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

First and foremost, we commend the FDA, HHS, and USDA for their efforts to develop a uniform definition of ultra-processed foods (UPFs) for policy and regulatory purposes. This is a critical first step in halting the rise of the epidemic of chronic disease in this country. We submit this comment as nonpartisan advocates who partner closely with scientists, corporations, and nonprofits. Such a collaboration underscores the importance of this issue, the growing consensus on a definition, and the urgent need to regulate ultra-processed foods to protect the health and safety of our citizens, especially our children.

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Introduction

Ultra-processed foods (UPFs) are a major driver of diet-related disease in the United States, contributing to obesity, diabetes, cardiovascular disease, and mental health conditions such as depression and anxiety (Lane et al., 2024). Approximately one American dies every four minutes due to preventable diseases associated with a high-UPF diet. (Nilson et al., 2025). In today's food supply, UPFs are the dominant source of harmful nutrient profiles—high in added or free sugars, unhealthy fats, and sodium—as well as additives associated with adverse health effects, including non-sugar sweeteners and synthetic colors (Martínez Steele et al., 2016; Popkin et al., 2024).

The evidence base is more than sufficient for regulatory action. While industry will point to a lack of large randomized controlled trials (RCTs), this has not been the standard for other regulated products. Tobacco, alcohol, and opioids were regulated based on converging epidemiological, mechanistic, and basic scientific evidence—not perfect knowledge (Brandt, 2007; Babor et al., 2010; Kolodny et al., 2015). RCTs are not ethically feasible for tobacco, alcohol, and opioids, and yet we have been able to regulate these products effectively. Researchers never ran double-blind randomized trials assigning people to smoke, yet rigorous observational studies and mechanistic evidence made it clear that smoking is hazardous to health. The RCTs that do exist already show that UPFs drive overconsumption and disrupt hunger and satiety regulation (Hall et al., 2019; Hamano et al., 2024; Dicken et al., 2025; Preston et al., 2025; Hägele et al., 2025).

Establishing a standardized definition of UPF is a critical first step toward proper research and regulation and ultimately toward the most transformative goal of ensuring that everyone has access to and consumes real, whole foods. Furthermore, FDA should create a proposed *"UPF Risk Assessment"* office or give authority to an existing office, such as the Office of Food Chemical Safety, Dietary Supplements & Innovation, to review this definition on a regular biannual basis.

Currently, a drawback of UPF research is an inconsistent definition across institutions, making scientific comparisons difficult. HHS is working to reestablish itself as the center of gold star research in the U.S. and around the globe. By defining UPF, federally funded research on the topic would be more in line with that objective.

A standard UPF definition opens opportunities for effective regulatory options. State and federal government agencies and legislative bodies can use this definition as a guide when addressing public health and nutrition priorities. Examples include the establishment of school lunch standards at state and federal levels to promote whole nutrient-dense foods and restrictions on the marketing of unhealthy UPFs to children. Governments can even use this definition to guide budgetary priorities for community health grant programs, research directives, agricultural subsidies, and revenue opportunities.

Such actions would be in line with the over 100 countries globally that have taken action against harmful industrial UPFs. Reducing consumption of UPF is a key priority in the battle to Make

America Healthy Again, but first, we must identify the target. A federally consistent definition, supported by scientific and community consensus, is the critical first step toward that goal.

A. Proposed UPF Definition and Criteria

Several definitions of UPFs exist, but most were not designed for regulatory use. Defining UPFs by specific ingredients alone is too narrow and an oversimplified approach that allows many unhealthy products to slip through while ignoring the broader harms of processing and concerning nutrient levels. Inspired by recent research from UNC-Chapel Hill (Popkin et al., 2024), we propose a practical, tiered definition that integrates both processing levels and nutritional components. A product should qualify as an ultra-processed food if it meets at least one of the following criteria:

1. Products that are high in salt, added or free sugar, and/or saturated fat, low in fiber, and contain classes of ingredients indicative of high processing.
2. Products with ingredients linked with specific harm.
3. Products with a substance or group of substances that are banned, restricted, or require a warning label in other state, federal, or international jurisdictions due to concerns about adverse health consequences.
4. Products with a substance or group of substances that may be hyperpalatable or may contribute to food addiction based on reputable, peer-reviewed scientific evidence.

1. Products that are high in salt, added or free sugar, and/or saturated fat, low in fiber, and contain classes of ingredients indicative of high processing

UPFs are a dominant source of unhealthy nutrient profiles—high in added or free sugars, sodium, unhealthy fats, and lacking fiber (Martínez Steele et al., 2016). Specifically, products should be considered UPFs if they contain **≥10% of calories from added or free sugars or saturated fats, or ≥1 mg of sodium per 1 kcal**, as outlined in the PAHO Nutrient Profile Model. While the 10% cutoff serves as a clear policy threshold, it is important to recognize that products with lower levels of free sugars or saturated fats are not inherently "healthy," and health risks increase progressively with higher percentages. Additionally, foods with a **carbohydrate to fiber ratio greater than 10:1** would be considered low fiber (with exemptions for animal-based products and beverages) (Fontanelli et al., 2020).

Products that meet the above-stated nutrition criteria should be considered UPFs if they also contain one or more substances having any of the following FDA-defined technical effects:

a. Surface-active agents
b. Stabilizers and thickeners
c. Propellants, aerating agents, and gases

d. Colors and coloring adjuncts

e. Emulsifiers and emulsifier salts

f. Flavoring agents and adjuvants, excluding spices and other natural seasonings and flavorings

g. Flavor enhancers, excluding spices and other natural seasonings and flavorings

h. Non-nutritive sweeteners

The 2024 UNC study showed that combining "high in saturated fat, salt, and sugar" (HFSS) thresholds with indicators of processing (i.e., additives) provides the most accurate way to identify UPFs. Relying on HFSS criteria alone misses about 16% of UPFs, but adding markers of processing closes this gap. International examples demonstrate that nutrient-based labeling and marketing restrictions can be an effective first step to reduce unhealthy consumption (Song et al., 2021; Tórtora et al., 2019; Taillie et al., 2021). However, nutrient-only policies also encouraged manufacturers to replace sugar with non-nutritive sweeteners and other harmful additives, changes that technically complied with the rules but failed to address the underlying risks of ultra-processing (Zancheta Richardo, 2021). To prevent these kinds of loopholes, **UPF definitions must capture both nutrient profiles and levels of processing**, **ensuring policies drive genuine improvements rather than superficial reformulation.**

The NOVA classification system for processing is widely used in research and highlights 12 classes of additives that signal heavy processing. However, NOVA can be subjective and challenging to apply in regulation (Braesco, et al., 2022). A clearer framework should identify processing by focusing on these additive classes as practical indicators.

Consequently, processing criteria alone are also insufficient. For instance, the 2024 UNC study found that if NOVA were the sole system to identify UPFs, it would miss 10% of HFSS products purchased by U.S. households. This evidence shows the need to combine nutrient thresholds with ingredient-based markers of high processing to create a more accurate, balanced, and policy-ready definition of UPFs.

2. Products with ingredients linked with specific harm

UPFs can also be identified by the presence of ingredients with documented health harms. Recent large-scale studies and reviews have linked UPF consumption to obesity, cardiovascular disease, Type 2 diabetes, dementia, cognitive decline, liver fat accumulation, stroke, and higher all-cause mortality (Lane et al., 2024; Nilson et al., 2025; Loftfield et al., 2024; Weinstein et al., 2025; Bhave et al., 2024; Kullmann et al., 2025; Mendoza et al., 2024). Ingredients linked to the following outcomes based on reputable peer-reviewed scientific evidence should automatically qualify products as UPFs:

a. Cancer

b. Cardiovascular disease

c. Metabolic disease

d. Developmental or behavioral issues

e. Reproductive harm

f. Obesity

g. Type 2 diabetes

h. Other health harms associated with UPF consumption

This criterion ensures that policy does not simply focus on how foods are processed or how many nutrients they have but also incorporates the growing body of evidence on their direct impacts on human health. Furthermore, the aforementioned proposed *FDA UPF Risk Assessment* office that would review this definition every two years should also be tasked with reviewing new and existing scientific studies linking ingredients to these harms, ensuring that products containing them are consistently and rigorously evaluated for inclusion as UPFs. By explicitly tying harmful substances to adverse outcomes, FDA and USDA can better prioritize regulation of UPFs that present the greatest risks.

3. ***Products with a substance or group of substances that are banned, restricted, or require a warning label in other state, federal, or international jurisdictions due to concerns about adverse health consequences***

The U.S. food supply contains more than 10,000 chemical additives, while other countries around the world permit far less. For example, the EU, Canada, Japan, Australia and New Zealand each have approved fewer than 900 additives. Many additives allowed in the U.S., such as certain dyes and preservatives, are already banned or require warning labels abroad due to links with cancer, endocrine disruption, or hyperactivity in children. Globally, at least 44 countries have introduced front-of-package (FOP) warning labels that alert consumers to high levels of sugar, sodium, or saturated fat.

Inspired by these international examples, the U.S. is experiencing a wave of legislative activity at the state level, specifically targeting harmful food additives. As of September 2025, ten states (Arizona, Arkansas, California, Delaware, Louisiana, Tennessee, Texas, Utah, Virginia, and West Virginia) have passed new laws with broad bipartisan support that restrict, prohibit, or require warning labels on certain harmful additives. There are bills pending in nine other states that also seek to ban certain harmful additives and/or create GRAS disclosure requirements. Additionally, California lawmakers have passed a first-of-its-kind bill to establish a statutory definition of UPFs and begin to phase out “particularly harmful ultra-processed foods” from their school foods.

Thus, products containing substances that are banned, restricted, or subjected to warning labels abroad and increasingly at the state level in the U.S. should clearly fall under the UPF definition. Aligning with international standards and global “best practices” would not only protect

consumers but also provide consistency across states and global markets, helping both regulators and manufacturers.

4. ***Products with a substance or group of substances that may be hyperpalatable or may contribute to food addiction based on reputable peer-reviewed scientific evidence***

UPFs are deliberately engineered for hyperpalatability, often by combining sugar, fat, and salt to achieve "bliss points" that drive overconsumption (Feskens, 2024). Research shows these foods can trigger reward pathways in the brain, leading to behaviors resembling food addiction (Gearhardt et al., 2011). Clinical trials in both the U.S. and Japan show that UPF diets lead to significantly higher daily calorie intake and weight gain compared to minimally processed diets, with evidence suggesting that faster eating rates, lower chewing frequency, and higher energy density may play key roles in driving overconsumption (Hall et al., 2019; Hamano et al., 2025).

The proposed *FDA Risk Assessment* office should evaluate peer-reviewed scientific evidence to identify substances or formulations that contribute to hyperpalatability and addictive potential. Hyperpalatability is an emerging area of study, with researchers developing new methods to measure and define it. One study demonstrated that foods with a fat-to-carbohydrate calorie ratio of roughly 1:1 strongly activate the brain's reward system (DiFeliceantonio et al., 2018). Participants in the study could accurately estimate energy density when consuming fat alone, but lost this ability when fat was combined with carbohydrates, leading to underestimation and overeating. This 1:1 ratio is rare in nature but common in manufactured foods, making it both a strong indicator of ultra-processing and an intuitive, practical tool for identifying UPFs.

Palatability is also shaped by additives that manipulate taste and texture. The World Health Organization's 2025 report highlights how additives interact with the gut microbiome and host organism. Recent studies (Whelan et al., 2024) show these interactions can increase cravings for UPFs, particularly those high in sugar and fat, creating a feedback loop that reinforces overconsumption. A 2025 study further confirmed that the harmful effects of a UPF diet were independent of total caloric intake (Preston et al., 2025). Processing does not have a neutral effect on the caloric impact of foods; it alters the food matrix, affects how nutrients interact, and how quickly food is consumed and absorbed. Calories absorbed slowly through a preserved food matrix do not have the same metabolic effects as calories from disintegrated, rapidly absorbed UPFs. Therefore, products containing additives or formulations designed to increase addictive potential should be included in the UPF definition.

B. Periodic Review and Exemptions

As mentioned in the opening statement and referenced in the Definition and Criteria above, the FDA should establish an *FDA Risk Assessment office*, or assign authority to an existing office, such as the Office of Food Chemical Safety, Dietary Supplements & Innovation, responsible for reviewing the UPF definition every two years in light of new research and scientific developments. Regular reassessment will ensure the definition remains evidence-based and responsive to emerging science.

Certain products should be formally exempt from the classification of UPFs when applied to policy, including the following:

a. A raw agricultural commodity

b. An unprocessed locally grown or raised agricultural product

c. Minimally processed prepared food, which may include foods in a variety of forms, including, but not limited to, whole, cut, sliced, diced, canned, pureed, dried, and pasteurized

d. Class 1 milk

All other exemptions should be subject to a rigorous, science-based review by the authorized office every two years to confirm that they remain justified and are not expanded in ways that weaken the integrity of the definition.

C. Regulatory Options

We don't need to reinvent the wheel to improve the health of our food supply. Many countries around the world have already established clear, effective regulations, policies, laws, and programs that the U.S. can and should adopt to support whole nutrient-dense foods and reduce the consumption of UPFs.

State and federal agencies should leverage this definition as part of their public health and nutrition efforts, directing grants and subsidies toward non-UPF whole foods and away from UPFs and the systems that bring them about. For example, grants could be directed to research harmful effects of UPFs as well as the development of food systems that contain limited UPF. The USDA can prioritize research that supports the production of specialty crops and whole proteins for human consumption over commodity products such as corn, wheat, soy, and sugar that make up the primary ingredients of UPF.

Such a reprioritization can extend to USDA crop subsidies and crop insurance. Currently, most agricultural subsidies support grains that are processed into UPF; thus, the U.S. is subsidizing the very foods that are contributing to our health issues.

A standard UPF definition would also enhance the FDA's role in regulating food additives. Having an actionable definition allows the FDA to demand safety data for these compounds, and in doing so, helps assist with the assessment of ingredient safety and approval. This could help bring the U.S. in line with the many countries that have already banned or require warning labels on many of these toxic ingredients. This improved ingredient oversight needn't be anti-business, as food companies have successfully reformulated their products with safer ingredients in Europe, Canada, and dozens of other countries.

Another regulatory tool that can help combat the consumption of UPF is front-of-package (FOP) labeling that is already mandatory or voluntary in 44 countries. These requirements alert consumers of ultra-processing or high levels of unhealthy ingredients in packaged foods. Countries in Europe and Latin America have implemented labels such as black octagons with

measurable results. For example, after Chile implemented warning labels in 2016, purchases of sugary drinks declined by 24% (Taillie et al., 2020). By having FOP labels based on the UPF definition that takes into account both nutritional profile and processing level, we can empower American consumers to make properly informed food choices.

Additionally, we can take direct action to restrict the marketing of certain foods to children, following best practice examples from around the world. 15-20 countries, including Chile, Brazil, UK, Ireland, Spain, Sweden, France, South Korea, and Canada, have introduced mandatory statutory bans or restrictions on the marketing of unhealthy foods to kids (Taillie, 2019). Norway recently enacted a law that makes it illegal to market products high in sugar, salt, or saturated fat to children under 18. Denmark is pursuing one of the strictest regulations, banning the promotion of junk food to children under the age of 15 on all major platforms, including social media. Within the EU, these policies have been studied extensively, shown effectiveness, and have become a crucial tool in fighting the obesity and chronic health epidemic (Safe Food Advocacy Europe, 2025).

Restricting the marketing of tobacco to children in the U.S. starting in 1996 substantially helped reduce youth smoking rates. Youth smoking rates decreased from 36% when marketing restrictions were implemented to less than 4% in 2021 (American Lung Association, 2024). Similarly, restrictions on advertising UPFs to children would help stem the onslaught of Type 2 diabetes in children and make parents' choices more straightforward. Too often, sugary cereals or toxic beverages are marketed as "part of a balanced diet" for children, making it nearly impossible as a parent to determine what is best to feed their children.

Furthermore, when the government has a direct responsibility for feeding children, such as school lunch programs and other supplemental nutrition programs, a clear definition of UPFs can guide school nutrition policy by setting enforceable standards that limit or prohibit UPFs in meals and vending, prioritize fresh and minimally processed foods in procurement and through commodity purchasing, and shape menu planning toward whole-food options. In a school setting, this definition also provides a framework for monitoring compliance, tracking reductions in UPF use, supporting student and parent education, improving menu transparency, and aligning school food programs with broader public health goals.

Conclusion

We are pleased that the administration is concerned with the effect of UPFs on Americans' health and is seeking input to establish a standard definition. UPFs are a primary driver in the global obesity and chronic disease epidemics (UNICEF, 2025). UPFs are robbing our children and our citizens of their health and must be addressed head-on. By using an actionable, tiered definition based on sound science, the government can best approach the research and regulation of these products.

Co-signees

FoodFight USA
Founded by entrepreneurs Todd Wagner and Lori McCreary, **FoodFight USA** is a nonprofit, nonpartisan movement dedicated to cleaning up America's tainted food supply, which has contributed to an alarming rise in chronic disease and early death among our citizens. Our mission is threefold: to stop self-regulation by food companies, empower consumers, and collaborate with American farmers to grow healthier foods that are economically viable and beneficial to consumers' health.

Eat Real
Eat Real exists to prevent diet-related illness before it starts. Our award-winning K-12 certification program gives school nutrition leaders the insight, data, and support they need to make their meal plans more nutritious, delicious, and responsibly sourced. As the only doctor-led children's health nonprofit in the school food space, we drive nutrition access, public awareness, and state and national nutrition policy to put real food on the table for our nation's kids.

Joseph R. Shaw, Ph.D.
Working to develop 3Rs compliant, cost-effective new approach methods (NAMs) for chemical safety assessments, Dr. Shaw is the U.S. lead on the European Commission Horizon 2020 funded Precision Toxicology project, which he co-developed. He works to apply fit-for-purpose models that integrate biomolecular information, reveal adverse outcome pathways, and predict harmful effects of chemicals across the Tree of Life, including humans. Dr. Shaw collaborates with regulators and other key stakeholders in applying Precision Toxicology in policy and law. He also works with directly with communities to use these tools to reduce the burden of harmful chemical exposure, especially in low-income countries.