October 22, 2025

Commissioner Martin Makary
U.S. Food and Drug Administration

Submitted electronically

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

Dear Commissioner Makary:

Consumer Federation of America appreciates your consideration of these comments on the U.S. Food and Drug Administration's request for data and information to help develop a uniform definition of ultra-processed foods (UPFs) for human food products in the U.S. food supply. As the government's RFI points out, researchers have linked UPFs to a range of negative health outcomes, including cardiovascular disease, obesity, and cancer. With this research, a prevailing definition of UPFs, based on the Nova classification system, has already coalesced. Adopting a federal UPF definition consistent with the prevailing one can help to educate consumers, prevent misleading claims, and promote consistency in future research.

Background

The toll of unhealthy diets in the U.S. is hard to overstate. Recent analysis indicates approximately one million people die annually from diet-related chronic diseases in the United States.[1] These deaths have delivered Americans the shortest lifespans of the 20 leading developed countries.[2][3] U.S. children increasingly suffer from diseases that in the past only affected adults, such as type-2 diabetes and fatty liver disease (now referred to as metabolic dysfunction-associated steatotic liver disease).[4] U.S. consumers now spend hundreds of billions of dollars—more than a

[1] Matthews, Emily D, and Emma L Kurnat-Thoma. "U.S. food policy to address diet-related chronic disease." Frontiers in public health vol. 12 1339859. 16 May. 2024, doi:10.3389/fpubh.2024.1339859
[2] Why Good Nutrition is Important. Center for Science in the Public Interest. Retrieved September 19, 2024, from https://www.cspinet.org/eating-healthy/why-good-nutrition-important
[3] Achenbach, J., Keating, D., McGinley, L., Johnson, A., & Chikwendiu, J. (2024, October 3). An epidemic of chronic illness is killing us too soon. Washington Post. https://www.washingtonpost.com/health/interactive/2023/american-life-expectancy-dropping/
[4] Cha, A. E. (2024, October 3). Fatty liver was a disease of the old. Then kids started getting sick. Washington Post. https://www.washingtonpost.com/health/interactive/2023/nonalcoholic-fatty-liver-disease-kids/

trillion dollars according to some estimates[5]—treating diet-related disease. Compared to adults with normal weight, those with obesity incur an average $2,505 in higher annual medical care costs.[6] Researchers estimate that in 2023, the economic impact of excess body weight on employers and employees alone exceeded $425 billion.[7] Across the nation, researchers estimate that nutrition-related chronic diseases cost $16 trillion over the period from 2011 to 2020.[8]

As diet-related disease has soared, so too has consumption of UPFs. Coined in 2009, the term "ultra processed" has garnered increasing attention from consumers and public health experts alike. As the RFI notes, UPFs have come to account for more than half of calories consumed by adults and children in the United States. In May 2025, the President's Make America Healthy Again (MAHA) Commission Assessment Report ("The MAHA Report: Make Our Children Healthy Again: Assessment") referred to UPFs 44 times. Civil society groups such as the American Heart Association have issued recommendations to "[r]educe the intake of most UPFs, especially junk foods."[9]

These recommendations reflect a growing consensus that rising UPF consumption has caused, and not just correlated with, rising rates of chronic disease. As the RFI notes, researchers have found links between consumption of these foods and a range of negative health outcomes, including cardiovascular disease, obesity, and certain cancers. Various theories account for these links. First and foremost, UPFs appear to cause disease by contributing to overeating, with UPFs' soft texture and modified food matrix, hyperpalatable formulations, and flavor additives serving to "hijack" the brain and override satiety signals that prevent overeating of less processed foods.[10] Research also suggests that diets high in UPFs may degrade the gut microbiome,[11] disrupt the endocrine system,[12] and even stymie healthy brain development.[13] In light of this evidence, federal policy should encourage reduced consumption of UPFs, with the understanding that some UPFs are

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[5] Lehner, P. (2016, August 15). The Hidden Costs of Food. Earthjustice. https://earthjustice.org/article/the-hidden-costs-of-food

[6] Cawley, J., Biener, A., Meyerhoefer, C., Ding, Y., Zvenyach, T., Smolarz, B. G., & Ramasamy, A. (2021). Direct medical costs of obesity in the United States and the most populous states. *Journal of Managed Care & Specialty Pharmacy, 27(3)*, 354–366. https://doi.org/10.18553/jmcp.2021.20410

[7] Dall, T.M., Sapra, T., Natale, Z. et al. Assessing the economic impact of obesity and overweight on employers: identifying opportunities to improve work force health and well-being. Nutr. Diabetes 14, 96 (2024). https://doi.org/10.1038/s41387-024-00352-9

[8] O'Neill Hayes, T., & Asres, R. (2022). The Economic Costs of Poor Nutrition. American Action Forum. https://www.americanactionforum.org/research/the-economic-costs-of-poor-nutrition/

[9] https://www.ahajournals.org/doi/10.1161/CIR.0000000000001365

[10] ***See, e.g.,*** Dicken, S. J., & Batterham, R. L. (2024). Ultra-processed Food and Obesity: What Is the Evidence? *Current Nutrition Reports*, *13*(1), 23–38. https://doi.org/10.1007/s13668-024-00517-z

[11] Naimi, S., Viennois, E., Gewirtz, A.T. et al. Direct impact of commonly used dietary emulsifiers on human gut microbiota. *Microbiome* 9, 66 (2021). https://doi.org/10.1186/s40168-020-00996-6

[12] Steele, E. M., Khandpur, N., Louzada, M. L. da C., & Monteiro, C. A. (2020). Association between dietary contribution of ultra-processed foods and urinary concentrations of phthalates and bisphenol in a nationally representative sample of the US population aged 6 years and older. *PLOS ONE*, *15*(7), e0236738. https://doi.org/10.1371/journal.pone.0236738

[13] Reales-Moreno, M., et al (2022). Ultra-Processed Foods and Drinks Consumption Is Associated with Psychosocial Functioning in Adolescents. *Nutrients*, *14*(22), Article 22. https://doi.org/10.3390/nu14224831

less harmful than others, and may even be "recommended as part of healthy dietary patterns," as the RFI points out.[14]

The Nova classification system defines UPFs and underpins research tying UPFs to disease.

When researchers talk about UPFs, they are referring to the "Nova" (Portuguese for "new") classification system, with few exceptions. According to the RFI, Nova is "the most common classification" of UPFs. This is an understatement. To be sure, some policy proposals have used the "ultra-processed" moniker as a shorthand to denote foods with certain controversial ingredients—like titanium dioxide, or even sunflower seed oil.[15] But research on diet-related disease outcomes fairly equates the term "ultra processed food" with the Nova classification system, even where it is critical of Nova's capacity to distinguish harmful from healthy foods.[16]

Under Nova, "ultra-processed foods are formulations of ingredients, mostly of exclusive industrial use, that result from a series of industrial processes."[17] These processes start with "the fractioning of whole foods into substances that include sugars, oils and fats, proteins, starches and fibre," which "are then submitted to hydrolysis, or hydrogenation, or other chemical modifications," and assembled "using industrial techniques such as extrusion, moulding and pre-frying."[18] The classification arose in response to concerns that "dietary recommendations typically use classifications of food . . . that largely ignore or minimize the significance of industrial food processing."[19]

The NOVA researchers have acknowledged some ambiguity around which products fall under the UPF definition, in part because manufacturers do not always disclose the extent to which they rely on "industrial processes." As a practical matter, therefore, they have advised reliance on "the ingredients labels that by law must be included on pre-packaged food and drink products." If that list "contains at least one item characteristic of the ultra-processed food group, which is to say, either food substances never or rarely used in kitchens, or classes of additives whose function is to make the final product palatable or more appealing ('cosmetic additives')," then the product is a UPF. Examples of these ingredients include "hydrolysed proteins, soya protein isolate, gluten, casein, whey protein, 'mechanically separated meat', fructose, high-fructose corn syrup, 'fruit juice

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[14] *See, e.g.,* Consumer Federation of America. *Ultra-processed Foods: Why They Matter and What to Do About It.* 2024, *available at*: https://consumerfed.org/reports/ultra-processed-foods-why-they-matter-and-what-to-do-about-it/

[15] *See* https://www.dlapiper.com/en/insights/publications/2025/07/states-move-ahead-with-maha-agenda-for-ultra-processed-food (describing Louisiana Senate Bill 14, a comprehensive law which, among other things, bans 15 ingredients in school meals, requires the disclosure of 44 ingredients on food products offered for sale in Louisiana, and calls for a disclaimer when foods served in food service establishments contain or were cooked using one or more of 8 listed seed oils.).

[16] *See, e.g., Food & Nutrition Research 2025, 69: 12217 - http://dx.doi.org/10.29219/fnr.v69.12217* ("Numerous studies examining the associations between exposure to UPFs, *as defined by the NOVA food classification system* and adverse health outcomes, have been published over the last years.") (emphasis added).

[17] https://pmc.ncbi.nlm.nih.gov/articles/PMC10260459/

[18] *Id.*

[19] Monteiro, C. A., Levy, R. B., Claro, R. M., Castro, I. R. R. de, & Cannon, G. (2010). A new classification of foods based on the extent and purpose of their processing. *Cadernos de Saúde Pública, 26*, 2039–2049. https://doi.org/10.1590/S0102-311X2010001100005

concentrate', invert sugar, maltodextrin, dextrose, lactose, soluble or insoluble fibre, hydrogenated or interesterified oil . . . flavours, flavour enhancers, colours, emulsifiers, emulsifying salts, sweeteners, thickeners, and anti-foaming, bulking, carbonating, foaming, gelling and glazing agents."[20] In applying this definition to dietary surveys and other dietary assessment tools, researchers have developed "best practices" to guide further research and reduce inconsistencies in how foods are categorized.[21]

While researchers may employ different algorithms or assumptions in applying the Nova classification system to categorize dietary data, Nova has supplied the common understanding of what UPFs are. The RFI cites a 2019 article by Michael J. Gibney for the proposition that "the definition of [ultra-processed] foods has varied considerably over time."[22] The industry has parroted this talking point, claiming that the UPF concept is "unscientific" and hopelessly ambiguous. In fact, the UPF definition has consistently relied on the Nova classification. One recent "umbrella review," for example, examines 45 meta-analyses and approximately 10 million study participants that together demonstrate higher risk of cardiovascular disease-related mortality, type 2 diabetes, anxiety, and other common mental disorders with an increased total exposure to UPFs "as defined using the Nova food classification system."[23] Notably, Gibney "has engaged in paid and non-paid consultancy for a wide range of food companies that manufacture processed foods" including "Unilever and Mondelez" the purveyors of Ben & Jerry's ice cream and Oreo's, respectively, and researchers have criticized his reliance on other, similarly conflicted authors.[24]

By codifying the Nova definition of UPFs, FDA can promote transparency and encourage disclosure of information not currently provided by ingredient labels.

FDA should not attempt to redefine UPFs as something different from how the Nova classification system defines that term. However, where the Nova definition presents ambiguities, FDA may create bright line rules to guide future policy and help consumers to understand which products qualify as UPFs. California's Senate Bill 1264 offers some guidance for how FDA may codify a list of ingredients that qualify a food as "ultraprocessed," drawing on existing provisions in the Code of Federal Regulations.[25] But the SB 1264 definition strays from the Nova classification system in other respects, and FDA should not follow its lead. Specifically, FDA should (1) not define as "ultraprocessed" all foods high in saturated fat, sodium, or added sugar; (2) not exclude from the UPF definition certain categories of foods such as alcoholic beverages; and (3) include in

[20] https://pmc.ncbi.nlm.nih.gov/articles/PMC10260459/

[21] Martinez-Steele E, Khandpur N, Batis C, Bes-Rastrollo M, Bonaccio M, Cediel G, Huybrechts I, Juul F, Levy RB, da Costa Louzada ML, Machado PP, Moubarac JC, Nansel T, Rauber F, Srour B, Touvier M, Monteiro CA. Best practices for applying the Nova food classification system. Nat Food. 2023 Jun;4(6):445-448. doi: 10.1038/s43016-023-00779-w. PMID: 37264165.

[22] Notice citing Gibney, M.J., "Ultra-Processed Foods: Definitions and Policy Issues." *Current developments in nutrition.* 2019; 3:nzy077. Accessed June 2, 2025. Available at *https://doi.org/10.1093/cdn/nzy077*.

[23] https://pmc.ncbi.nlm.nih.gov/articles/PMC10899807/

[24] https://www.foodpolitics.com/2022/02/25014/

[25] *See* AB 1264, "Pupil nutrition: restricted school foods and ultraprocessed foods of concern: prohibition." (as amended Sept. 4, 2025), available at: https://legiscan.com/CA/text/AB1264/id/3267685 (citing 21 CFR s 170.3(o)).

its definition UPFs made by "industrial processes," even when they do not contain a characteristic UPF ingredient.[26]

First, foods "high in" sugar, salt and fat are not the same as UPFs. To be clear, FDA should continue to pursue policies such as a front-of-pack labeling that target "high in" foods, which researchers have shown to overlap significantly with UPFs.[27] However, conflating these two categories of (mostly) unhealthy foods will undermine efforts to inform consumers and promote healthier diets. The UPF concept arose in response to nutritionists' failure to distinguish foods with similar macronutrient profiles made by radically different processes. Macronutrients still matter, and in many scenarios, may matter more than concerns about a particular food's UPF status. But that tension calls for a nuanced approach to regulation, not an alternative UPF definition. The RFI cites examples of healthy UPFs (e.g. yogurt) as grounds to "consider unintended consequences of an overly-inclusive definition of UPFs that could discourage intake of potentially beneficial foods." But the UPF definition is already set. FDA may choose to treat some UPFs differently from others for regulatory purposes, but departing from the Nova definition on the grounds that it is "overly-inclusive" will sow confusion and undermine the agency's credibility.

Second, for similar reasons, categorical exclusions from the UPF definition for products like alcoholic beverages are ill-advised. FDA may be tempted to exclude alcohol from judgments about what is "ultra-processed" because federal regulations exempt most of these products from disclosing ingredients, obscuring whether they fall within the definition. But as popular influencers have pointed out, many top-selling alcoholic beverages contain "cosmetic additives" like artificial dyes, added flavors, and emulsifiers.[28] FDA should not allow these UPFs to "fly under the radar" simply because their manufacturers do not have to disclose their ultra-processed ingredients on the label.

Finally, FDA may have its greatest opportunity to add value for consumers by codifying a UPF definition that accounts for certain "industrial processing" techniques. Existing food labeling rules do not require a manufacturer to disclose whether ingredients result from such processing techniques, despite evidence that they may have a significant impact on public health. Extrusion may provide the clearest example. In a recent citizen petition to FDA, former FDA Commissioner David Kessler has argued that FDA should revisit the GRAS status of foods relying on extrusion technology because "the impact of extrusion on starch digestibility is profound."[29] Taking that assertion as true, or even plausible, many consumers will value information that differentiates products made via extrusion. Yet ingredient labels do not make clear when a manufacturer has used extrusion technology. Two foods—e.g. a bag of artisanal tortilla chips and original flavor Fritos™—may have the same ingredients (corn, corn oil, and salt) and yet one of the two is "ultra processed," under Nova, by virtue of its use of extrusion. By making a rule that designates original flavor Fritos™ and other extrusion produced foods as "ultraprocessed," FDA can create a price signal for a comparatively healthier set of foods.

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[26] *See id.* at s.104661.
[27] https://pmc.ncbi.nlm.nih.gov/articles/PMC10943474/
[28] https://foodbabe.com/the-shocking-ingredients-in-beer/
[29] https://www.regulations.gov/docket/FDA-2025-P-3071/document

FDA should provide exemptions for foods on an application specific basis while maintaining a consistent UPF definition.

FDA should make its baseline UPF definition as comprehensive as possible, with the goal of supporting standards to govern manufacturers' claims that their food is "not ultra-processed," "non-UPF," etc. Use of such claims could help to level the playing field for processed food manufacturers that rely on simpler, and often more expensive, ingredients. "Non-UPF" claims could also create incentives for food manufacturers to drop unnecessary additives, and even help to educate many consumers. To be sure, many "healthy" foods—e.g. plain yogurt with the emulsifier pectin—would not be eligible to make the "non-UPF" claim, but to allow otherwise would sow confusion and undermine confidence in FDA's definition.

Other applications of FDA's UPF definition may impose additional conditions or exemptions to accommodate "healthy" foods that are also ultra-processed, and to prevent overconsumption of non-UPF foods that are nonetheless unhealthy. Policies to reduce UPF consumption should complement, rather than compete with, policies to promote nutritionally balanced diets. New standards for school meals, for example, may aim to both reduce calories from UPFs and promote foods with healthier macronutrient profiles by targeting a subset of "particularly harmful" UPFs, as well as foods "high in" saturated fat, sugar, and salt. Again, California's AB 1264 provides an example, directing regulators to determine a subset of "ultraprocessed food of concern and restricted school foods." Federal regulators might enact similar standards by exempting UPFs that meet the FDA "healthy" definition from school meal standards intended to limit UPFs.

Should that approach be taken, regulators at USDA will have to grapple with deficiencies in FDA's definition of "healthy" foods. Most glaring, the definition extends to foods containing non-nutritive sweeteners. Federal policies have laid the groundwork for these sweeteners to become ubiquitous in the food supply, with over 25 percent of children now estimated to consume them as part of their normal diet.[30] However, a growing body of research has raised concerns about the long-term impacts of low-calorie sweetener consumption.[31] These concerns have led many public health authorities to reexamine policies on sweeteners. For example, the Dietary Guidelines for Americans now recommend against feeding children under 2 foods with non-nutritive sweeteners, and New York City has banned non-nutritive sweeteners from all food and beverages at "sites serving a majority of children age 18 or younger."[32] Fixing FDA's "healthy" definition, however, goes beyond the scope of this rulemaking.

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[30] Sylvetsky AC, Jin Y, Clark EJ, Welsh JA, Rother KI, Talegawkar SA. Consumption of Low-Calorie Sweeteners among Children and Adults in the United States. J Acad Nutr Diet. 2017 Mar; 117(3):441-448.e2. doi: 0.1016/j.jand.2016.11.004.

[31] *See, e.g.,* Fowler SP, Williams K, Hazuda HP. Diet soda intake is associated with long-term increases in waist circumference in a biethnic cohort of older adults: the San Antonio Longitudinal Study of Aging. J Am Geriatr Soc. 2015 Apr;63(4):708-15. doi: 10.1111/jgs.13376; Debras C, Chazelas E, Sellem L, Porcher R, Druesne-Pecollo N, Esseddik Y et al. Artificial sweeteners and risk of cardiovascular diseases: results from the prospective NutriNet-Santé cohort BMJ 2022; 378 :e071204 doi:10.1136/bmj-2022-071204; Suez et al. "Personalized microbiome-driven effects of non-nutritive sweeteners on human glucose tolerance." Cell, Vol. 185: 18, (Aug. 19, 2022), DOI: https://doi.org/10.1016/j.cell.2022.07.016.

[32] *See* New York City Food Standards, available at: https://www.nyc.gov/site/foodpolicy/governance-initiatives/nyc-food-standards.page

Conclusion

We commend FDA for taking this step towards addressing UPFs' profound impact on public health. FDA should adopt a federal definition grounded in the Nova classification system, which informs the research linking UPFs to diet-related disease. FDA should resist calls to conflate its UPF definition with other factors related to dietary quality, such as macronutrient content, or to circumscribe its definition to exclude foods that clearly meet the Nova definition. In doing so, its definition will establish a solid foundation for policies that effectively reduce harms from UPFs.

Sincerely,

Thomas Gremillion
Director of Food Policy
Consumer Federation of America