

September 4, 2025

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)

Dear Dockets Management Staff,

Dairy Council of California appreciates the opportunity to submit comments for consideration by the Food and Drug Administration (FDA), U.S. Department of Health and Human Services, and U.S. Department of Agriculture (USDA). Our comments include current evidence to be considered in response to Docket No. FDA-2025-N-1793. We commend the agencies' efforts to improve the health of the U.S. population and acknowledge the importance of developing a uniform, evidence-based definition of ultra-processed foods (UPF or UPFs) for human food products.

As a science-based nutrition organization, Dairy Council of California collaborates with partners to elevate the health of children and communities through the pursuit of lifelong healthy eating patterns. Funded by California's dairy farm families and milk processors and under the guidance of the California Department of Food and Agriculture, Dairy Council of California's registered dietitian nutritionists and experts in nutrition science, education, agricultural literacy and community health engage with partners in school, health care and community settings, working together to achieve nutrition security and optimal health. Each year these collective efforts improve access to nutritious foods and provide nutrition education and resources for millions of people in California and beyond, demonstrating the dairy community's contribution to sustainable nutrition and community health.

We appreciate the U.S. government for taking important steps to regulate unsafe and unhealthy foods. However, it is essential to recognize the complexities involved in defining food quality based solely on processing levels. A more nuanced approach that considers nutritional value, cultural relevance and accessibility would more effectively support healthy eating.

## **Examining UPFs and Food Ingredients With Respect to Public Health**

Most Americans across all age groups have poor-quality diets, underconsuming important food groups (fruits, vegetables, whole grains and dairy) and ultimately experiencing nutrient shortfalls of public health concern, particularly calcium, potassium, vitamin D and fiber. Interest in addressing UPFs through policy, regulation and guidelines is an increasingly important and timely topic, yet many scientists and health organizations express caution to ensure credible scientific research and data drive decision-making.<sup>2,3</sup>

Not all processed foods are created equal, and some are shown to be beneficial to health. Many processed foods—like frozen vegetables, canned beans or pasteurized milk, retain their nutritional value during processing and are essential for food safety, convenience and accessibility. Research shows that while some UPFs (e.g., sugar-sweetened beverages) are consistently linked to poor health outcomes, others (like yogurt or whole-grain cereals) may have neutral or even protective effects. Current classification focuses on the extent of processing rather than nutritional composition, which can be misleading to citizens, especially those trying to stretch limited food dollars.

People often choose food that might be considered ultra-processed for a variety of reasons, including convenience, affordability, longer shelf life, ease of preparation, food safety and even optimizing nutrient content. To improve the nutritional profile of foods and beverages, food companies have innovated, reformulated and introduced new foods to reduce the content of sodium, sugar and/or saturated fat, as well as add in certain nutrients and/or food groups to encourage increased consumption. This reformulation has required application of many technologies and processes that play a role in improving public health, yet these advances are not often considered in current classifications for UPFs.

Using dairy products as an example, processing via pasteurization is critical for ensuring the safety and quality of fluid milk, thereby enabling its use in the production of nutritious foods such as yogurt, kefir, cheese, etc. Most people over age 9 do not consume the recommended three dairy servings each day. The presence of isolated nutrients such as added sugar, sodium or saturated fat does not make these foods less nutrient-dense but rather creates a wider variety of products available to meet people's individual needs for taste, cost, accessibility, cultural traditions and preferences.

Dairy milk and the foods like cheese and yogurt that are made from it provide a unique matrix of nutrients and bioactive components that contribute to health across the processing spectrum. Research has demonstrated that different dairy foods may contribute to health outcomes due to their unique structures and nutrient matrices:

- A daily serving of cheese, regardless of fat level, is linked to reduced risk of multiple health outcomes, including mortality and heart disease.<sup>4</sup>
- Eating yogurt is linked to better lactose digestion and tolerance, while fermented dairy food consumption is consistently associated with reduced risk of breast cancer, colorectal cancer, and type 2 diabetes; and improved weight, cardiovascular, bone and gut health.<sup>5</sup>

 Research has found no association between flavored milk consumption and growth, body composition or risk of obesity in children and adolescents. Furthermore, children who drank flavored milk consumed one extra serving of their recommended daily dairy servings compared to non-flavored milk drinkers, which contributed to higher intakes of important nutrients.<sup>6,7</sup>

Reducing consumption of nutrient-poor UPFs is one important way to address the rising rates of chronic disease, but if not done with proper science-based efficacy, an UPF definition may ultimately reduce intakes of key nutrients and further reduce overall diet quality. Additionally, recommendations that are solely based on processing levels rather than nutrient density could negatively affect federal nutrition assistance programs, widening the gap in nutrition security for low-resourced communities and vulnerable populations, including children and older adults.

## Gaps in Research: Furthering Scientific Understanding

Within the past decade, various food classification systems were developed to categorize foods based on what degree of processing they undergo, but these categorizations typically refer more to formulation (such as specific ingredients, added nutrients or additives) than to steps of processing. Although interest in limiting the consumption of UPFs continues to rise, substantial gaps remain in the understanding of the mechanisms by which this broad category of foods may play a causal role in adverse health outcomes. Efforts to create policies and regulations based on subjective systems such as Nova, being the most well-known, could result in consumer confusion and a negative perception of nutrient-dense foods. Nova assumes that all commercially manufactured foods have lower nutritional value and ultimately lead to poor health outcomes based on the presence of specific components such as salt, added sugar and the like. This categorization system also assumes that consumers do not add sugar, salt or fat to unprocessed food at home, thus oversimplifying how people eat and cook in general. It dismisses the proven health benefits of dietary patterns made up of the right balance of nutrient-dense foods at all levels of processing. From a food science perspective, food processing serves many purposes such as to improve taste, improve or preserve nutritional content, preserve product integrity and quality and confer other food attributes (both potentially positive and negative).8

The body of science today is insufficient to support the hypothesis that lower consumption of UPFs as currently defined by the Nova system will result in improved diet quality; one might argue that avoiding these foods could cause health inequity by reducing the intake of key nutrients. For example, according to research published in the *Journal of Nutrition*, implementing the Nova system in dietary recommendations could omit several nutrient-dense foods recommended in the Dietary Guidelines for Americans. This proof-of-concept study provided 91% of calories from UPFs (within the Nova category 4) while fitting within a healthy dietary pattern as recommended in Dietary Guidelines for Americans, 2020–2025. The Healthy Eating Index score resulted in 86 out of a possible 100 points, which is significantly higher than the current average American Healthy Eating Index score across age groups. The study concluded that healthy dietary patterns could include calories from UPFs, still receive a high diet quality score and contain adequate amounts of most macro- and micronutrients.

People choose foods that may be labeled as ultra-processed for many reasons, including convenience, the time and expertise needed for preparation, food safety, storage, affordability, accessibility, flavor preferences, nutrition, reduced waste and perishability. In 2023, 13.5% of U.S. households experienced food insecurity and lacked access to adequate nutritious food to feed their families due to limited resources. These factors should inform how UPFs are defined to ensure policies do not worsen hunger and malnutrition by further restricting access to affordable food.

To determine adequate Supplemental Nutrition Assistance Program benefit allowances, USDA's Thrifty Food Plan demonstrates that both processed and unprocessed foods make up a nutritious, practical, cost-effective diet prepared at home for a family of four. As these programs are critical to support nutrition security, caution needs to be exercised when considering food processing classification systems for the purpose of policy and dietary guidance as it could price families out of otherwise healthy food options due to processing alone.

Another concern with UPFs is the use of food additives. Food additives undergo a rigorous process to ensure they meet safety standards for food use. <sup>12</sup> Since the FDA already uses rigorous food safety processes, further evidence is needed to understand what additives might be harmful and if current federal safety protocols and regulations align with these findings. If certain potentially harmful additives are restricted beyond the scope of current FDA regulations, a rigorous, evidence-based process is required to establish such determinations.

# **Developing Categorization Systems for UPFs**

The inconsistency and wide variability in definition and classification of UPFs in various systems impacts our overall understanding of the research conducted thus far, as well as its implications on human health. Furthermore, multiple organizations and subject matter experts have noted the weak evidence underpinning current UPF research and the need for food processing classification systems to be treated with caution.<sup>13,14,15</sup>

Implementing policy or dietary guidance to limit all intake of foods currently classified as UPFs under systems such as Nova requires additional evaluation to fully understand the impact on people's ability to meet daily nutrient recommendations to support health without compromising food access, affordability and safety. More research is needed to better understand the potential beneficial and adverse effects of different food processing levels and methods on nutrition and health. <sup>16</sup>

A variety of tools can help researchers and policymakers understand eating patterns, identify nutrient deficiencies and make policy decisions that can contribute to improving people's eating habits and overall health. A few examples of tools to assess diet quality include:

- GroceryDB: Guides consumers toward less-processed foods.
- <u>Healthy Eating Index</u>: Measures how well a set of foods aligns with the Dietary Guidelines for Americans.

- <u>Tufts Food Compass</u>: Assesses and scores the healthfulness of a variety of foods and beverages.
- <u>Supporting Food & Nutrition Security through Healthcare</u>: A publication offering an overview of how health care systems can address food and nutrition insecurity and improve diet quality through Food is Medicine interventions.

Processing may also have an impact on the food matrix, impacting the nutrient structure either positively or negatively, for which there is emerging evidence of relevance for nutrient delivery, biological response and potentially consumption behavior. A stronger evidence base, consisting of both observational studies and randomized control trials, will allow for a more balanced and critical review of how foods subjected to various processes influence human health to inform future evidence-based dietary guidance and impactful policies.

Although a nutrient-dense and balanced diet could theoretically be prepared at home each day, practical challenges such as time, cost, convenience, consumer education, storage and preparation facilities must be considered. Factors essential to a global and equitable food supply, including food safety, waste reduction and sustainability, should be addressed in research and guidance on the classification of UPFs and the inclusion or exclusion of specific food categories in the diet.

Ensuring broad stakeholder representation is essential for creating equitable and effective food policies. It is crucial to include voices from underrepresented groups, particularly those impacted by food access challenges. Their perspectives bring valuable insights that can shape inclusive solutions, enhance community well-being and foster sustainable food systems. A truly representative decision-making process must prioritize diversity to address the needs of all constituents.

#### Recommendations

Dairy Council of California agrees with efforts to create a consensus definition of UPFs, with consistency in classification as it relates to various processing methods, nutrient density, and presence of specific components and food additives and their purposes (both positive and negative). A consensus definition of UPFs should not reduce or limit nutrient-dense foods such as milk, cheese and yogurt that support health.

We propose that the following considerations guide the process:

- a. There is a need for longer-term studies on UPFs, as well as studies that reflect the nuances between various UPFs, processing impacts on the food matrix and differing associations with health outcomes (both positive and negative).
- b. Further exploration of the mechanisms behind UPFs is needed, with questions about energy density, hyperpalatability, non-nutritive ingredients and degree of processing.
- c. Food processing manufacturers should have ample opportunity to share innovative solutions for addressing food additives and reformulations, opening the door for proactive policy approaches.

- d. There is a need to consider including UPF-specific characteristics in dietary assessment methods and federal databases.
- e. Further research on food additives is needed to determine whether current safety regulations and review protocols are sufficient or could be improved. Additionally, as these determinations are made, it is important to build in transitional timelines and identify safe alternatives and ensure cost containment is considered.
- f. There is a need to evaluate the impacts of UPF policy on federal nutrition assistance programs and their ability to provide nutrition security to the population they serve, understanding impacts on cost, convenience and time.

We appreciate the opportunity to submit these comments.

Sincerely,

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<sup>1.</sup> US Department of Agriculture and US Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at <u>DietaryGuidelines.gov</u>.

<sup>2.</sup> O'Connor LE, Herrick KA, Papier K. Handle with care: challenges associated with ultra-processed foods research. *Int J Epidemiol*. 2024;53(5):dyae106. doi:10.1093/ije/dyae106

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<sup>5.</sup> Savaiano DA, Hutkins RW. Yogurt, cultured fermented milk, and health: a systematic review. *Nutr Rev.* 2021;79(5):599-614. doi:10.1093/nutrit/nuaa013

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