4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1793]

DEPARTMENT OF AGRICULTURE

Ultra-Processed Foods; Request for Information

AGENCY: Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS); U.S. Department of Agriculture (USDA)

ACTION: Notice; request for information.

SUMMARY: FDA and USDA (we) are requesting data and information to help develop a uniform definition of ultra-processed foods (UPF or UPFs) for human food products in the U.S. food supply. A uniform UPF definition, developed as part of a joint effort by federal agencies, would allow for consistency in research and policy to pave the way for addressing health concerns associated with the consumption of UPFs.

DATES: Either electronic or written comments on the notice must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-1793 for "Ultra-Processed Foods; Request for Information." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

FDA: Claudine Kavanaugh, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-4647; or Meadow Platt, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

USDA: Eve Stoody, Food and Nutrition Service, United States Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314, 703-305-2062.

SUPPLEMENTARY INFORMATION:

I. Background

The United States faces a growing epidemic of preventable diet-related chronic diseases, such as cardiovascular disease, and type 2 diabetes, which are leading causes of death and disability in the U.S. (Ref. 1). Improving nutrition is therefore one of the most important public health interventions for reducing chronic illnesses and premature death, and for helping make Americans healthier.

Over the last decade, concerns have grown significantly about the increased availability and consumption of foods that researchers have termed "ultra-processed." Researchers have found links between consumption of these foods and a range of negative health outcomes, including cardiovascular disease, obesity, and certain cancers (see, e.g., Refs. 2, 3, 4). Consumption of these foods may also be associated with lower diet quality, increased caloric intake, and the intake of food additives (see, e.g., Refs. 5, 6, 7). Some researchers have estimated that more than half of calories consumed by adults and children in the U.S. are from foods that the researchers classified as ultra-processed (Refs. 8, 9).

In May 2025, the President's Make America Healthy Again (MAHA) Commission released "The MAHA Report: Make Our Children Healthy Again: Assessment" (MAHA Report) (Ref. 7). Among other topics, the MAHA Report highlights the prevalence of certain processed foods in the U.S. food system and notes the health concerns associated with their consumption (Ref. 7; see also Refs. 8, 9). FDA and the National Institutes of Health (NIH) have also announced plans to invest in gold standard science through the new NIH-FDA Nutrition Regulatory Science Program to help better understand how and why consumption of ultra-processed foods can harm people's health (Ref. 10).

There is no single, universally accepted definition of UPFs, and the definition of such foods has varied considerably over time (see, e.g., Ref. 11). Classification systems may use

either the terms “ultra-processed” or “highly processed,” and the classification of a food can vary between systems due to differing approaches to the definition (Refs. 12, 13).

The most common classification, developed by Brazilian researchers in 2009, is the “Nova” system (Ref. 14). In its latest iteration, the Nova system classifies foods into four food categories: group 1, unprocessed or minimally processed foods; group 2, processed culinary ingredients; group 3, processed foods; and group 4, ultra-processed foods (Ref. 15). The Nova system identifies ultra-processed foods (group 4) based on multiple factors; these factors include things like the use of certain ingredients and substances (such as emulsifiers, bulking agents, or thickeners), industrial processing technologies, as well as sophisticated packaging, that result in a palatable and appealing product (Refs. 15, 16, 17).

However, concerns have been raised about the full ability of UPF classification systems to accurately capture the characteristics of UPFs that may impact health. For example, on one hand, there is overlap between foods considered to be ultra-processed and foods that are high in added sugars, sodium, and saturated fat, which independently are recommended to be limited by the *Dietary Guidelines for Americans, 2020-2025* (Refs. 6, 18). Foods commonly considered to be ultra-processed encompass a broad range of industrially processed foods, such as soft drinks and many packaged snacks. On the other hand, foods considered to be ultra-processed may also include foods such as whole grain products or yogurt, which are known to have beneficial effects on health and are recommended as part of healthy dietary patterns (see Ref. 18). It is important therefore to consider unintended consequences of an overly-inclusive definition of UPFs that could discourage intake of potentially beneficial foods.

Recently, some U.S. states have sought to establish their own definitions of “ultra-processed foods,” with proposed definitions varying. These proposed state definitions include, among others:

- Proposals to define UPFs as foods that include substances intended to have a certain effect on food (such as stabilizers and thickeners, coloring or flavoring agents) (see,

e.g., Pennsylvania, 2025 Bill Text PA H.B. 1132; California, 2025 Bill Text CA A.B. 1264);

- Proposals to define UPFs as foods that have undergone certain processing steps (such as hydrogenation of oils or hydrolysis of proteins) (see, e.g., Massachusetts, 2025 Bill Text MA H.B. 539); and
- Proposals to define UPFs as foods that include one of anywhere between 10 and 15 listed ingredients (see, e.g., Florida, 2025 Bill Text FL S.B. 1826 (seeking to define UPFs as foods that include one of 11 listed ingredients); Louisiana, 2025 Bill Text LA S.B. 117 (seeking to define UPFs as foods that include one of 15 listed ingredients); North Carolina, 2025 Bill Text NC H.B. 874 (seeking to define UPFs as foods that include one of 11 listed ingredients); Arkansas, 2025 Bill Text AR H.B. 1962 (seeking to define UPFs as foods that contain one of 10 listed ingredients); Alabama, 2025 Bill Text AL H.B. 580 (seeking to define UPFs as foods that contain one of 11 listed ingredients); South Carolina, 2025 Bill Text SC S.B. 589 (seeking to define UPFs as foods that contain one of 11 listed ingredients); Kentucky, 2025 Bill Text KY H.B. 439 (seeking to define UPFs as foods that contain one of 11 listed ingredients)).

Additionally, some third-party organizations are starting to develop their own definitions for UPFs.

There is a clear need for a uniform definition of UPFs to allow for consistency in research and policy. With this Request for Information, we seek data and information that would enable us, as part of a joint federal agency effort, to define UPFs.

II. Issues for Consideration and Request for Information

We invite comment on the questions below. Please explain your answers and provide references and data, if possible. To the extent that you rely on an existing definition of UPFs (or a facet of such definition) to inform your responses, please state which specific definition it is.

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.

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.

b. Ingredients that appear toward the end of an ingredient list may contribute minimally to the overall composition and weight of a finished food (for example, ingredients may sometimes be listed as containing 2% or less by weight of the finished food (21 CFR 101.4(a)(2))). What types of these less prominent ingredients

(e.g., ingredients that may share a similar composition, function, or purpose) might be used to characterize a food as ultra-processed?

Further, ingredients that function as flavorings are either natural flavors or artificial flavors; colorings are either certified (for instance, "FD&C Red No. 40") or non-certified (for instance, "colored with beet juice") (21 CFR 101.22). Should these various types of flavors and colors be considered separately when characterizing a food as ultra-processed? Please provide supporting data and explain your rationale in your response.

c. To what extent, if any, should the relative amount of an ingredient used in a food influence whether the food should be characterized as ultra-processed? Please provide supporting data and explain your rationale in your response.

d. What, if any, other ingredients or ingredient-related criteria not discussed previously should or should not be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.

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.

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.

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.

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.

d. What, if any, other processing-related techniques should or should not be used to characterize a food as ultra-processed? Please provide supporting data and explain your rationale in your response.

4) Is the term "ultra-processed" the best term to use, or is there other terminology that would better capture the concerns associated with these products? If there is another term to consider, please name and define that term and provide specific scenarios and citations (if available) to support its use.

5) 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.

6) 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?

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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2. Lane M.M., Davis, J.A., et al., “Ultraprocessed food and chronic noncommunicable diseases: a systematic review and meta-analysis of 43 observational studies.” *Obesity Reviews*. 2021;22(3):e13146. Accessed June 6, 2025. Available at https://doi.org/10.1111/obr.13146.

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5. Hall, K.D., Ayuketah, A., et al., “Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake.” *Cell Metabolism*. 2019; 30:67-77. Accessed June 2, 2025. Available at: https://doi.org/10.1016/j.cmet.2019.05.008.

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cross-sectional analysis of packaged foods," *The Lancet Regional Health – Americas*. 2024; 32: 100713. Accessed June 2, 2025. Available at https://doi.org/10.1016/j.lana.2024.100713.

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*18. U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary Guidelines for Americans, 2020-2025.* 9th ed. 2020. Accessed June 2, 2025. Available at https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf.

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