

WASHINGTON LEGAL FOUNDATION  
2009 Massachusetts Avenue, NW  
Washington, DC 20036  
(202) 588-0302

September 23, 2025

Via regulations.gov  
Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Md. 20852

Re: Ultra-Processed Foods; Request for Information (Docket No. FDA-2025-N-1793)

Dear Sir or Madam:

Washington Legal Foundation (WLF) appreciates the opportunity to comment in response to the joint USDA/FDA Request for information about “ultra-processed foods.”<sup>1</sup> WLF is concerned that any attempt to define “ultra-processed foods” will run into serious practical problems that would render any resulting definition useless—or worse, misleading. As a result, leveraging that definition to modify FDA’s compelled-speech requirements for nutrition labeling would violate the First Amendment.

WLF is a public-interest law firm and policy center promoting free enterprise, individual rights, limited government, and the rule of law. It has a keen and demonstrated interest in protecting the First Amendment from FDA overreach and regularly files comments to that effect.<sup>2</sup>

WLF shares FDA’s aspirations for “reducing chronic illnesses and premature death, and for helping make Americans healthier.”<sup>3</sup> But it’s not enough to have good intentions. In a world where both time and resources are scarce, the use of federal resources to define ultra-processed foods and use that definition for research and regulatory purposes is the wrong choice.<sup>4</sup>

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<sup>1</sup> 90 Fed. Reg. 35305 (July 25, 2025).

<sup>2</sup> *E.g.*, *WLF v. Friedman, Acting Comm’r of FDA*, 13 F. Supp.2d 51 (D.D.C. 1998); WLF Comment, *Proposed Rule: Front-of-Package Nutrition Information*, Docket No. FDA-2024-N-2910 (July 15, 2025).

<sup>3</sup> 90 Fed. Reg. at 35307.

<sup>4</sup> Anna K. Abram, et al., *Expert Insights: FDA, HHS and USDA Serve Up Ultra-Processed Food RFI*, *Wolters Kluwer Health Law Daily*, 2025 WL 2167927 (July 31, 2025) (“A uniform definition is

## I. “Ultra-Processed Food” Defies Helpful or Healthful Definition.

Imagine categorizing things by whether they have wheels. This definition excludes certain things—sausages, for example, or your grandmother, who is not a bicycle. But if the goal is to reduce traffic fatalities on American roads, that list is woefully unhelpful.

It is overinclusive—it includes Hot Wheels toy cars and grocery carts, as well as minivans and motorcycles. It would also be underinclusive to the mission: it ignores pedestrian traffic, how roads are structured, and distractions alongside the highway. Coming up with a single federal definition of what qualifies as a “thing with wheels” to help reduce traffic deaths is a fool’s errand.

Something similar is going on here. There is no real scientific basis for any proposed definition of “ultra-processing.” Creating a definition that lacks a solid, scientific foundation means that line-drawing will uselessly “dissolve in practical application.”<sup>5</sup> Is “ultra-processed” simply a term about manufacturing food in a specific way—which is itself health-neutral? Or is it bureaucratic name-calling—branding vast swathes of commercial products as unhealthy to deter their consumption? No matter which definition we toggle toward, something significant about the Request’s actual mission is being lost.

As Gary Taubes aptly put it, “Assume for the moment that UPF is . . . just a synonym for junk food and fast food. Would we bother designing studies that try to identify mechanisms by which all junk/fast foods *en masse* might be ruining our health: candy bars, sodas, chips, French fries, McDonald’s hamburgers, etc., all harmful in the same way because they’re all junk? Would we assume that other foods with similar macronutrient compositions are not harmful because, well, they’re not junk foods? Mom’s apple pie is benign but McDonald’s apple pie isn’t?”<sup>6</sup> He’s right—we wouldn’t do that, unless something intrinsic to *all modern food processing* was a culprit. And there’s no evidence that such a massive overgeneralization is remotely the case.

Let’s start with the existing federal definition for “processed food.” That “means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking,

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likely to serve as the foundation for future regulatory actions, including potential changes to product labeling and marketing standards”).

<sup>5</sup> *Buckley v. Valeo*, 424 U.S. 1, 42 (1976) (per curiam).

<sup>6</sup> Gary Taubes, *Are Ultra-Processed Foods the Problem?*, Uncertainty Principles (June 8, 2025); <https://perma.cc/ANB9-PZBA>.

freezing, dehydration, or milling.”<sup>7</sup> Federal regulations build out on that definition—confusingly in a joint definition of “manufacturing/processing”—to provide an exhaustive list of “making food from one or more ingredients.”<sup>8</sup>

The Request posits, then, that there’s some types of “processing” that are inevitably unhealthy and suggests the pejorative “ultra-processed” as a shorthand for those techniques or ingredients. The prefix “ultra” seems to be roughly used as a synonym for “excessively” or “extremely.” So not merely mixed, but *really* mixed in an extreme way. There are genuine problems with focusing generally “not on nutrient intake but on the degree of processing of foods.”<sup>9</sup> It’s just a category error. And what’s true for computers is true for federal agencies: garbage-in, garbage-out.

Take emulsifiers. Many of the Request’s proposed ultra-processed food definitions focus on emulsifiers. Emulsification is, broadly speaking, stirring. Emulsifiers, in a sense, just make the stirring last longer. The government defines emulsifiers as merely “[s]ubstances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.”<sup>10</sup> That’s health-neutral—it’s merely a “physical or technical functional effect[] for which direct human food ingredients may be added to foods.”<sup>11</sup>

Unsurprisingly, then, not all emulsified products pose risks to the Nation’s nutrition and diet. That definition would label as health hazards nutritional-supplement beverages used to treat individuals with serious malnutrition issues, such as Ensure. Emulsifiers are also used in baby formula—a literal life-saver for children with latching issues or whose parents are unable to breastfeed.<sup>12</sup>

Let’s focus on California for a second. That State’s recently passed definition of ultra-processed food goes after much more than emulsifiers—listing out eight problematic terms that somehow “ultra” the “processing.”<sup>13</sup> One odd example is “flavor enhancers.” California keys that term to its federal definition. Flavor enhancers are “[s]ubstances added to supplement, enhance, or modify the original

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<sup>7</sup> 21 U.S.C. § 321(gg).

<sup>8</sup> 21 C.F.R. § 117.3.

<sup>9</sup> M.J. Gibney, *Ultra-Processed Foods: Definitions and Policy Issues*, Current Developments in Nutrition, Vol. 3, No. 2 (Feb. 2019); <https://doi.org/10.1093/cdn/nzy077>.

<sup>10</sup> 21 C.F.R. § 170.3(o)(8).

<sup>11</sup> *Id.* § 170.3(o).

<sup>12</sup> See Gibney, *Ultra-Processed Foods: Definitions and Policy Issues*.

<sup>13</sup> 2025 Bill Text CA A.B. 1264.

taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.”<sup>14</sup> Once again, that’s health-neutral, it has nothing to do with the healthiness of the “enhanced” food being consumed. Perhaps some specific chemical that *happens* to be a flavor enhancer may plausibly pose a hazard, but that doesn’t mean that *all* flavor enhancers do. This false-positive problem is shot through many of the proposed definitions of ultra-processed foods—yet another indication that the category itself just isn’t ready for the Federal Register.

At bottom, the Request’s focus on excessive processing seems to derive from a skepticism—perhaps a preconceived notion—about commercially available food by large producers. That aversion lends itself to absurd results and spoils the entire project.

Consider the National Center for Health Statistics’s recent effort to track American consumption of “ultra-processed” foods. Using Brazil’s Nova classification system, which is named in the Request, yielded a result where the largest source of America’s ultra-processed food is just . . . sandwiches.<sup>15</sup> An undifferentiated label that broadly covers sandwiches, among the most commonly consumed dishes in America, is not remotely helpful. And by lumping a turkey-and-sprouts on whole-grain in with a Philly cheesesteak, it also ignores real (and obvious) sandwich-to-sandwich health distinctions.

Americans are fortunate to live in the wealthiest country on the planet, living under a rule-of-law system that encourages the bringing to market of efficient, cheap, and plentiful food. That’s the result of massive modernizations and rationalizations of the food production process. The Request’s presumption that this system—either in whole or in part (but we don’t know which part, evidently)—is hazardous to health stands on a category error: processing matters, not nutrient content.

Doubling down on this error risks barreling the public health agencies of the U.S. government into apophenia, not measurable science. This Request should be put aside, and the scarce resources of the USDA and FDA moved in more promising scientific directions that might yield tangible benefits for the Nation.

## **II. Changing Nutrition Labeling to Emphasize “Ultra-Processed Food” Would Be Unconstitutional.**

While not a direct focus of the Request, it seems natural that a federal definition for “ultra-processed food” would soon migrate to a mandatory federal

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<sup>14</sup> 21 C.F.R. § 170.3(o)(11).

<sup>15</sup> Anne M. Williams, et al., *Ultra-processed Food Consumption in Youth and Adults: United States, August 2021-August 2023*, NCHS Data Brief No. 536 (Aug. 2025).

labeling system. That risk is yet another reason not to adopt a federal definition in the first place.

The First Amendment requires that the federal government do considerable work before it may legally use private actors as billboards for state messaging. When compelled speech has survived judicial review in the commercial context, it generally has been because the courts found those regimes evidence-based and aimed at fraud and abuse. “Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest.”<sup>16</sup>

This demand for rigor and tailoring is essential. Labeling regimes can “succeed[] only if people get the right information at the right time in the right quantity in the right way with the right emphasis *and* interpret and use it in the right fashion.”<sup>17</sup> That entire chain must be completed for a compelled speech regime to meet its mark. Because virtually any offered federal definition would suffer from the same under- and over-inclusivity problems identified above, slapping a pejorative of “ultra-processed” on the universe of items captured by that mismatched definition means that the disclosure failure would occur directly at the “right information” gate<sup>18</sup>—with the upshot rendering the related compelled speech requirement unconstitutional.

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The Request asks whether “the term ‘ultra-processed’ [is] the best term to use, or is there other terminology that would better capture the concerns associated with these products?”<sup>19</sup> That formulation asks us to think past the sale—assuming that “these products,” however defined, are the unified source of some harm or hazard.<sup>20</sup> That’s terribly unlikely to be so, as discussed above.

But the question does get at something worth considering. The term “ultra-processed” is not “the best term to use,” devoid as it is of any inherent meaning or

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<sup>16</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985) (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980)).

<sup>17</sup> Omri Ben-Shaher and Carl Schnieder 175, *More Than You Wanted to Know: The Failure of Mandated Disclosure* (Kindle Ed. 2014) (emphasis in original).

<sup>18</sup> *Id.*

<sup>19</sup> 90 Fed. Reg. at 35308.

<sup>20</sup> *Id.*

scientific consensus.<sup>21</sup> But there is no better “term.” The problem is the search for a universal term that focuses on food preparation and construction, rather than nutritional content itself.

So WLF counsels that the U.S. government abandon using the term “ultra-processed” entirely . . . and replace it with nothing.

Respectfully submitted,

Cory L. Andrews  
*General Counsel*

Zac Morgan  
*Sr. Litigation Counsel*

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<sup>21</sup> *Id.*