on FDA's and USDA's joint Request for Information on ultra-processed foods. Please do not hesitate to contact us if we can provide further information.

Respectfully submitted,



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[23] Bernstein J, Brown A, Burton-Freeman B, et al. (2025). Guiding Principles for Science-Based Food Classification Systems Focused on Processing and Formulation. Preprints. https://doi.org/10.20944/preprints202507.1896.v1.