COALITION FOR METABOLIC HEALTH

October 6, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Brooke L. Rollins
Secretary of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250

The Honorable Dr. Martin A. Makary
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Submitted via *www.regulations.gov*
[Docket No. FDA-2025-N-1793]

Dear Secretary Kennedy and Secretary Rollins:

The Coalition for Metabolic Health (CMH) appreciates the opportunity to respond to the joint Request for Information issued by the U.S. Food and Drug Administration, the U.S. Department of Health and Human Services, and the U.S. Department of Agriculture regarding ultra-processed foods.

CMH is a national alliance of researchers, clinicians, philanthropists, nonprofits, business leaders, and advocates ushering in a new era in healthcare by advancing metabolic health as a national priority. As members, we share a commitment to reducing the burden of chronic disease and advancing evidence-based nutrition and public health policy. We view this as a crucial opportunity to help ensure that any federal approach to UPFs is scientifically rigorous, operationally effective, and aligned with public health objectives.

The definition of UPFs has become one of the most contested issues in nutrition science. The term is widely used in research and policy debates, but its boundaries remain unsettled. Experts remain divided over whether it represents a scientifically coherent category that can be applied in ways that meaningfully guide policy. This submission highlights areas of broad agreement, acknowledges genuine disagreements, and outlines a path forward that avoids premature definitions while addressing the well-documented metabolic harms associated with modern diets.

Areas of Agreement

There is a broad consensus that current consumer tools are inadequate. Nutrition labels and ingredient lists often confuse rather than clarify, leaving individuals without clear guidance about which foods most undermine metabolic health. While some advocate for greater regulation of front-of-package advertisements, at this stage, agencies should first

recognize the need for more transparent, evidence-based consumer guidance rather than adding new labels that may themselves confuse.

The stakes are high because certain categories of foods appear to drive overconsumption, poor satiety, and metabolic harm, as tested in several randomized controlled trials. At the same time, the length and design of these studies have been topics of criticism.

In addition, a broader epidemiological record, considered a lower quality of evidence, shows associations between higher intake of foods typically considered ultra-processed and adverse health outcomes. A 2024 *BMJ* umbrella review found increased UPF consumption linked to a higher risk of multiple poor health outcomes. A 2024 *BMJ* cohort study reported marginally higher all-cause mortality associated with a higher intake of UPFs. These findings are reinforced by an additional umbrella review published in *Food Chemistry*.

Nutrient profiles — the amount of nutrients such as carbohydrates, fats, proteins, vitamins, and minerals in a food item — provide one important lens for understanding these harms. Diets high in refined carbohydrates and added sugars, and low in dietary fiber, have long been associated with metabolic dysfunction, diabetes, and cardiovascular disease. Industrial processing compounds these risks by stripping foods of their natural fiber and micronutrients, producing nutrient-poor, energy-dense products and generating "acellular" nutrients that disrupt glycemic and metabolic responses. Several studies show that U.S. diets are already typically deficient in micronutrients.

Critical Nuances

Nutrient profiles alone, however, cannot capture health impacts. Foods with similar nutrient profiles can have dramatically different metabolic effects depending on how they influence satiety, glycemia, and insulin response. Research published in *JAMA* on the glycemic index has shown this clearly.

Beyond their nutrient profiles, many foods considered ultra-processed operate like a form of polysubstance use. By combining sugar, refined carbs, fats, salt, and cosmetic additives, they may engage reward pathways in ways that resemble addictive substances such as nicotine or alcohol. A growing body of neuroscience and psychiatry research supports this view, underscoring the need for more rigorous study of food addiction mechanisms. Concerns also extend to some additives: studies show that emulsifiers and nitrites can disrupt the gut mucosa and have been associated with colorectal cancer.

Finally, UPF consumption — or what is typically classified as such — is shaped by political, economic, and cultural forces. Subsidies, low cost, marketing, and convenience make these products ubiquitous. In the process, they may displace nutrient-dense, culturally rooted foods.

Areas of Debate

Where perspectives diverge most is on whether UPFs should be defined as a regulatory category. Some argue the term is little more than a rebranding of "junk food" that adds limited clarity. They warn that focusing on industrial processing risks misclassifying foods by method rather than metabolic effect. A homemade brownie, for example, can be just as

harmful as a packaged candy bar. Yet under most classification systems, only the latter would be flagged, potentially misclassifying the homemade brownie as less concerning. From this perspective, regulatory and dietary guidance should focus on refined carbohydrates, added sugars, and other food components that have been demonstrated to induce metabolic risk, in addition to formulations with a high degree of artificiality or cosmetic additives.

This tension is perhaps most visible in debates over the Nova classification, first articulated in *Public Health Nutrition*. Nova groups foods by the extent and purpose of industrial processing and has become a reference point in research and policy discussions. Still, it is also frequently criticized for a lack of precision and potential misclassification.

Recent analysis in the *New England Journal of Medicine* underscored these concerns, noting that Nova relies on ambiguous criteria, produces inconsistent classifications across food categories, and risks misleading both consumers and regulators. The article further highlighted that some products labeled as ultra-processed may, in fact, be health-promoting, such as certain varieties of olive oil-based dressings. At the same time, certain "culinary" ingredients that do not trigger the UPF designation (such as refined grains and added sugars) can be harmful, illustrating the danger of basing policy on a blunt metric rather than on established metabolic risks.

A 2025 *BMJ* analysis similarly cautioned that short diet studies without proper wash-in and washout periods are prone to bias. Policymakers abroad have raised comparable concerns: the UK House of Lords Food, Diet and Obesity Committee found that while Western diets high in UPFs are harmful, the Nova system "lacks sufficient precision to be suitable for the characterisation or regulation of individual foods."

Supporters counter that, despite certain limitations, Nova remains the most widely recognized framework and provides a practical starting point for analysis. Its adoption has enabled cross-country comparisons and a growing body of epidemiological research, although it is considered to be low-quality evidence. Analyses in *Animal Frontiers* and *Nature Reviews Endocrinology* suggest Nova could be refined to emphasize food structure, processing purpose, and formulation intent — elements that may better distinguish industrial formulations from traditional or minimally processed foods. Another way to refine the use of Nova is to apply it within the context of overall dietary patterns. For instance, consuming a single Nova-classified food may not pose significant health risks, but a diet in which more than half of total calories come from ultra-processed foods is likely to be detrimental to health.

From this perspective, a shared definition can create consistent standards and enable policy tools such as marketing restrictions, front-of-package warnings, procurement rules, and incentives for reformulation. Without such a framework, proponents caution, efforts to curb UPF consumption risk being fragmented and less effective.

Ultimately, the disagreement reflects a fundamental divide. Some view the concept of UPFs as inherently flawed and are concerned that using it would do more harm than good, while others see value in a refined Nova framework that emphasizes food structure, formulation purpose, proportions of ultra-processed foods within the overall diet, and physiological outcomes such as stimulating cravings, metabolic health impact, hypertension, and

diabetes. At its core, the split mirrors a broader debate in nutrition science: whether foods should be classified by ingredient or formulation identity or by their metabolic effects and long-term health outcomes.

Recommendations

Building on both the areas of consensus and the differences outlined above, FDA and USDA can still chart a constructive path forward. The agencies should avoid oversimplified heuristics — such as ingredient counts, whether a food "could be made at home," or whether its components are "pronounceable." Energy density, based on calorie count, should also be used with caution, as it risks misclassifying nutrient-rich foods like nuts and avocados while overlooking the metabolic risks of refined carbohydrates.

A more effective approach would focus on components that consistently contribute to harm: refined carbohydrates, added sugars, and excessive use of additives indicative of artificiality (e.g., certain types of preservatives, cosmetics, modified vegetable oils, emulsifiers, artificial food dyes, and flavorings) proven to disrupt human physiology. Policy should also recognize the protective role of fiber and micronutrients, account for nutrient degradation caused by processing, and emphasize outcomes such as glycemic response, satiety, and long-term metabolic health, rather than focusing solely on static nutrient counts.

More substantial evidence will be essential. NIH-FDA collaborations should expand interventional research on overconsumption, metabolic harm, and the displacement of nutrient-dense traditional foods. Better clinical research is also needed, including trials with sufficient duration to assess chronic effects and minimize confounding and other sources of bias. This will require a substantial increase in NIH funding, consistent with the aims of the government's Nutrition Regulatory Science Program.

Public education on the physiological impacts of industrial formulations should also be prioritized so consumers receive clear, actionable guidance.

In summary, CMH underscores that while the harms of refined carbohydrates are clear, the consensus on defining UPFs is not clear and therefore requires further research, especially with regard to food additives. In the meantime, a flexible, evidence-informed approach — focused on refined carbohydrates and metabolic outcomes — offers the best path to protecting public health. FDA and USDA should avoid rigid definitions that risk misclassification and instead apply criteria most likely to identify foods driving metabolic harm.

Thank you for the opportunity to comment.

Respectfully,

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