NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
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via electronic submission: [Regulations.gov**]**

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United States Department of Agriculture,
1320 Braddock Place,
Alexandria, VA 22314

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

The New York City (NYC) Health Department is pleased to submit a comment to the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) on the Request for Information (RFI): Ultra-Processed Foods (UPF or UPFs). We commend the FDA and the USDA for pursuing a standard definition of UPF, which will have implications for policy and research efforts and provide additional clarity to consumers. The FDA and the USDA have the opportunity to consider a thoughtful approach to a UPF definition that complements a finalized rule for healthy label claim criteria, as well as proposed initiatives, including the Nutrition Info box and phase II sodium reduction targets. Further, the FDA and the USDA have the opportunity to consider other policies to reduce consumption of unhealthy UPF, including establishing added sugars reduction targets, as previously recommended by the NYC Health Department.

A healthy diet emphasizes whole and minimally processed foods and contains lower amounts of nutrients of concern, such as added sugars, saturated fat, and sodium often found in UPF. UPFs can also contain other additives, like butylated hydroxyanisole (BHA), which is associated with cancer.[1,2,3] Consuming high amounts of these nutrients of concern is associated with increased risk of chronic disease. UPF research is a growing

area, but there remain many unknowns. A clear definition for UPF based on objective criteria is critical to allow for the development of a strong scientific research base for UPF and their associated health harms.

Across food and nutrition policies and programs, the NYC Health Department promotes a balanced eating pattern of mostly whole and minimally processed food, including lots of plants, to reduce risk of chronic diseases such as type 2 diabetes, high blood pressure, and heart disease. For example, the NYC Food Standards are evidence-based nutrition guidelines for all foods purchased and served by NYC agencies and their sub-contractors, and apply to approximately 219 million meals and snacks every year. The NYC Food Standards, which are reviewed and updated at least every three years based on the latest nutrition research, offer a practical basis for guidance regarding UPF. Additional details specific to the NYC Food Standards and UPFs can be found in response to specific questions below.

The NYC Health Department offers responses below to select requests for information.

1. *What, if any, existing classification systems or policies should we consider in defining UPFs? What are the advantages and challenges in applying these systems (or aspects of them) to classify a food as ultra-processed? What are characteristics that would or would not make a given system (or aspect of the system) particularly suitable for the U.S. food supply? Please provide supporting data and explain your rationale in your response.*

   NYC Health Department Response: We rely on the existing literature base, which most commonly uses the NOVA classification system for defining UPFs. This system, however, has challenges, as noted in the FDA and USDA request:

   - The NOVA classification system captures a wide-range of products; for example, products that are classified as Group 4: Ultra-Processed Foods range from those with no nutritional value such as sugary drinks to products that are more nutrient-dense, such as whole wheat bread. While these latter products are considered ultra-processed in the NOVA classification system, they are not nutritionally equivalent to other UPF that offer little to no nutritional value. In determining a definition for UPF, the FDA and USDA should consider both the merits and impact of including a product's nutrient profile as well as the method and extent of processing.
   - Another challenge to using the NOVA classification system to identify UPFs in the U.S. food supply is that food package labeling does not allow for consumers, policymakers, or researchers to consistently identify processing methods used during food production. Limitations of current labeling requirements that would preclude identification of a UPF should be taken into account when establishing a UPF definition and, more importantly, future labeling proposals should be considered to support consumer and researcher identification of the to-be-established UPF definition by the FDA and USDA.

In light of these challenges with the NOVA classification system, an alternative approach can be found in the citizen's petition that Dr. David A. Kessler recently submitted to the FDA to limit the exposure of refined carbohydrates used in industrial processing. In Dr. Kessler's petition, he calls for a focus on three groups of processed refined carbohydrates used in industrial processing and associated with cardio-metabolic chronic disease risk: 1) starch conversion products, including maltodextrin and certain sweeteners, including corn syrup, corn solids, glucose syrups, dextrose, invert sugar, xylose, maltose, and high fructose corn syrups; and 2) refined flour and starches that are subjected to food extrusion

technology, including wheat, corn, tapioca, oat and potato flour, and starches that are processed by extraction or similar technology, and 3) sucrose, refined flours, or starches that are used with emulsifiers (e.g., mono- and diglycerides of fatty acids, DATEM, sodium stearoyl lactylate, polysorbates); dough conditioners and strengtheners (e.g., azodicarbonamide, L-cysteine, calcium peroxide); humectants (e.g. propylene glycol); stabilizers and gums (e.g., carboxymethylcellulose, methylcellulose); or modified starches and fillers (e.g. regelatinized starch, modified food starch, dextrins). These ingredients cover many, but not all UPFs. If this approach is used by the FDA and USDA, then some additions, including processed meats, should be considered to more comprehensively address UPFs associated with health harms.

2. *FDA-required ingredient labeling provides important information to consumers about what is in packaged foods. The ingredient declaration on a food label lists each ingredient by its common or usual name (21 CFR 101.4(a)(1)). This ingredient name sometimes provides information on specific forms of the ingredient used, such as "flour" versus "whole grain flour." Additionally, ingredients are declared in descending order of predominance by weight (21 CFR 101.4(a)), which may help a consumer determine the relative proportion of whole versus processed ingredients. For certain types of ingredients, such as flavorings, colorings, and chemical preservatives, labeling must also provide the function of the ingredient (see 21 CFR 101.22). The following questions focus on the ingredient list on the labeling of packaged foods.*

    a. *In considering ingredients that appear toward the beginning of an ingredient list (that is, ingredients that likely form most of a finished food by weight), what types of ingredients (e.g., ingredients that may share a similar composition, function, or purpose) might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.*

        NYC Health Department Response: We believe ingredients should be considered when characterizing UPFs, regardless of the quantity used. The FDA and USDA should establish and maintain a concrete list of ingredients used in industrially manufactured products that may categorize a food as ultra-processed. These ingredients may include, but are not limited to, high fructose corn syrup and the ingredients which are banned by the NYC Food Standards: artificial colors including caramel colors and titanium dioxide, low- and no-calorie sweeteners, azodicarbonamide, potassium bromate, potassium iodate, butylated hydroxyanisole, and propylparaben. Some ingredients may not be problematic until they are industrially processed, such as starch subject to extrusion technology, or when used for specific uses, such as rosemary extract used to cure meat. The FDA and USDA may consider including ingredients under certain processing conditions or uses as part of their list (please see Dr. Kessler's petition and below responses to question 3 for more details on such processing).

3. *FDA defines "manufacturing/processing," in part, to mean making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients (21 CFR 117.3; see also 21 U.S.C. 321(gg) for the statutory definition of "processed food"). Certain FDA regulations, such as standards of identity, may prescribe methods of production or formulation (see, e.g., 21 CFR part 133). Processing of a food is often achieved*

by a combination of physical, biological, and chemical methods; however, while processing information is sometimes found on food labeling, manufacturers are not always required to disclose processing information on food labeling. The following questions focus on the processing of an ingredient or a mixture of ingredients into the finished food and whether certain processing methods may contribute to a food being considered ultra-processed.

NYC Health Department Response:
The NYC Food Standards do not allow processed meats, including ultra-processed meats (as defined by the NOVA classification system), to be served as of 2025 because they have been linked with cancer. Since processing information is not always available on food labeling, the NYC Food Standards define processed meats by either the type of processing or the presence of certain ingredients. NYC agencies currently determine if a meat is processed based on the presence of food preservatives (i.e., anoxomer, calcium disodium EDTA, disodium EDTA, 4-hydroxymethyl-2, 6-di-tert-butylphenol, potassium nitrate, sodium nitrate, TBHQ, THBP) and/or natural curing or fermenting agents (i.e., celery-based products, wine, Swiss chard-based products, lactic acid starter culture, cherry-based products, vegetable juice powder, rosemary extract) – in addition to product packaging that includes the following terms: cured, fermented, salted or smoked.

a. *Processing a food through physical means may include cutting, extracting juice by an application of force, heating, freezing, extrusion, and other physical manipulations. What physical processes might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.*

NYC Health Department Response: Specific to meat, the NYC Food Standards consider processed meat to be meat, poultry or fish that has been transformed to enhance flavor or improve preservation by the physical process of smoking, defined as to expose meat to smoke from burning wood or apply liquid smoke ingredients to meat).[4]

Physical processes that might be used to characterize foods made from refined grains as UPF, for example extraction and extrusion, are well described in Dr. Kessler's petition.

b. *Processing a food through biological means may include non-alcoholic fermentations of the food by microorganisms (for example, bacteria and yeasts), enzymatic treatment, and other biological manipulations. What biological processes might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.*

NYC Health Department Response: Specific to meat, the NYC Food Standards consider processed meat to be meat, poultry or fish that has been transformed to enhance flavor or improve preservation by the biological process of fermentation, defined as adding fermentative bacteria to meat to add flavor or stop the growth of harmful organisms).[4]

c. *Processing a food through chemical means may include pH adjustment and other chemical manipulations. What chemical processes might be used to characterize a food*

as ultra-processed? Please provide supporting data and explain your rationale in your response.

NYC Health Department Response: Specific to meat, the NYC Food Standards consider processed meat to be meat, poultry or fish that has been transformed to enhance flavor or improve preservation by the chemical process of curing, defined as adding salt; sugar; or any source of nitrates or nitrites, preservatives listed in 21 CFR Part 172, Subpart B; celery-based products; wine; Swiss chard-based products; lactic acid starter culture; cherry-based products; vegetable juice powder; or rosemary extract to meat for color development; flavor enhancement; preservation; or safety); and salting, defined as to preserving meat with sodium.[5]

Separately, the cooking method of foods can be a way to classify them as a UPF, for example, deep-frying or pre-frying foods. The NYC Food Standards require no deep frying but, as manufacturers are not required to disclose processing on food labeling, the NYC Food Standards cannot ensure that pre-fried foods are not purchased or served.

4. *FDA and USDA are aware of ongoing research on nutrition and other attributes relating to the health outcomes associated with consumption of UPFs. As noted in the background, FDA is also initiating a joint effort with NIH to answer questions such as how and why UPFs can harm people's health.*
    a. *In considering nutritional attributes (such as information presented on the Nutrition Facts label), to what extent, if any, and how, should nutritional composition or the presence of certain nutrients be incorporated in a definition of UPFs? Please provide supporting data and explain your rationale in your response.*

    b. *What other attributes, such as energy density or palatability, might be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response. If relevant to your answer, please also provide suggestions on how these attributes can be measured and/or potentially be incorporated into a definition of UPFs, if they are not readily apparent on the food labeling.*

NYC Health Department Response: The FDA and USDA should only consider attributes with a clear scientific definition or provide a clear scientific definition and rationale for any attribute that will be considered as a factor when determining a product is a UPF. This will ensure a UPF definition is measurable and can be consistently applied across products. While palatability does not have an objective definition, hyper-palatability has been characterized by researchers as a combination of different levels of fat, carbohydrates, simple sugars, and sodium.[6] This characterization is practical because it allows for the operationalization of the concept of hyper-palatability – it relies on nutrients (i.e. fat, sugar, and sodium) that can be objectively measured that also contribute to a product's hyper-palatability. A similar approach can be considered by the FDA and USDA – when establishing a UPF definition, we encourage the FDA and USDA to be clear regarding the nutrient levels at which a product may be considered hyper-palatable, thereby qualifying it to be designated as a UPF.

5. *FDA and USDA are exploring whether and how to incorporate various factors, such as the ones discussed in the questions above, into a uniform definition of UPFs. How might these factors be integrated in the classification of a food as ultra-processed in a way that can be systematically measured and applied to foods sold in the U.S.? And what considerations should be taken into account in incorporating such a classification in food and nutrition policies and programs?*

   NYC Health Department Response: As mentioned previously, the NYC Food Standards offer an example of how food processing can be incorporated into policies. The NYC Food Standards restrict highly processed foods through limits on sodium, added sugars, and saturated fat, restricting processed meat, and with requirements for whole grains and minimums for fiber. Additionally, in the updates that were released in August 2025, the NYC Food Standards expanded the restriction on low- and no-calorie sweeteners (LNCS) in food and beverages served to all ages from a previous limit that applied only to children age 18 and younger, and established new restrictions on all artificial colors, certain flour additives (azodicarbonamide, potassium bromate, potassium iodate), and preservatives (propyl paraben and butylated hydroxyanisole (BHA)). For example, grain-based snacks must contain, per serving, $\leq$ 200 mg of sodium, $\leq$ 10 g added sugars, $\geq$ 2 g fiber per serving, and must not contain LNCS, artificial colors, azodicarbonamide, potassium bromate, potassium iodate, propyl paraben, or BHA. Together these requirements support serving nutrient dense, satisfying foods that support the City's chronic disease reduction goals.

In summary, when establishing a UPF definition, the FDA and USDA should consider the following l components together in determining what makes a food UPF, including a stated list of ingredients, set nutrient levels, and type of processing, especially as it applies to specific ingredients. The definition should work in conjunction with existing and upcoming FDA and USDA policies to avoid consumer or manufacturer confusion. Overall, the FDA and USDA should consider a definition with clear criteria that is easy to operationalize for researchers (who may seek to study the impact of UPF), manufacturers (who may seek to decrease their portfolio of UPF to better support consumer health and consumer demand), consumers (to inform decision making for themselves and their families), and policy makers who may seek to apply a UPF definition to improve food and nutrition programs in the U.S., including but not limited to school meals, Child and Adult Care Food Program, Dietary Guidelines for Americans, and USDA commodity foods.

Thank you for the opportunity to comment on this RFI.

Sincerely,

[redacted]

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Health and Mental Hygiene

[1] National Toxicology Program, U.S. Department of Health and Human Services. RoC Profile: Butylated Hydroxyanisole; 15th RoC 2021.

[2] Joint FAO/WHO Expert Committee on Food Additives, World Health Organization & Food and Agriculture Organization of the United States. Specifications for the Identity and Purity of Food Additives and their Toxicological Evaluation: Some Antimicrobials, Antioxidants, Emulsifiers, Stabilizers, Flour-Treatment Agents, Acids and Bases, Ninth report of the Joint FAO/WHO Expert Committee on Food Additives. Geneva: World Health Organization; 1965.

[3] EFSA Panel on Food Additives and Nutrient Sources Added to Food, 2004. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to para hydroxybenzoates (E 214-219). *EFSA Journal* 2004; 2(9):83, 26 pp. doi:10.2903/j.efsa.2004.83

[4] Murano, P. *Understanding Food Science and Technology*. Wadsworth Thomson Learning; 2003.

[5] Murano, P. *Understanding Food Science and Technology*. Wadsworth Thomson Learning; 2003.

[6] Fazzino TL, Rohde K, Sullivan DK. Hyper-Palatable Foods: Development of a Quantitative Definition and Application to the US Food System Database. Obesity (Silver Spring). 2019 Nov;27(11):1761-1768. doi: 10.1002/oby.22639. PMID: 31689013.