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Rockville, MD 20852

### **Comment on Ultra-Processed Foods; Request for Information (Docket No. FDA-2025-N-1793)**

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the U.S. Food and Drug Administration, U.S. Department of Health and Human Services, and U.S. Department of Agriculture's (FDA/HHS/USDA's) request for information (RFI) to help develop a uniform definition of ultra-processed foods (UPF) for human food products in the U.S. food supply.

#### **About CSPI**

CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. CSPI has an extensive history of advocating for policies that aim to improve the nutritional quality of the U.S. diet through food labeling, menu labeling, restaurant nutrition standards, school meals and competitive foods nutrition standards, and federal dietary guidance. CSPI publishes *Nutrition Action* (NA) and is supported by the subscribers to NA, individual donors, and foundation grants. CSPI is an independent organization that does not accept any corporate funding.

#### **Introduction**

The United States faces a diet-related chronic disease epidemic. Each year, over 350,000 U.S. deaths from cardiovascular disease, cancer, diabetes, and kidney disease are attributable to poor diet.<sup>1</sup> These deaths are entirely preventable. The average U.S. diet scores 58 out of 100 on the Healthy Eating Index, a tool designed to assess how well diets align with evidence-based federal dietary guidance.<sup>2</sup> This is due to both systemic and individual factors that result in people in the United States not eating enough healthy, wholesome foods like fruits, vegetables, whole grains, and seafood, and eating too much refined grain, added sugar, sodium, and saturated fat.<sup>3</sup>

U.S. diets are dominated by industrially processed foods.<sup>4,5,6</sup> Scientific evidence clearly shows that consumption of foods with excess added sugar, sodium, and saturated fat content is driving disease,<sup>7</sup> and emerging evidence from experimental research is beginning to shed light on additional characteristics of processed foods beyond nutrient content that contribute to excess calorie intake, weight gain, and related health problems.<sup>8,9,10</sup> Research has yet to conclusively identify all mechanisms through which certain processed foods cause overeating and health problems. But the ongoing chronic disease epidemic creates a need to provide dietary guidance and create policies surrounding these foods, even as the evidence continues to evolve.

The RFI correctly notes that there is no single, universally accepted definition of UPF or classification system for foods based on type or amount of processing. The Nova classification system (and its definition of UPF) is most commonly used in research, but several other classification systems exist<sup>11</sup> and several U.S. states have adopted laws with unique definitions of UPF. Nova's definition of UPF is potentially over-inclusive because prospective cohort studies suggest some subgroups of Nova-defined

UPF have no association with health outcomes or are even beneficial to health.<sup>12,13</sup> Conversely, many UPF definitions used in state bills are under-inclusive in capturing harmful products, including only a handful of additives and leaving out many processed foods linked to health harms.

## Executive Summary

We agree with FDA/HHS/USDA that there is a clear need for a uniform definition of UPF to allow for consistency in research and policy as it pertains to the U.S. Overall, the policy goal of defining UPF should be to identify the set of processed foods that scientific evidence shows are clearly linked to health concerns so that government policies can assist people with limiting those foods in their diets. It is crucial that any definition can be easily operationalized for policy, and that such operationalization of that definition minimizes potential unintended consequences that could cause harm.

We appreciate that, among other useful questions, FDA has asked for feedback on whether the term UPF is the best term to use, or if there is other terminology that would better capture the concerns associated with these products. While we encourage FDA/HHS/USDA to consider an alternative term that would more precisely convey harm (see section 3d below, in response to Question 4 in the RFI), we will use the term “UPF” throughout this comment to refer to the subset of processed products that are harmful.

Our comments include the following:

- 1. Recommended definitions.** We recommend that FDA/HHS/USDA first define “processed foods.” “Processed foods” could be defined as any foods that are not part of Nova Group 1 (“unprocessed or minimally processed foods”) or Nova Group 2 (“processed culinary ingredients”). FDA/HHS/USDA should then define “UPF” (or the terminology discussed in section 3d below) as the subset of processed foods that scientific evidence shows are clearly linked to health concerns, using evidence-based nutrition, ingredient, and food category criteria. “UPF” should include processed foods that contain high unhealthy nutrient density, high calorie density, processed meat, sweetened beverages, processed refined carbohydrates, or ingredients strongly linked to cancer or other serious health concerns.
- 2. Immediate policy recommendations.** Even before new, uniform definitions are finalized, there are many actions that FDA and USDA can and should take to address the harms of our industrially processed food supply. These include strengthening and finalizing FDA’s proposed rule on mandatory front-of-package nutrition labeling; requiring cancer warnings on processed meats; finalizing FDA’s proposed sodium reduction targets for industry; adopting added sugar reduction targets for industry; overhauling the food chemical regulatory system by closing the Generally Recognized As Safe (“GRAS”) loophole, improving post-market assessment of food chemical safety, and taking risk management action to address unsafe chemicals and products in the food supply; requiring specific disclosure of all food ingredients; and supporting schools to do more scratch cooking and serve more healthy, wholesome foods.
- 3. Responses to specific questions posed by the RFI.** In addition to our comments on considerations for defining UPF, we share recommendations for alternative terminology and additional considerations for incorporating the definition into food and nutrition policies and programs. With regard to terminology, we note that the term “ultra-processed” implies “very” or “extremely” processed, but since the extent, type, or purpose of processing does not necessarily relate to whether or not a food presents health risks, we encourage FDA/HHS/USDA to consider defining and applying a different term instead of UPF. With regard to policy considerations, we encourage FDA and USDA to: consider how UPF-related labeling claims will interact with existing claims in the marketplace such as “healthy” and “natural”; partner with the Alcohol and Tobacco Tax and Trade Bureau (TTB) to ensure alcoholic beverages that otherwise meet the

definition of UPF are categorized as UPF; and avoid implementing any policies that would limit people's access to convenient, affordable foods with no clear harms to health. Once the agencies finalize their definition, the government should explore taxes, marketing restrictions, warning labels, and federal procurement restrictions on harmful UPF. Such policies must be considered with a focus on protecting vulnerable groups, such as children, without exacerbating food insecurity, poverty, and inequality; must be accompanied by sufficient resources and technical assistance; and must be implemented with adequate lead time, to facilitate successful implementation.

## Detailed Comments

### 1. Recommended System for Defining “Processed Foods” and “Ultra-Processed Foods”

We recommend that FDA/HHS/USDA first define “processed foods” and then define UPF as the subset of processed foods that are harmful. The agencies' policy goal in defining UPF should be to identify the set of processed foods that scientific evidence shows are clearly linked to health concerns so that government policies can assist people with limiting those foods in their diets. It is crucial that any definition can be easily operationalized for policy, and that the operationalization of that definition for policy minimizes potential unintended consequences that could cause harm.

As noted in the introduction, the Nova classification system is commonly used to define UPFs, but we perceive its definition of UPF as over-inclusive as a way to define products that are harmful for health, and we are concerned about unintended consequences because of this (see section 3a below). However, we do believe the agencies could apply some aspects of the Nova system. Nova is useful for developing a definition of “processed foods” because it identifies foods that should be excluded from that definition, namely foods in Nova categories 1 and 2, which encompass unprocessed/minimally processed foods and processed culinary ingredients.

While Nova's definition of UPF intends to capture the “extent and purpose of the industrial processing” that products undergo, information about the full range of physical, chemical, and biological processes used to manufacture a food product (or their purposes) is not typically available to consumers or regulators and we do not believe this information is always essential in evaluating a product's benefits or risks. We recommend that FDA/HHS/USDA develop a definition of UPF that can be applied based on information found on product labels, using evidence-based nutrition, ingredient, and food category criteria.

**“Processed foods”** should capture most multi-ingredient food formulations in the U.S. food supply.<sup>a</sup> Specifically, we recommend defining “processed foods” as any foods that are not part of Nova Group 1 (“unprocessed or minimally processed foods”) or Nova Group 2 (“processed culinary ingredients”). Notably, many calorie-dense foods like nuts and olive oil that meet FDA's definition of “healthy” would not be considered “processed foods” under this definition.

**“UPF”** should be processed foods characterized by any of the six characteristics detailed below: high unhealthy nutrient density, high calorie density, processed meat, processed refined carbohydrates, and ingredients strongly linked to cancer or other serious health concerns.

We appreciate Commissioner Makary's remarks stating that the definition of UPF may evolve over time<sup>14</sup> (presumably as the scientific evidence evolves). If the evidence identifies additional characteristics driving harms of processed foods, they should be added to the definition of UPF.

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<sup>a</sup> FDA/HHS/USDA should consider all foods, including conventional foods and dietary supplements, when defining “processed foods” and “ultra-processed foods.” Infant formula and medical foods should be exempt.

#### **a. High unhealthy nutrient density**

We recommend that processed foods be considered to have high unhealthy nutrient density if they contain excess sugar, sodium, or saturated fat. Every day, the average American adult consumes 40% more sodium, 40% more added sugars, and 40% more saturated fat than is recommended in the 2020-2025 Dietary Guidelines for Americans.<sup>15,16</sup> Meanwhile, approximately 47% of adults have hypertension, 10% of adults have cardiovascular diseases, and 14% of the population has diabetes, with Type 2 diabetes accounting for approximately 90-95% of these cases.<sup>17,18</sup> Each of these conditions is strongly linked to excess intake of salt, added sugar, or saturated fat.<sup>19</sup> High unhealthy nutrient density could be defined based on the nutrient profile model (NPM) from Chile's Food Labeling and Advertising Law of 2016 (*i.e.*, foods with >10 grams of total sugar, 400 milligrams of sodium, or 4 grams of saturated fat per 100 grams of solid food, or >5 grams of sugar, 100 milligrams of sodium, or 3 grams of saturated fat per 100 milliliters of liquid beverage) or the Pan American Health Organization's (PAHO) NPM (*i.e.*,  $\geq 10\%$  of total energy from free sugars,  $\geq 1$  mg sodium per 1 calorie, or  $\geq 10\%$  of total energy from saturated fat).<sup>20</sup> Chile's NPM would capture about 77 percent of packaged foods and 35 percent of packaged beverages in the current U.S. food supply, while PAHO's NPM would capture 88% of packaged foods and 51% of beverages.<sup>21</sup> In contrast, applying FDA's definition of high added sugar, sodium, and saturated fat content (*i.e.*,  $\geq 20\%$  of the Daily Value per serving) would capture only 48% of packaged foods and 32% of packaged beverages in the U.S. food supply.<sup>22</sup> We recommend applying Chile's or PAHO's nutrient density criteria instead of FDA's high nutrient content criteria to ensure the definition of UPF captures sugary processed foods with small serving sizes as well as processed foods sweetened with ingredients like fruit juice or concentrated fruit puree that contain sugars that are not classified as "added sugars" by FDA. Overall, this criterion would incentivize manufacturers to reduce the amount of sugar, sodium, and saturated fat in foods to avoid the "UPF" designation.

#### **b. High calorie density**

We recommend that processed foods be considered to have high calorie density if they contain more than 275 calories per 100 grams of solid food or 70 calories per 100 milliliters of liquid beverage, applying a definition of high calorie density developed for Chile's Food Labeling and Advertising Law of 2016<sup>23</sup> (FDA has no comparable definition). Randomized trials have found that ultra-processed diets result in more caloric intake and weight gain (or less weight loss) compared to minimally processed diets, even when the diets are matched for nutrient content.<sup>24, 25, 26</sup> The authors of these studies have suggested that these effects were driven in part by calorie density. The UPF in these studies, like many UPF, simply contained more calories per bite than the studies' minimally processed foods due to the breakdown of the food matrix and reduction of water content, which made it easier for participants to consume more calories more quickly. This criterion ensures that the term UPF captures carbohydrate-rich snack foods like certain corn or potato chip products that are calorie-dense but not high in sugar, sodium, or saturated fat, but does not capture foods like nuts or olive oil that are calorie-dense but meet FDA's definition of "healthy" because they are not included in our proposed definition of "processed foods."

#### **c. Is or contains processed meat**

We recommend defining processed meat as meats that have been transformed through curing, fermentation, salting, smoking, or the use of preservatives. This criterion is important because consumption of processed meat is strongly linked to increased risk of colorectal cancer, so much so that processed meat is classified as a human carcinogen by the World Health Organization's International Agency for Research on Cancer (IARC).<sup>27</sup> Furthermore, studies linking consumption of UPF to type 2 diabetes and heart disease find that processed meat, as a UPF subgroup, is a key driver of the associated health risks for the entire UPF category.<sup>28, 29, 30, 31, 32, 33</sup> New York City already restricts these products from the city government's food procurement system<sup>34</sup> and provides clear guidance on how to identify such foods based on their labels.<sup>35</sup>

**d. Is a sweetened beverage**

We recommend defining sweetened beverages to include any beverage that lists sugar or any other added sweetener as an ingredient. This criterion is important because studies linking consumption of UPF to mortality and heart disease find that sugar-sweetened beverages and artificially sweetened beverages, as UPF subgroups, are key drivers of the associated health risks for the entire UPF category.<sup>36,37,38,39</sup> There is widespread scientific consensus that regularly consuming sugar-sweetened beverages is linked to weight gain, type 2 diabetes, cardiovascular disease, and tooth decay.<sup>40,41,42,43</sup> Evidence on the risks of consuming other sweetened beverages is more limited, especially among children. A 2019 policy statement from the American Academy of Pediatrics asserted that the long-term safety of non-nutritive sweeteners in childhood has not been assessed in humans.<sup>44</sup> In light of this uncertainty, several health authorities have advised that consuming beverages with non-nutritive sweeteners is not recommended in children.<sup>45,46</sup> Philadelphia already taxes all sweetened beverages and has clear regulations listing ingredients that constitute added sweeteners.<sup>47</sup>

**e. Is or contains processed refined carbohydrates**

We recommend defining processed refined carbohydrates based on the citizen petition submitted by Dr. David Kessler to FDA in August 2025.<sup>48</sup> This would include most refined sweeteners, flours, and starches (*i.e.*, many of the ingredients considered by FDA to be “added sugars” plus certain other carbohydrates that are not considered added sugars but are closely related). Dr. Kessler’s petition notes that in 2015, the Dietary Guidelines Advisory Committee (DGAC) concluded that there is strong evidence that these substances increase risk of obesity, type 2 diabetes, and cardiovascular disease. This is also consistent with the 2025 DGAC’s conclusion that a “healthy dietary pattern for individuals ages 2 years and older is ... lower in red and processed meats, sugar-sweetened foods and beverages, refined grains, and saturated fat.”<sup>49</sup> (emphasis added) FDA should develop clear guidance, similar to New York City’s guidance on processed meat referenced above, on how to identify foods containing processed refined carbohydrates based on their labels.

**f. Contains any additive or ingredient with a strong link to cancer or another serious health concern**

Due to failures of FDA’s pre- and post-market systems for evaluating food chemical safety, many additives and ingredients are currently used in the U.S. food supply despite clear evidence of harm. Ideally, harmful additives and ingredients would not be allowed in food, but until FDA thoroughly reforms its food chemical safety regulations so our food supply is free from harmful substances, all such additives should qualify a product as a UPF. Some of these substances have been classified as ingredients to avoid in CSPI’s Chemical Cuisine food chemical safety database<sup>50</sup> (see Appendix A), but this list is not exhaustive. FDA should identify additional additives and ingredients that are reliably linked to health risks and that have not undergone rigorous, transparent post-market safety assessments by FDA, perhaps using its draft chemical risk ranking tool<sup>51</sup> and other monitoring and surveillance techniques.

**2. Immediate Policy Recommendations**

Even before new, uniform definitions are finalized, there are many actions that FDA and USDA can take to address the harms of our industrial food supply. Policies that FDA and USDA can and should prioritize right away include:

**a. Strengthen and finalize FDA’s proposed rule on mandatory front-of-package nutrition labeling**

FDA should adopt mandatory labels that clearly identify foods that are “High In” added sugar, sodium, and saturated fat as well as prominent disclosures on foods containing low and no-calorie sweeteners stating that they are not recommended for children.<sup>52</sup> FDA could also adopt mandatory front-of-package labels for processed foods with high caloric density, similar to those required in Chile, Mexico, and Argentina.<sup>53</sup>

**b. Require cancer warnings on processed meats**

USDA should require warning labels on processed meat products stating: “USDA WARNING: Frequent consumption of processed meat products may increase your risk of developing cancer of the colon and rectum. To protect your health, limit your consumption of such products.” CSPI requested that USDA adopt such warnings in a 2016 citizen petition, citing the 2015 IARC review concluding that processed meat is carcinogenic to humans.<sup>54</sup> Our petition was denied in 2019. USDA should reconsider this decision.

**c. Finalize the proposed sodium reduction targets and adopt added sugar reduction targets for industry**

FDA should finalize its guidance providing voluntary Phase II sodium reduction targets for the food industry.<sup>55</sup> FDA should also monitor and evaluate industry progress on sodium reduction, and consider mandatory targets if food companies are not meeting the voluntary targets.<sup>56</sup> It should also establish added sugar reduction targets for industry, modeled after the sodium reduction targets, as requested in a 2023 citizen petition from CSPI and the New York City Department of Health and Mental Hygiene.<sup>57</sup>

**d. Overhaul the food chemical regulatory system**

Some of the harms of our industrial food supply are attributable to the use of unsafe additives and ingredients, such as unsafe preservatives, flavors, and dyes, which are present in our food due to inadequacies in the federal food chemical regulatory system. This broken regulatory system allows poorly tested chemicals to enter the food supply and to stay there long after reliable evidence of harm is published. By reforming the food chemical regulatory system, FDA can address some of the concerns related to UPF without needing to wait for the term to be defined. Three ways FDA should overhaul the food chemical regulatory system include: closing the GRAS loophole, improving post-market assessment of food chemical safety, and taking risk management action to address unsafe chemicals and products in the food supply.

**i. Close the GRAS loophole**

FDA should use its existing regulatory authority to reform the GRAS process, preferably by closing the GRAS loophole entirely such that all new food ingredients and new uses of existing ingredients undergo the pre-market approval process for food additives codified by Congress in 1958.<sup>58</sup> Barring that, FDA should require pre-market notification for all GRAS substances and new food ingredients, and the agency should evaluate those notices and require companies to wait for an affirmative determination of “safe” before the new substance enters the market or is used in a novel way. FDA should also, under its post-market assessment program, review all substances previously deemed GRAS without the agency being provided notice. These GRAS reforms align with previous recommendations made by CSPI.<sup>59</sup> FDA should request additional authority and resources from Congress to effectively and efficiently administer a mandatory pre-market review system.

**ii. Improve post-market assessment of food chemical safety**

FDA should reform its proposed framework for conducting post-market safety assessments of food chemicals,<sup>60</sup> taking into consideration the recommendations from our January and August 2025 comments to FDA.<sup>61,62</sup> Our recommendations would better ensure the framework and resultant assessments are rigorously scientific, systematic, objective, reproducible, transparent, based on high quality data, and appropriately focused on addressing the riskiest chemicals and maximizing public health protection.

**iii. Take risk management action to address unsafe chemicals and products in the food supply**

For food chemicals for which risks have been identified, such as those listed in Appendix A, or where risks are identified through the improved FDA post-market safety assessment system, FDA and USDA should take swift, decisive risk management actions to protect consumers. Such actions might include:

banning a substance from food entirely, banning a substance from certain types of products (*e.g.*, those marketed to children) or certain settings (*e.g.*, foods served in schools), reducing Acceptable Daily Intakes and permitted levels of use, requiring warning labels on any foods containing a substance of concern, and/or educating the public about the risks of such substances. FDA should not rely on voluntary action from the food industry to manage risks of unsafe food chemicals.

**e. Require specific disclosure of all food ingredients, including flavors, colors, and spices**

The vague terms “natural flavor,” “artificial flavor,” “artificial color,” and “spices” often appear in the ingredients lists of processed foods and can collectively refer to thousands of chemicals, many of which have not been formally approved by FDA and some of which are verifiably unsafe.<sup>63</sup> FDA and USDA should require full disclosure of all ingredients, including flavors, spices, and colors, on food labels to better enable consumers to make informed decisions about the foods they consume and to better enable FDA to identify flavor ingredients that entered the market with insufficient pre-market review, as discussed in CSPI’s 2024 report, “Hidden Ingredients.”<sup>64</sup> We recognize that compound flavors can contain more than a hundred individual ingredients, making full on-package disclosure practically challenging. Thus, full disclosure mandates could allow online disclosure but should favor label disclosures.

**f. Support child nutrition programs in developing infrastructure for scratch cooking and providing more healthy, wholesome foods.**

Child nutrition programs (including the National School Lunch Program, School Breakfast Program, Summer Food Service Program, and Child and Adult Care Food Program) will need robust funding and technical assistance to shift to serving more healthy, wholesome foods, in part by doing more scratch cooking. A 2024 survey asked school nutrition providers from 1,390 unique school districts across the country to indicate whether various issues represented a “significant challenge,” “moderate challenge,” or “not a challenge” for their school meal program. Top challenges included food costs (98% rated this a moderate or significant challenge), labor costs (95%), equipment costs (91%), and staff shortages (89%).<sup>65</sup> In a recent survey of 428 school food authorities in California, most respondents cited insufficient federal funding (including for school meals, for necessary kitchen equipment of kitchen facilities/storage, and to recruit new staff) as barriers to increasing scratch cooking.<sup>66</sup> In the Child and Adult Care Food Program, operated by child care centers and family day care homes, 93% of providers say their reimbursement does not cover the labor costs to provide meals (under the current meal pattern).<sup>67</sup> USDA should immediately provide robust, easily accessible grant funding and programmatic support to assist with scratch cooking for child nutrition programs. Additional investment from Congress will be necessary for program-wide change. Increased per-meal reimbursements, performance-based reimbursements, kitchen equipment grants and loans, reinstating the Local Food for Schools Cooperative Agreement, and increased funding for commodities are all strategies recommended by the National Alliance for Nutrition and Activity.<sup>68</sup>

Additional federal policy actions that would help address the harms of our industrial food supply and promote diets rich in healthy, wholesome foods and beverages, include: ensuring sufficient funding for the Supplemental Nutrition Assistance Program (SNAP) and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); ensuring access to safe and appealing tap water across the United States; and implementing sweetened beverage taxes, junk food marketing restrictions, and federal procurement nutrition guidelines.

**3. Responses to Specific Questions Posed by the RFI**

**a. Question 1: No existing classification system is fully appropriate for adoption by FDA/HHS/USDA in defining UPF.**

The agencies’ policy goal in defining UPF should be to identify the set of processed foods that scientific evidence shows are clearly linked to health concerns so that government policies can assist people with

limiting those foods in their diets. As previously described in section 1 of this comment, we believe there are elements of the Nova classification system that are useful for developing a definition of “processed foods” and we propose that UPF should be defined as a subset of “processed foods.” However, we are not advocating that FDA/HHS/USDA adopt a definition of UPF entirely aligned with Nova because Nova was developed with goals beyond identifying foods posing direct health or safety concerns, resulting in a definition that is not appropriate for the U.S. regulatory context.

Nova was developed by Brazilian researcher Carlos Monteiro in 2010 with the goal of describing the foods interfering with and transforming traditional Brazilian diets to the detriment of public health.<sup>69</sup> In Monteiro *et al.*’s paper introducing the new classification system, the researchers emphasized the need for a system that considers both the “extent and purpose of the industrial processing” applied to foods, and their proposed definition of UPF included products designed “to replace home-prepared dishes.”<sup>70</sup>

Instead of assessing risks only based on the presence of harmful nutrients, ingredients, food groups, pathogens, or contaminants, as the U.S. regulatory system does, Nova considers additional factors like corporate intent (*i.e.*, the purpose of processing from the manufacturer’s perspective). A 2019 paper explaining what UPF are and how to identify them states:

Processes and ingredients used for the manufacture of ultra-processed foods are designed to create highly profitable products (low-cost ingredients, long shelf-life, branded products) which are liable to displace all other NOVA food groups. Their convenience (imperishable, ready-to-consume), hyper-palatability, branding and ownership by transnational corporations, and aggressive marketing give ultra-processed foods enormous market advantages over all other NOVA food groups. Marketing strategies used worldwide include vivid packaging, health claims, special deals with retailers to secure prime shelf space, establishment of franchised catering outlets, and campaigns using social, electronic, broadcast and print media, including to children and in schools, often with vast budgets. All this explains why ultra-processed foods have been successful in displacing unprocessed or minimally processed foods and freshly prepared dishes and meals – or ‘real food’ – in most parts of the world.<sup>71</sup>

FDA, HHS, and USDA do not have the expertise or explicit directive from Congress to regulate the food supply based on corporate intent to prevent companies from selling food products designed to displace fresh or home-prepared foods, in the absence of direct health or safety concerns.

In Brazil, where only one-fifth of calories come from UPF as defined by Nova,<sup>72</sup> the government has implemented multiple policies in an attempt to limit consumption of UPF and maintain more traditional dietary patterns—including incorporating recommendations to avoid UPF into Brazil’s national dietary guidelines<sup>73</sup> and implementing food standards that restrict certain UPF in schools.<sup>74</sup> However, the U.S. context is different from Brazil’s because the majority of our calories come from UPF, as defined by Nova.<sup>75,76,77</sup>

Most of the scientific literature linking UPF to adverse health outcomes is based on prospective cohort dietary studies that are limited by their potential for residual confounding. These studies also have various different approaches for operationalizing the Nova definition of UPF. These are among the reasons that the 2025 DGAC, which reviewed the evidence on the association between UPF and growth, body composition, and risk of obesity, found only “limited” evidence that diets higher in UPF are associated with greater adiposity and greater risk of overweight and/or obesity in children and adults.<sup>78,79</sup>

Many prospective cohort studies have found that the Nova UPF definition is associated with increased risk of a variety of adverse health outcomes<sup>80</sup>; however, when researchers disaggregate associations by UPF subcategory, they consistently find that different subcategories have different associations with health outcomes—some positive, some negative, and some neutral.<sup>81,82,83,84,85,86</sup> In many studies,

processed meats and sugar-sweetened beverages appear to be driving negative associations between UPF and health risks. For example, in a study that assessed the relationship between Nova-defined UPF intake and cardiovascular disease in three large prospective cohorts of U.S. adults, the highest vs. lowest quintile of overall UPF intake was associated with a significantly higher risk of cardiovascular disease [HR: 1.11 (95% CI: 1.06–1.16)].<sup>87</sup> However, when researchers examined the association between cardiovascular disease risk and the highest vs. lowest quintile of Nova-defined UPF intake excluding sugar-sweetened beverages and processed meats, that association went away [HR: 1.00 (95% CI: 0.96–1.05)].<sup>88</sup> Many of the UPF subcategories that studies suggest are beneficial for health when disaggregated from the broader “overall UPF” category (*e.g.*, UPF yogurt, UPF whole grain breads, and UPF whole grain cereals) are important sources of nutrients for U.S. consumers. Thus, if the U.S. government implemented policies to limit consumption of all UPF, as defined by Nova, there could be unintended negative consequences on healthy food access and diet quality.

It is possible that the drivers of negative UPF health associations are not entirely due to food group subcategories, and instead are related to energy density or other traits that span across food groups, but are more concentrated in specific groups that appear to be driving these associations. More research is needed in this area, which was echoed in the 2025 DGAC’s recommendation that future DGACs should continue examining the association between UPF and growth, body composition, and risk of obesity, as well as other health outcomes such as type 2 diabetes, cardiovascular disease, cancer, and cognitive decline.<sup>89</sup>

In the U.S. context, we believe it is most prudent and legally supportable for dietary guidance and policies to focus on limiting foods clearly and directly linked to health harms. Our proposed definition is specifically designed to capture the subcategories of processed foods that are most clearly linked to adverse health outcomes, based on the best available evidence.

**b. Question 2: Products with harmful ingredients should be considered UPF regardless of the quantity of the ingredient present.**

Products containing processed meat or other additives or ingredients strongly linked to cancer or other health concerns should be considered UPF regardless of the quantity of the ingredient present. Considering that quantities of all ingredients are not disclosed on ingredient labels, quantitative thresholds cannot be set for ingredients that are only listed on the ingredient label (*i.e.*, that are absent from the nutrition label), meaning presence/absence on the ingredient list is the only viable approach to taking ingredients into consideration for defining UPF using publicly available information.

**c. Question 3: FDA/HHS/USDA should consider nutrition, ingredient, and food category criteria instead of processing methods when defining UPF.**

The definition of UPF must rely on publicly available information to be useful for research and policy purposes. Since information about the full range of physical, chemical, and biological processes used to manufacture a food product is not typically available, nutrition, ingredient, and food category criteria should be applied instead. This is also useful for ensuring the definition remains evidence-based, since most processing methods have not been broadly associated with health harms. Processed meats and processed refined carbohydrates are exceptions. For processed meats, specific processing methods including curing, fermentation, salting, smoking, and the use of preservatives define this category of meat that is associated with cancer risk.<sup>90</sup> The New York City Food Standards Implementation Guide includes a way to identify such foods based on their label information.<sup>91,92</sup> Processed refined carbohydrates, as defined in the petition submitted by Dr. David Kessler, include a specific list of ingredients that are considered refined sweeteners, flours, or starches, along with any “refined flour and starches that are subjected to food extrusion technology.”<sup>93</sup> In his petition, Kessler explains: “The effects of extrusion technology on human metabolism have not been fully studied and understood” but the extrusion process “exposes food ingredients to high temperatures and shear forces, disrupts the food matrix, and makes the

food into new shapes with new texture” and “these processes increase how quickly we digest these foods.”<sup>94</sup> We recommend FDA/HHS/USDA consult with food scientists to develop clear guidance, similar to New York City’s guidance on processed meat referenced above, on how to identify foods containing processed refined carbohydrates based on their labels.

If new evidence emerges that links other processing methods to health harms, the definition of UPF should be updated along with guidance on how to identify relevant foods using label information.

**d. Question 4: FDA/HHS/USDA should consider alternative terms that would more precisely align with a definition aiming to identify the set of processed foods that scientific evidence shows are clearly linked to health concerns.**

As previously discussed, the overriding policy goal of defining UPF or a similar term should be to identify the set of processed foods that scientific evidence shows are clearly linked to health concerns so that government policies can assist people with limiting those foods in their diets. The term “ultra-processed” implies “very” or “extremely” processed, but we do not recommend defining the term “UPF” based on the extent, type, or purpose of processing because this information is not always available and primarily considering the extent to which a food is processed would not necessarily result in the identification of the most harmful processed foods. FDA/HHS/USDA should consider whether to define and apply a different term instead of UPF that would more precisely align with their policy objective, such as “harmful processed foods.”

**e. Question 5: FDA/HHS/USDA should consider the presence of excess added sugar, sodium, and saturated fat, as well as high energy density, when defining UPF.**

As noted above, we believe that excess added sugar, sodium, and saturated fat, as well as high energy density, should all be incorporated into a definition of UPF, due to high-quality research that has shown these components to collectively increase risk of weight gain, hypertension, type 2 diabetes, and cardiovascular disease.<sup>95,96,97,98</sup>

**f. Question 6: Additional considerations for incorporating UPF into food and nutrition policies and programs**

**i. FDA and USDA should consider how UPF-related labeling claims will interact with existing claims in the marketplace.**

FDA Commissioner Dr. Marty Makary has indicated that the new definition of UPF may encourage companies to label foods as “Non-UPF,”<sup>99</sup> and “Non-UPF” claims have already entered the marketplace.<sup>100,101</sup> We encourage FDA and USDA to issue guidance regarding the use of “Non-UPF” claims that describes how such claims should be defined and when such claims are not permitted because they may be considered misleading. The agency should consider how the definition of “Non-UPF” will intersect with FDA’s definition of “healthy,” any future definition of “healthy” that USDA adopts to align with FDA’s, and with consumers’ perceptions of products labeled “healthy” or “natural.” Some products, such as whole milk or red meat, may be considered “Non-UPF” but not FDA Healthy. Such products should only be allowed to bear “Non-UPF” claims if such claims are accompanied by disclosures clarifying that they are not healthy, such as “High In Saturated Fat” disclosures. In general, reliance upon voluntary “Non-UPF” labeling claims is inadequate for addressing the risks posed by UPF. FDA and USDA should instead rely upon the regulatory approaches we recommend elsewhere in this comment.

**ii. FDA and USDA should partner with the Alcohol and Tobacco Tax and Trade Bureau (TTB) to ensure that relevant alcoholic beverages are regulated as UPF.**

Unlike other foods and beverages, which are regulated by FDA and USDA, most alcoholic beverages are regulated by the TTB. Like many non-alcoholic beverages, alcoholic beverages can have high sugar,

sodium, and saturated fat content, and often contain ingredients (other than alcohol), such as synthetic dyes, caramel coloring, aspartame, and more, that are linked to cancer or other serious health concerns.<sup>102</sup> For example, Cutwater Piña Colada has 32 grams of sugar in a 12-ounce can,<sup>103</sup> Baileys Irish Cream has 4 grams of saturated fat per 1.7-ounce serving,<sup>104</sup> and Four Loko (Sour Galactic Punch flavor) contains natural and artificial flavors, synthetic colors, and artificial sweetener.<sup>105</sup> Relevant beverages (*i.e.*, those characterized by high unhealthy nutrient density, high calorie density, processed refined carbohydrates, or ingredients strongly linked to cancer or other serious health concerns) should be captured in the definition of UPF (and related policies) regardless of whether they do or do not contain alcohol, and regardless of which federal agency regulates their labeling.

TTB should finalize its proposed rule to require Alcohol Facts labeling,<sup>106</sup> and issue a proposed rule to require full ingredient lists on alcoholic beverages, to facilitate consumers' ability to identify alcoholic beverages that are UPF.

**iii. FDA/HHS/USDA should avoid adopting a definition of UPF that could lead to policies that would limit people's access to convenient, affordable foods with no clear health harms.**

A key danger of the government adopting an over-inclusive definition of UPF is that this could lead to policies that restrict physical or financial access to convenient, affordable foods without strong evidence of direct harm. For example, USDA must not define UPF in a way that could lead to the restricting of healthy, safe foods from programs like SNAP, WIC, and the National School Lunch Program. These programs are intended to promote nutritious diets for children and for Americans with low incomes. In addition to avoiding implementing policies linked to an overly broad UPF definition, USDA must accompany any attempt to limit access to UPF with increases in access to affordable, healthy, wholesome foods; resources for implementing changes at schools and other institutions; nutrition education; and robust evaluations of the impact of restrictive policies on diet quality as well as potential unintended consequences.

**iv. Once the agencies finalize their definition, the government should support and implement policies to reduce consumption of UPF.**

Assuming FDA/HHS/USDA adopt a science-based definition of UPF that captures processed foods linked to health concerns (*i.e.*, our proposed definition), the federal government should explore taxes, marketing restrictions, warning labels, and federal procurement restrictions on certain UPF. Such policies must be considered with a focus on protecting vulnerable groups, such as children, without exacerbating food insecurity, poverty, and inequality. These initiatives must also be accompanied by sufficient resources and technical assistance, and be implemented with adequate lead time, to facilitate successful implementation.

Thank you for considering our comments on this RFI.

Sincerely,

Eva Greenthal, MS, MPH  
Senior Policy Scientist  
[egreenthal@cspi.org](mailto:egreenthal@cspi.org)

Aviva Musicus, ScD  
Science Director

Anupama Joshi, MS  
Vice President of Programs

Peter Lurie, MD, MPH  
Executive Director and President

Appendix A.

**Food Additives & Ingredients Rated “Avoid” in Center for Science in the Public Interest’s Chemical Cuisine Additive Safety Rating System, August 2025**

| <b>Food Chemical</b>                              | <b>Purpose</b>         | <b>Health Concern</b>     |
|---------------------------------------------------|------------------------|---------------------------|
| Acesulfame potassium                              | Sweetener              | Cancer                    |
| Aloe vera                                         | Flavoring              | Cancer                    |
| Aspartame (Equal, AminoSweet)                     | Sweetener              | Cancer                    |
| Azodicarbonamide                                  | Coloring               | Cancer                    |
| Brominated vegetable oil (bvo)*                   | Emulsifier             | Neurological & Behavioral |
| Butylated hydroxyanisole (bha)                    | Preservative           | Cancer                    |
| Caramel coloring                                  | Coloring               | Cancer                    |
| Cyclamate*                                        | Sweetener              | Cancer                    |
| Ginkgo biloba                                     | Vitamins & Supplements | Cancer                    |
| Olestra (olean)                                   | Oil & Oil Substitutes  | Digestive                 |
| Potassium bromate                                 | Other                  | Cancer                    |
| Potassium iodate                                  | Other                  | Cancer                    |
| Propyl gallate                                    | Preservative           | Cancer                    |
| Saccharin                                         | Sweetener              | Cancer                    |
| Sodium nitrate (nitrite)                          | Preservative           | Cancer                    |
| Sucralose (Splenda)                               | Sweetener              | Cancer                    |
| Synthetic food dyes                               | Coloring               | Neurological & Behavioral |
| TBHQ (tert-butylhydroquinone)                     | Preservative           | Cancer                    |
| Titanium dioxide                                  | Coloring               | DNA Damage                |
| Trans fat (partially hydrogenated vegetable oil)* | Oil & Oil Substitutes  | Cardiovascular            |

\*Already banned in the United States

Source: <https://www.cspi.org/page/chemical-cuisine-food-additive-safety-ratings>

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