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By Electronic Submission

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. 90 FR 35305 (July 25, 2025).

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to respond to the request for information (RFI) on so called "ultra-processed foods" issued by the Food and Drug Administration (FDA) and Department of Agriculture (USDA). CRN supports federal government efforts to reduce the prevalence of diet-related chronic conditions in the U.S., particularly in children. We further understand the agencies seek a uniform definition of ultra-processed foods (UPF) or an alternate term to support research and policy activities related to uncovering how and why UPF harm health, as outlined in the recent Make Our Children Healthy Again Strategy.[2]

CRN appreciates that the RFI recognized the importance of specifying parameters for UPF to ensure it is not overly inclusive. For example, UPF should not include nutritional products that are specifically intended to help Americans achieve good health. Under the umbrella of food, there are categories of products that are intended to not only provide nutrition (conventional food), but to also support health and wellness and adhere to

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 180 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

[2] Make America Healthy Again Commission. Strategy Report: Make Our Children Healthy Again. Available at: https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf.

current guidelines and federal definitions. Specifically, dietary supplements are regulated as a category of food and are intended to provide nutritional and/or health benefits by virtue of vitamins, minerals, and other dietary ingredients included in them. Although dietary supplements generally align with food regulations, they are subject to category-specific regulations, including nutrition labeling. In fact, due to key differences from conventional foods, FDA proposed to exempt dietary supplements from front-of-package nutrition labeling requirements in its proposed rule.[3] CRN reiterates key comments related to dietary supplement differences below. Any federally proposed definition of UPF should clarify that dietary supplements are out of scope. In addition, functional foods are a category of nutrient-dense foods formulated to provide specific health benefits; any proposed definition should consider nutritional attributes, such as nutrient density and the inclusion of nutritional ingredients intended to promote the structure or function of the body, to avoid inadvertent inclusion of functional foods in the definition. By design, the category of dietary supplements is not to be conflated with conventional foods and is completely opposite to the expressed purpose of defining so-called UPF. Similarly, functional foods, although similar to conventional foods, are intended to confer specific health benefits to consumers and would therefore interfere with stated research or policy objectives.

CRN would appreciate the opportunity to engage in future federal activities related to nutrition research and policy with the goal of reversing the rise in diet-related chronic diseases, an important public health issue relevant to the dietary supplement and functional food industry. We look forward to additional details about the application of a definition for UPF and more opportunities to provide feedback on any proposed definition to support research and policy.

Dietary supplements align with the vision for a healthy America

The Make America Healthy Again Assessment and Make Our Children Healthy Again Strategy recommend addressing the rise in diet-related chronic diseases through nutrition research and policy to empower consumers to make healthier food choices and achieve proper nutrition. The MAHA Commission highlights extensive research to better understand chronic disease prevention strategies, including research on the potential health benefits of dietary supplements. These guiding documents do not intend for dietary supplements to be covered under the umbrella of UPF. On the contrary, dietary supplements are to be considered as a tool to achieve healthy diets which play a role in chronic disease prevention.

[3] U.S. Food and Drug Administration. Proposed Rule: Food Labeling: Front of Package Nutrition Information. 90 FR 5426 (January 16, 2025).

Moreover, consumers use dietary supplements as part of a healthy lifestyle. CRN's 2024 Consumer Survey reports that the most popular products are vitamin and mineral supplements; and the most common reasons cited for using dietary supplements are for overall health and wellness; immune health; energy; skin/hair/nail care; and filling nutrient gaps in the diet.[4] In addition, users of dietary supplements report that supplements are essential to maintaining health and are significantly more likely than non-users to report other healthy behaviors such as eating a balanced diet, exercising regularly, visiting their doctor regularly, or getting a good night's sleep. Further, an analysis shows dietary supplements play a role in reducing risk of chronic diseases while potentially generating hundreds of billions in healthcare cost savings over the course of nine years.[5]

FDA and USDA should clarify that dietary supplements are not in scope of any potential definition of "ultra-processed foods"

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines dietary supplements as products intended to be consumed orally to supplement the diet and may contain dietary ingredients including vitamins, minerals, herbs and other botanicals, amino acids, and other dietary substances, as well as concentrates, metabolites, constituents, extracts, or combinations of any of the categories of dietary ingredients. Dietary supplements are typically consumed as tablets, capsules, softgels, chews, gummies, liquids, or powders. The common serving size is relatively small compared to food serving sizes e.g., 1 or 2 tablets, softgels, or gummies, etc. As defined, dietary supplements typically do not contain substantial amounts of macronutrients and calories as food products intended to comprise a core part of the diet. Instead, they provide micronutrients such as vitamins and minerals and other dietary substances to supplement the diet and to promote health and wellness. For example, dietary supplements provide essential nutrients, including vitamin D, calcium, potassium, and dietary fiber whose underconsumption in the U.S. population are linked to health problems, such as osteoporosis and heart disease. Moreover, dietary supplements typically do not provide nutrients that should be limited in a healthy diet, such as saturated fat, sodium, and added sugars. If they contain these nutrients at all, the level is low.

Although dietary supplements are regulated as a category of food, they are subject to separate nutrition labeling provisions at 21 CFR 101.36; are exempt from nutrition labeling

[4] CRN-IPSOS Consumer Survey on Dietary Supplements. 2024. Available at: https://www.crnusa.org/2024survey.
[5] Frost & Sullivan. 2022. Supplements to Savings: U.S. Health Care Cost Savings from the Targeted Use of Dietary Supplements, 2022–2030. Council for Responsible Nutrition (CRN) Foundation. Available at: https://www.crnusa.org/sites/default/files/HCCS/00-CRN-Supplements-to-Savings-2022-FullReport.pdf.

provisions for food at 21 CFR 101.9; and thus, supplements bear the Supplement Facts label instead of the Nutrition Facts label. The Supplement Facts label presents the product serving size; servings per container; dietary ingredients, the quantitative amount and percent Daily Value of each, if Reference Daily Intakes (RDIs) have been established for the dietary ingredient (nutrient), and other ingredients. The Supplement Facts label will also declare total calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with 21 CFR 101.9(c). Many dietary supplements, in accordance 21 CFR 101.36, do not declare macronutrients and nutrients of concern such as saturated fat, sodium, and added sugars on the Supplement Facts label because they do not contain any or enough of these nutrients to warrant disclosure.

The supplementary nature of dietary supplements in the diet is inherently different from the role of conventional foods generally; and their intended uses to promote health make them categorically distinct from so called UPF. To avoid any unnecessary confusion, FDA and USDA should clarify that dietary supplements are not in the scope of any potential definition of UPF for use in nutrition-related research or policy.

Nutritional attributes should be considered in the definition of "ultra-processed foods"

FDA and USDA recognize that an unintended consequence of an overly inclusive definition of UPF is discouragement of consumption of potentially beneficial foods. CRN could not agree more, especially considering the existence of a diverse category of foods that is specifically formulated to provide health benefits. These functional foods include protein intended to support muscle maintenance; nutrition bars or shakes to support intake of vitamins, minerals, amino acids, essential fatty acids, and other beneficial nutrients; oral products to support hydration/rehydration; and other products that bear the Nutrition Facts label and are designed for health benefits. Question 5 of the RFI asks about consideration of nutritional composition or the presence of certain nutrients in a definition of UPF. CRN believes nutritional composition is an important factor to consider in a definition of UPF because a definition that operationally includes foods with nutritional attributes may lead to confounding research results and detrimental policy recommendations.

The *Dietary Guidelines for Americans, 2020-2025* recommend healthy dietary patterns composed of nutrient-dense foods, limits on sodium, saturated fat, and added sugars, as

well as limits on calories.[6] Foods that support this recommendation, including functional foods, should not be included in the definition of UPF. Further, the Scientific Report of the Dietary Guidelines Advisory Committee identifies an array of nutrient shortfalls (including vitamin A, thiamin (vitamin B1), riboflavin (vitamin B2), niacin (vitamin B3), vitamin B6, folate, vitamin B12, vitamin C, vitamin E, copper, iron, magnesium, phosphorous, zinc, vitamin K, and iodine in the population across the lifespan. In addition, the report emphasizes vitamin D, calcium, potassium, and dietary fiber as nutrients of public health concern for most Americans, where underconsumption is linked to adverse health conditions.[7] Moreover, FDA regulations in 21 CFR 101.54 permit the use of nutrient content claims on food product labeling, including terms such as "good source," "high," and "more" to describe the content of specific nutrients to help consumers identify options that help them meet nutrient recommendations.

Food products providing a variety of essential nutrients that help Americans achieve nutrient adequacy should not be considered UPF. In addition, food products that contain a balanced amount of calories and nutrients in the context of a daily diet should not be considered UPF. Further, food products that bear substantiated claims to provide a health benefit should not be considered UPF. Functional foods are designed to be nutrient dense with added vitamins, minerals, and other nutritional ingredients, with the express purpose of promoting health through nutrition, thus contributing to healthy dietary patterns and overall health and wellness. FDA and USDA should clarify that nutrient-dense functional foods are not in the scope of a uniform definition of UPF for use in nutrition-related research or policy.

Consideration of processing methods in any definition of "ultra-processed foods" should be science-based and avoid inadvertent inclusion of beneficial foods

Question 3 of the RFI focuses on the processing of ingredients and whether certain processing methods may contribute to a food being considered ultra-processed. A wide range of processing techniques are used to produce ingredients in dietary supplements and functional foods. For example, fermentation is a long-established process using microorganisms such as bacteria, yeast, or fungi, to efficiently and sustainably produce vitamins, amino acids, probiotics, enzymes, and other bioactive compounds. Enzymatic hydrolysis is a well-established process in which proteins are broken down to improve digestibility and reduce allergenic potential. For example, hydrolyzed animal and plant-

[6] 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.
[7] 2025 Dietary Guidelines Advisory Committee. 2024. *Scientific Report of the 2025 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Health and Human Services and Secretary of Agriculture*. U.S. Department of Health and Human Services. https://doi.org/10.52570/DGAC2025.

based proteins are widely used in adult nutritional supplements formulated for individuals with increased protein needs. Esterification is a chemical technique used to produce more stable forms of vitamins; chemical extraction is used to isolate bioactive constituents from natural plants; filtration is a common physical process used to remove contaminants or undesired compounds. Often, a combination of processing methods is used to produce ingredients and ingredient mixtures that go into dietary supplements. Dietary supplements themselves are subject to processing, including application of coatings to tablets to control moisture, taste, or release rate. The processing of dietary supplements helps them meet good manufacturing practice requirements for purity, strength, and composition.

Overall, a variety of processing methods are employed to create beneficial, safe, and quality dietary supplements and functional foods. FDA and USDA should ensure that beneficial and science-based technologies are not inadvertently mischaracterized. Any potential definition of UPF should be science-based and should not result in unintended consequences that could limit access to beneficial foods.

Conclusion

CRN commends the agencies' intentions to curb the rising prevalence of diet-related chronic diseases through enhanced nutrition research and science-based policy. Although dietary supplements are regulated as food, they are distinct from conventional foods and are uniquely designed to supplement the diet to support adequate nutrition and to promote health, which place them in a category distinct from the stated purpose of creating a uniform definition of UPF. Dietary supplements and functional foods play a role in helping Americans achieve nutrient adequacy and in promoting health and wellness. CRN believes it is necessary for any proposed definition to exclude dietary supplements from its scope. In addition, an operational definition should consider nutritional attributes so that foods beneficial for health, such as nutrient-dense functional foods, are not inadvertently included but expressly excluded.

Thank you for considering our comments.

Sincerely,

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