

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Petition to Ban Use of the Term “Natural        )  
Flavor” in Food Ingredient Labeling        )

Docket No. \_\_\_\_\_

CITIZEN PETITION

Submitted by:

Consumer Federation of America

November 8, 2023

## I. INTRODUCTION

This petition seeks to eliminate consumer confusion caused by the term “natural flavor.” According to USDA’s FoodData Central database of 451,767 “branded” products, 136,953 products, or over 30%, contain “natural flavor.”<sup>1</sup> “Natural flavor” ranks as the fourth most commonly occurring ingredient on food labels in the United States,<sup>2</sup> and it is a characteristic ingredient of so-called ultra-processed foods (UPFs).<sup>3</sup> The ingredient’s rise in popularity has coincided with increasing UPF consumption.<sup>4</sup> Indeed, a study earlier this year found that the proportion of U.S. household food purchases containing added flavors increased from 34.2% to 41.7% between 2001 and 2019.<sup>5</sup> Overall, the annual U.S. consumption of “synthetic flavoring” exceeds 600 million pounds.<sup>6</sup>

Survey research has shown that many consumers perceive “naturally” flavored foods to have health advantages over those with “artificial flavors.”<sup>7</sup> Yet few meaningful distinctions exist between “natural flavors” and “artificial flavors,” which are often chemically indistinguishable.<sup>8</sup> By contrast, a growing body of research suggests that many consumers may want to avoid food with added flavors—whether “natural” or “artificial.” Added flavors are “a marker for ultra-processing of food,” which researchers have flagged as “potential contributors to the obesity epidemic.”<sup>9</sup> Allowing some added flavors to appear as “natural flavors” creates an illusion of wholesomeness and creates confusion among consumers wishing to avoid UPFs, or simply seeking higher quality foods.

FDA should help consumers to understand the character of UPFs, which may induce overeating

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<sup>1</sup> Pehrsson, P.R., et al. *FoodData Central: USDA Global Branded Food Products Database*. Accessed: Oct. 17, 2023; Available: <https://fdc.nal.usda.gov/>.

<sup>2</sup> Andrews, D. *Synthetic ingredients in Natural Flavors and Natural Flavors in Artificial flavors*. Environmental Working Group. <https://www.ewg.org/foodscores/content/natural-vs-artificial-flavors/>

<sup>3</sup> “Ultra-processed foods are defined within the NOVA classification system, which groups foods according to the extent and purpose of industrial processing. Processes enabling the manufacture of ultra-processed foods include the fractioning of whole foods into substances, chemical modifications of these substances, assembly of unmodified and modified food substances, frequent use of cosmetic additives and sophisticated packaging. . . . A practical way to identify an ultra-processed product is to check to see if its list of ingredients contains at least one item characteristic of the NOVA ultra-processed food group, which is to say, either food substances never or rarely used in kitchens (such as high-fructose corn syrup, hydrogenated or interesterified oils, and hydrolysed proteins), or classes of additives designed to make the final product palatable or more appealing (such as *flavours*, flavour enhancers, colours, emulsifiers, emulsifying salts, sweeteners, thickeners, and anti-foaming, bulking, carbonating, foaming, gelling and glazing agents).” Monteiro C.A., Cannon G., Levy R.B., Moubarac J.C., Louzada M.L., Rauber F., Khandpur N., Cediel G., Neri D., Martinez-Steele E., Baraldi L.G., Jaime P.C. Ultra-processed foods: what they are and how to identify them. *Public Health Nutr.* 2019 Apr;22(5):936-941. doi: 10.1017/S1368980018003762. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10260459/> (emphasis added).

<sup>4</sup> See Wang L, Martínez Steele E, Du M, Pomeranz JL, O'Connor LE, Herrick KA, Luo H, Zhang X, Mozaffarian D, Zhang FF. Trends in Consumption of Ultraprocessed Foods Among US Youths Aged 2-19 Years, 1999-2018. *JAMA.* 2021 Aug 10;326(6):519-530. doi: 10.1001/jama.2021.10238. PMID: 34374722; PMCID: PMC8356071 (“From 1999 to 2018, the estimated percentage of total energy from consumption of ultraprocessed foods increased from 61.4% to 67.0%”).

<sup>5</sup> Dunford, E. K., Miles, D. R., Popkin, B. (2023). Food Additives in Ultra-Processed Packaged Foods: An Examination of US Household Grocery Store Purchases. *Journal of the Academy of Nutrition and Dietetics*, 123(6), 889-901.

<https://doi.org/10.1016/j.jand.2022.11.007>

<sup>6</sup> Schatzker, M. (2015, November). *How Flavor Drives Nutrition*. Pudget Consumers Co-op.

<https://www.pccmarkets.com/sound-consumer/2015-11/how-flavor-drives-nutrition/>

<sup>7</sup> Tyler Murley & Edgar Chambers, IV, The Influence of Colorants, Flavorants and Product Identity on Perceptions of Naturalness, 8 *Foods* 317 (Aug. 4, 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6722695/>.

<sup>8</sup> Bloom, J. (2017). *Natural and Artificial Flavors: What’s the Difference?*. American Council on Science and Health.

<https://www.acsh.org/sites/default/files/Natural-and-Artificial-Flavors-What-s-the-Difference.pdf>

<sup>9</sup> Neumann, N. J., & Fasshauer, M. (2022). Added Flavors: Potential Contributors to Body Weight Gain and Obesity?. *BMC Medicine*, 20(417). <https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-022-02619-3>

and are associated with a wide range of health problems.<sup>10</sup> Retiring the regulatory term “natural flavors” to describe certain added flavors represents a simple, straightforward step towards better informing consumers. Under the rule change proposed in this petition, the agency would not erase the distinction between “artificial” and “natural” added flavors under the current rules. Rather, it would simply require that manufacturers replace the terms “natural flavor” and “natural flavorings” with the more accurate, objective terms, “added flavor” and “added flavorings.” A manufacturer seeking to communicate the natural quality of a flavor ingredient would still be able to refer to that ingredient by its common or usual name, e.g. lemon oil, mint extract, etc. This simple rule change will both help consumers to identify more wholesome, less processed foods, and also create a more level playing field for producers of those foods.

## II. ACTION REQUESTED

CFA requests that FDA amend 21 C.F.R. § 101.22 to eliminate use of the word “natural” in the terms “natural flavor” and “natural flavoring.” Specifically, CFA requests that FDA:

- 1) Amend 21 C.F.R. § 101.22(a)(3) to read:

The term **added natural** flavor or **natural added** flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. **Natural Added** flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in § 172.510 of this chapter.

- 2) Amend 21 C.F.R. § 101.22(g)(3) to read:

In cases where the flavor contains solely **natural added** flavor(s) **that do not include artificial flavors**, the flavor shall be so labeled, e.g., “strawberry flavor”; **or “banana flavor.”**, ~~or “natural strawberry flavor.”~~ In cases where the flavor contains both a **natural flavor** and an artificial flavor **and other added flavor**, ~~or the flavor shall be so labeled, e.g., “natural and artificial strawberry flavor.”~~ In in cases where the flavor contains a solely artificial flavor(s), the flavor shall be so labeled, e.g., “artificial strawberry flavor”.

- 3) Amend 21 C.F.R. § 101.22(h)(1) to read:

Spice, **natural added** flavor, and artificial flavor may be declared as “spice”, “**natural added** flavor”, or “artificial flavor”, or any combination thereof, as the case may be.

- 4) Amend 21 C.F.R. § 101.22(h)(7) to read:

Because protein hydrolysates function in foods as both flavorings and flavor enhancers, no protein hydrolysate used in food for its effects on flavor may be declared simply as “flavor,”

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<sup>10</sup> Yin Zhang & Edward L. Giovannucci (06 Jun 2022): *Ultra-processed foods and health: a comprehensive review*, Critical Reviews in Food Science and Nutrition, DOI: 10.1080/10408398.2022.2084359.

~~“natural added flavor,”~~ or “flavoring.” The ingredient shall be declared by its specific common or usual name as provided in § 102.22 of this chapter.

5) Amend 21 C.F.R. § 101.22(i)(1)(i) to read:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in “strawberry shortcake”, and the food contains ~~natural added~~ flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may ~~be immediately preceded by the word “natural” and shall be~~ immediately followed by the word “flavored” in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ~~“natural strawberry flavored shortcake,” or~~ “strawberry flavored shortcake”.

6) Amend 21 C.F.R. § 101.22(i)(1)(ii) to read:

(ii) If none of the ~~natural added~~ flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as “artificially flavored.”

7) Amend 21 C.F.R. § 101.22(i)(1)(iii) to read:

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other ~~natural added~~ flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words “with other ~~natural added~~ flavoring” or **“with other added flavor”** in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

### III. Statement of grounds

#### A. Factual Grounds

Meaningful labeling rules benefit consumers and the food industry alike. Added flavors have become popular because they allow food manufacturers to replace expensive ingredients like vanilla extract from vanilla beans with cheaper ingredients such as vanillin derived from natural or synthetic sources.<sup>11</sup> As a result, the added flavor industry has now reached an estimated \$16.27 billion in size, with continued rapid growth forecasted.<sup>12</sup> At a typical retailer, most packaged food products contain added flavors, and a consumer may not even be able to find foods without added flavors in a wide

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<sup>11</sup> See, e.g. Patrick van Zwanenberg & Erik Millstone (2015) Taste and Power: The Flavouring Industry and Flavour Additive Regulation, *Science as Culture*, 24:2, 129-156, DOI: 10.1080/09505431.2014.937686. (“Flavourings are cosmetic additives that are used in processed food and drink products. They are used extensively by the food industry, partly to disguise unpleasant flavours and odours created by processing, but especially to minimise costs by enabling cheap ingredients, such as fats, sugars and carbohydrates, to appear as if they came from expensive and tasty ones, such as fruit, coffee or chocolate.”).

<sup>12</sup> *Food Flavors Market: Information by Type (Natural Flavors, Artificial Flavors), End-User (Beverages, Dairy and Frozen Products, Savory and Snacks), and Region – Forecast Till 2031*. (2023, April 12). Straits Research. <https://straitsresearch.com/report/food-flavors-market>

range of categories—from ice cream to crackers to mayonnaise. In response to consumer demand, some manufacturers have opted to leave out added flavors from their products.<sup>13</sup> However, the prevalence of “natural” claims on foods with added flavors, and particularly the term “natural flavor” itself, tilts the playing field against these companies.

Consumers should not have to settle for products with ingredients they do not understand and would rather avoid simply because foods without those ingredients are not available. Changing the term “natural flavor” to “added flavor” will not by itself ensure that the highly consolidated food industry offers more options with comprehensible ingredients. However, it will eliminate significant consumer confusion and give needed support to companies attempting to sell products without added flavors. More products without added flavors, in turn, could generate significant public benefits, as explained further below.

### **III.A.1. An increasing body of scientific research indicates that added flavors may induce overeating and thereby contribute to obesity and other diet-related disease.**

The proliferation of added flavors in food coincides with the acceleration of an obesity and diet-related disease epidemic whose costs are difficult to overstate.<sup>14</sup> Researchers have posited two potential mechanisms by which foods with added flavors may contribute to weight gain. First, added flavors may cause overeating by simply making foods taste more appealing and encouraging “hedonic eating” by a consumer, even after the consumer’s energy requirements are met, or indeed, far exceeded. Second, added flavors may cause overeating by confounding a consumer’s ability to correctly attribute calories and other nutrients to foods. The following discusses these two mechanisms.

#### **III.A.1.i. A characteristic ingredient of UPFs, added flavors, are used to make food “hyper-palatable” and may induce overeating.**

UPFs make up an increasingly large share of Americans’ diets,<sup>15</sup> and they are increasingly blamed for the nation’s expanding epidemic of obesity and diet-related disease.<sup>16</sup> According to the researchers who coined the term, “ultra-processed foods are designed to create highly profitable (low-cost ingredients, long shelf-life, emphatic branding), convenient (ready-to-consume), hyper-palatable products liable to displace all other [less processed foods].”<sup>17</sup> Policymakers abroad have incorporated

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<sup>13</sup> See, e.g. Berry, D. (2023, August 15). *One Company’s Reasons For Not Using ‘Natural Flavors’*. Food Business News. <https://www.foodbusinessnews.net/articles/24441-one-companys-reasons-for-not-using-natural-flavors>

<sup>14</sup> According to one recent estimate, the aggregate medical cost due to obesity among adults in the United States was \$260.6 billion in 2016. Cawley, J., Biener, A., Meyerhoefer, C., Ding, Y., Zvenyach, T., Smolarz, B.G., Ramasamy, A. (2021). Direct medical costs of obesity in the United States and the most populous states. *J Manag Care Spec Pharm.* (3):354-366. doi: 10.18553/jmcp.2021.20410. However, such figures capture only a fraction of the misery caused by diet-related disease. See, e.g. The Rockefeller Foundation (2021, July). *True Cost of Food Measuring What Matters to Transform the U.S. Food System*. Accessed at: <https://www.rockefellerfoundation.org/report/true-cost-of-food-measuring-what-matters-to-transform-the-u-s-food-system/> (estimating that “productivity loss associated with diet and/or food,” combined with “direct medical costs attributable to diet and/or food” exceeds \$1 trillion).

<sup>15</sup> Wang supra note 4.

<sup>16</sup> See Zhang supra note 10 (noting that “accumulating longitudinal studies associating ultra-processed foods with major health outcomes.”).

<sup>17</sup> Monteiro supra note 3.

the UPF's definition into dietary guidance,<sup>18</sup> with the French government going so far as to set a goal of reducing UPF consumption by 20%.<sup>19</sup> However, researchers continue to grapple with precisely why UPF consumption appears to cause weight gain.<sup>20</sup>

One straightforward explanation is simply that UPFs “taste good.” More specifically, UPFs excel in promoting “hedonic eating,” or eating for pleasure. This “hyperpalatable” character of UPFs reflects more than just added flavors. Indeed, some researchers have defined the category of “hyper-palatable foods,” distinct from UPFs, as solely a function of whether a food combines high levels of salt, sugar, and fat.<sup>21</sup> However, added flavors are essential to the “tastiness” of many UPFs. As one industry publication points out, their use is “directly linked to the pleasure of consumption.”<sup>22</sup> When this pleasure drives hedonic eating that overrides the “homeostatic control of food intake,” weight gain results.<sup>23</sup>

Of course, consumers will always seek out foods that taste good, and defenders of added flavors may bristle at the suggestion that food manufacturers reformulate products to reduce their appeal. However, “taste” does not lend itself to a simple definition, and in particular, the “tastiness” of UPFs raises special concerns. One group of researchers have pointed out that “nutrient composition alone cannot explain the influence of UPFs on the risk of obesity,” and suggested that UPFs may cause harm by hijacking the brain’s reward circuitry.<sup>24</sup> This reward circuitry includes both a physiological “pleasure” response—or the “hedonic response to or the pleasantness of a stimulus”—and what the researchers call “wish” or “motivation to increase consumption.” This latter response raises special concerns with respect to UPFs and their constituent components. As the researchers explain, “UPFs may stimulate appetite even when energy requirement has been satisfied, thus overcoming homeostatic hunger/satiety action mechanisms. Over time, as a result of repeated exposure to UPFs, ‘wish’ selectively becomes higher . . . favoring impulsive comfort food overconsumption leading to unhealthy dietary choices and weight gain.”<sup>25</sup>

The impact of UPFs on neural circuitry raises special concerns with respect to children. In a prospective study involving 1,175 children, also published earlier this year, higher consumption of ultra-processed products at 4 years of age was associated with “fussy eating” habits three years later, possibly reflecting a negative feedback loop in which “children’s food preferences and counter-productive parents’ behaviours may increase the consumption of ultra-processed foods, limiting diet

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<sup>18</sup> Braesco, V., Souchon, I., Sauvant, P. et al. (2022). Ultra-processed foods: how functional is the NOVA system?. *Eur J Clin Nutr* 76, 1245–1253. <https://doi.org/10.1038/s41430-022-01099-1>

<sup>19</sup> *Avis relatif aux objectifs de santé publique quantifiés pour la politique nutritionnelle de santé publique (PNNS) 2018-2022*. (2018, March 22). Haut Conseil de la Santé Publique. Retrieved October, 2023, from <https://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=648>

<sup>20</sup> Levy, R., Barata, M., Leite, M., & Andrade, G. (2023). How and why ultra-processed foods harm human health. *Proceedings of the Nutrition Society*, 1-8. [doi:10.1017/S0029665123003567](https://doi.org/10.1017/S0029665123003567)

<sup>21</sup> Demeke, S., Rohde, K., Chollet-Hinton, L., Sutton, C., Kong, K., & Fazzino, T. (2023). Change in hyper-palatable food availability in the US food system over 30 years: 1988–2018. *Public Health Nutrition*, 26(1), 182-189. [doi:10.1017/S1368980022001227](https://doi.org/10.1017/S1368980022001227)

<sup>22</sup> *The importance of adding natural flavours to processed foods*. (2020, January 10). BRF Ingredients. Retrieved October 2023, from <https://www.brfindredients.com/en/blog/posts/natural-flavours-processed-foods/>

<sup>23</sup> Neumann supra note 9.

<sup>24</sup> Calcaterra, V., Cena, H., Rossi, V., Santero, S., Bianchi, A., Zuccotti, G. (2023). Ultra-Processed Food, Reward System and Childhood Obesity. *Children*. 10(5):804. <https://www.mdpi.com/2227-9067/10/5/804>

<sup>25</sup> *Id.*

variety and intensifying food fussiness afterwards.”<sup>26</sup> In other words, young children may come to reject foods that are not ultra-processed, leading to increased consumption of UPFs, and even less tolerance for other foods. Neuroimaging studies have shown that when children view unhealthy foods, they experience activation in brain regions implicated in reward and cognitive processes that also tend to be most affected in patients with eating disorders.<sup>27</sup> Relatedly, studies suggest that UPFs “may trigger addictive processes that drive compulsive patterns of intake,” with higher levels of UPF consumption associated with a higher risk of behavioral eating disorders.<sup>28</sup> Indeed, in one study, researchers found that eating disorder patients reported consuming exclusively UPFs when binge eating.<sup>29</sup>

To what extent do synthetic flavors, including “natural flavors,” contribute to the “hyperpalatable” or even “addictive” quality of UPFs? The answer is unclear. Food companies are not required to demonstrate that novel food ingredients will not lead their customers to overeat. And as discussed further below, FDA has not reviewed the safety of most flavoring ingredients at all. Instead, under the “Generally Recognized as Safe” or “GRAS” process, the agency allows food companies to self-determine safety, with a voluntary notification process that many companies choose to ignore.<sup>30</sup> Consumers therefore have good reason to harbor skepticism towards added flavors, and food additives more generally. This skepticism has increased alongside obesity rates in recent years, and increasingly applies to the term “natural flavor.”<sup>31</sup> As new evidence sheds light on how “natural flavors” may spur compulsive eating, the persistence of such a counterintuitive, misleading term in federal regulation has become all the more outrageous.

### **III.A.1.ii. Added flavors may induce overeating by disrupting normal “flavor-nutrient learning” processes.**

Flavor-nutrient learning refers to how humans connect the taste and feel of a food with how it affects the body. The process progresses more rapidly with novel foods, and young children are particularly impressionable.<sup>32</sup> Nevertheless, every time an individual eats a food and the body responds to it, the flavor-nutrient learning process takes place to some extent.<sup>33</sup> Throughout human evolution, the flavor-nutrient learning process has enabled individuals to match the taste and feel of a given food—e.g. a strawberry—with that food’s nutrient profile. In doing so, the process enables an individual to seek out foods that correspond to their body’s nutritional needs.

Researchers have posited that added flavors may disrupt the flavor-nutrient learning process in a way that subsequently causes overeating and weight gain. The difference between consuming added

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<sup>26</sup> Milhassi Vedovato, G., Vilela, S., Severo, M., Rodrigues, S., Lopes, C., and Oliveira, A. (2021). Ultra-processed food consumption, appetitive traits and BMI in children: a prospective study. *British Journal of Nutrition*, 125(12), 1427-1436. [doi:10.1017/S0007114520003712](https://doi.org/10.1017/S0007114520003712)

<sup>27</sup> Via, E., Contreras-Rodríguez, O. (2023). Binge-Eating Precursors in Children and Adolescents: Neurodevelopment, and the Potential Contribution of Ultra-Processed Foods. *Nutrients*. 15(13):2994. [doi: 10.3390/nu15132994](https://doi.org/10.3390/nu15132994).

<sup>28</sup> *Id.*

<sup>29</sup> Ayton A., Ibrahim A., Dugan J., Galvin E., Wright O.W. (2021). Ultra-processed foods and binge eating: A retrospective observational study. *Nutrition*. 84:111023. [doi: 10.1016/j.nut.2020.111023](https://doi.org/10.1016/j.nut.2020.111023).

<sup>30</sup> See Neltner, T., and Maffini, M. (2014). *Generally Recognized as Secret: Chemicals Added to Food in the United States*. Natural Resources Defense Council. <https://www.nrdc.org/sites/default/files/safety-loophole-for-chemicals-in-food-report.pdf>

<sup>31</sup> See, e.g. Donna Berry. “One company’s reasons for not using ‘natural flavors,’” *Food Business News*, (Aug. 15, 2023) available at: <https://www.foodbusinessnews.net/articles/24441-one-companys-reasons-for-not-using-natural-flavors>

<sup>32</sup> Yeomans, M.R. (2012). Flavour–nutrient learning in humans: an elusive phenomenon? *Physiol Behav*. 106:345–55. <https://doi.org/10.1016/j.physbeh.2012.03.013>.

<sup>33</sup> Neumann supra note 9.

strawberry flavor in a UPF, versus consuming an actual strawberry, provides an illustration. Notwithstanding differing varieties and growing conditions, one strawberry's nutrient profile fairly resembles another's. As a result, the experience of eating strawberries leads to a comparatively consistent intake of nutrients, which supports the brain's and gut's ability to correctly predict how much food to eat to acquire the needed nutrients.

By contrast, different foods with "strawberry flavor" will have nutrient profiles that vary wildly. Depending on the individual's eating history, the taste and feel of a "strawberry flavored" food may create an expectation of nutrients that are not actually contained within the food, disrupting flavor-nutrient associations and causing uncertainty in the body. This uncertainty leads to "compensatory overeating"; as an individual's capacity to predict the nutrients within a food deteriorates, the individual eats more to increase the odds of acquiring sufficient nutrients.<sup>34</sup> According to one analogy, the consumer of UPFs comes to resemble the driver of a car with a broken gas gauge, condemned to "fill up" more often than necessary to avoid getting stranded on the highway.<sup>35</sup>

A growing body of research supports the theory that ingredients in UPFs—including low-calorie sweeteners and fat substitutes as well as added flavors—contribute to impaired flavor-nutrient associations that "increase food intake, bodyweight, and adiposity."<sup>36</sup> Of particular relevance to this petition, animal feed producers have used added flavors for more than 40 years to increase feed intake and weight gain among livestock. Studies of rats, goats, ponies, pigs and weaning pigs, lactating cows and calves, baboons and other animals indicate that added flavors can succeed in promoting increased weight gain.<sup>37</sup>

### **III.A.2. Added flavors raise safety, allergenicity, and ethical concerns.**

Flavoring ingredients are subject to little safety oversight. This regulatory void dates back decades. When the Food Additive Amendment of 1958 outlined regulations for approving novel food additives by the FDA, Congress included an exemption for substances that are "generally recognized as safe."<sup>38</sup> This exemption opened the door for companies to declare the ingredients in their products "GRAS" without a formal safety review.<sup>39</sup> Early on, the Flavor and Extracts Manufacturers Association (FEMA), developed a list of criteria to qualify flavoring ingredients for GRAS status. The criteria were not based on experimental evidence and departed from toxicological expert advice.<sup>40</sup> Nevertheless, in 1965, FEMA's "expert" panel of scientists, paid by the industry association, designated 1,124 flavors as GRAS, mostly on the grounds of "experience based on common use in food".<sup>41</sup> Several of those approved flavors turned out to be carcinogens.<sup>42</sup>

As evidence of safety concerns emerged, the food flavoring industry curtailed the use of some,

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<sup>34</sup> *Id.*

<sup>35</sup> See Mark Schatzker. *The End of Craving*.

<sup>36</sup> Hardman, C. A., Ferriday, D., Kyle, L., Rogers, P. J., Brunstrom, J. M. (2015). So Many Brands and Varieties to Choose from: Does This Compromise the Control of Food Intake in Humans? *PLoS ONE* 10(4). <https://doi.org/10.1371/journal.pone.0125869>

<sup>37</sup> Neumann *supra* note 9.

<sup>38</sup> See Food Additive Amendment of 1958, Pu. L. No. 85-929 (1958); 21 U.S.C. § 321(s).

<sup>39</sup> Neltner *supra* note 30.

<sup>40</sup> Van Zwanenberg *supra* note 10.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*



but not all, carcinogenic additives.<sup>43</sup> For example, in 2016, the Center for Science in the Public Interest (CSPI) petitioned the FDA to ban seven substances in food flavorings - methyleugenol, benzophenone, ethyl acrylate, myrcene, pulegone, pyridine, and styrene - based on carcinogenicity evidence published years earlier by the U.S. National Toxicology Program.<sup>44</sup> In 2018, faced with a lawsuit challenging the agency's inaction, FDA finally removed the seven ingredients from its list of approved food additives.<sup>45</sup> However, the food industry continues to use more than 3,000 additives that have never been formally tested by the FDA and could pose serious health risks.<sup>46</sup> Approximately 1,000 of those chemicals are considered "secret GRAS," meaning the FDA "does not know the identity of these chemicals and does not have documentation showing that they are safe to use in food."<sup>47</sup>

In addition to carcinogenicity and other long-term toxicity concerns, FDA's lax oversight of "natural flavors" and other food additives raises special concerns for consumers with allergies, and those seeking to avoid animal products. The FDA requires food product labels to indicate whether they contain any of the nine major allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame.<sup>48</sup> However, several other foods like buckwheat, celery, lupin, molluscan shellfish, and mustard may cause severe reactions and can hide in products with additives like natural flavors.<sup>49</sup> Additionally, the vague terminology may lead consumers to misapprehend whether an added flavor contains animal products. Individuals who have religious or ethical reasons for avoiding certain animal products may see a label such as "natural vanilla flavor" and assume the flavor is solely derived from vanilla beans. However, "natural vanilla flavor" may also contain castoreum, an animal product.<sup>50</sup> More commonly, the recipe for a given "natural flavor" may include hydrolyzed proteins from dairy and other animal sources.<sup>51</sup>

Ultimately, broader reforms should replace the GRAS loophole with meaningful safety assessments for food additives, and require comprehensive disclosures of flavor ingredients that address allergy and ethical concerns. In the meantime, however, labeling added flavors more accurately will reduce confusion among consumers seeking to avoid safety hazards, allergens, or undeclared animal products. It will also help to level the playing field for foods without added flavors that do not raise these safety, allergenicity, and ethical concerns.

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<sup>43</sup> Center for Science in the Public Interest. (2022, September 29). *Banned additives*. <https://www.cspinet.org/banned-food-additives>

<sup>44</sup> Center for Science in the Public Interest. (2018, October 5). *FDA removes 7 carcinogenic flavorings from approved food additives list*. <https://www.cspinet.org/news/fda-removes-7-carcinogenic-flavorings-approved-food-additives-list-20181005>

<sup>45</sup> U.S. Food and Drug Administration. (2018, October 5). *FDA Removes 7 Synthetic Flavoring Substances from Food Additives List*. <https://www.fda.gov/food/cfsan-constituent-updates/fda-removes-7-synthetic-flavoring-substances-food-additives-list>

<sup>46</sup> Pew Charitable Trusts. (2013, November 13). *Fixing the Oversight of Chemicals Added to Our Food*. Accessed at: <https://www.pewtrusts.org/en/research-and-analysis/reports/2013/11/07/fixing-the-oversight-of-chemicals-added-to-our-food>

<sup>47</sup> Neltner supra note 30.

<sup>48</sup> Grimshaw, K. (2013, November). *Food Labelling for the Food Allergic Consumer*. <https://farrp.unl.edu/food-labelling-food-allergic-consumer>

<sup>49</sup> Food Allergy Research and Resource Program. *Other Priority Allergens*. Accessed at: <https://farrp.unl.edu/informalotherpriority>

<sup>50</sup> Burdock, G.A. Safety Assessment of Castoreum Extract as a Food Ingredient. *International Journal of Toxicology*, 2007. 26(1): p. 51-55.

<sup>51</sup> See, e.g., Michelle Mitchell, Nigel P. Brutnon, Richard J. Fitzgerald & Martin G. Wilkinson (2013) The Use of Herbs, Spices, and Whey Proteins as Natural Flavor Enhancers and Their Effect on the Sensory Acceptability of Reduced-Salt Chilled Ready-Meals, *Journal of Culinary Science & Technology*, 11:3, 222-240, DOI: 10.1080/15428052.2013.769869

### III.A.3 Desirable foods without added flavors cost significantly more to produce and labeling should help consumers to identify them.

In addition to public health, FDA should adopt the proposed amendment to level the playing field for food manufacturers foregoing added flavors, and to facilitate consumers' ability to identify foods whose ingredients conform with common use of the term "natural." Survey research indicates that consumers seek to avoid "artificial" ingredients, including artificial flavors, and tend to prefer, all else equal, a product made with "natural flavor" versus "artificial flavor." An online survey of 932 U.S. consumers found that respondents significantly preferred foods with "natural" rather than "artificial flavor" listed as an ingredient.<sup>52</sup> In another online survey of over 5,000 purchasers of food products challenged in class action lawsuits for alleged misleading use of "natural" claims, consumers systematically preferred products with a "natural claim," choosing those products 68% of the time when presented with "otherwise identical real-world food labels."<sup>53</sup> Yet another online survey showed that consumers are willing to pay an average 8% more for products with natural claims, provided the claim is featured prominently on the retailer's website.<sup>54</sup>

The research further indicates widespread misunderstanding of the term "natural flavor." For example, large numbers of the consumers who bought foods subject to lawsuits indicated that they understood the claim "All Natural Flavors" on a Dreyer's ice cream label to mean "All of the ingredients in the product are natural," or "None of the ingredients in the product are manmade or artificial." To the extent that a claim of "all natural flavors" simply means that the product only contains "natural flavors" and not "artificial ones," as defined by FDA regulations, this understanding is clearly erroneous, since the product could contain other, non-flavor ingredients (e.g. preservatives) that are "artificial" or "manmade." But many "natural flavors" themselves are "manmade" insofar as they contain "artificial or synthetic emulsifiers, modifiers, and solvents," so long as those chemicals do not perform a flavor, coloring, or preservative function.<sup>55</sup> And again, natural and artificial flavors are often chemically indistinguishable, leading to what some defenders of food additive safety deride as "confusing and incorrect uses of the terms 'natural' and 'artificial'".<sup>56</sup>

But while the distinction between artificial and natural flavors may not hold up to serious scrutiny, even the most ardent supporters of synthetic flavors acknowledge that important differences exist between these ingredients and the foods they seek to imitate. Vanilla provides an example. Natural and artificial vanilla flavors "contain the same principal flavor chemical, vanillin."<sup>57</sup> As alluded to already, food scientists can derive the "natural" variety of vanillin from various sources other than vanilla beans.<sup>58</sup> They can also make artificial vanillin entirely from petrochemicals. Either process can produce

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<sup>52</sup> Murley, T., Chambers, E. 4th. (2019). The Influence of Colorants, Flavorants and Product Identity on Perceptions of Naturalness. *Foods*. 8(8):317. [doi: 10.3390/foods8080317](https://doi.org/10.3390/foods8080317)

<sup>53</sup> Hooker, N., Simons, C. T., & Parasidis, E. (2018). Natural Food Claims:

Industry Practices, Consumer Expectations, and Class Action Lawsuits. *Food and Drug Law Journal* 73(2), 319-337.

<sup>54</sup> Liu, R., Hooker, N. H., Parasidis, E., Simons, C. T. (2017). A Natural Experiment: Using Immersive Technologies to Study the Impact of "All-Natural" Labeling on Perceived Food Quality, Nutritional Content, and Liking. *Journal of Food Science*, 82(3) 825-833. <https://doi.org/10.1111/1750-3841.13639>

<sup>55</sup> See Goodman, M. J. (2017). The Natural vs. Natural Flavors Conflict in Food Labeling: A Regulatory Viewpoint, *Food & Drug Law Journal*, 72(1), 78, 94.

<sup>56</sup> Bloom, supra note 8.

<sup>57</sup> *Id.*

<sup>58</sup> Benavides, N. (2022). What's in A Flavor? A Proposal to Address Consumer Confusion Surrounding Natural Flavoring, *Food & Drug Law Journal* 77(4) 377, 382; see also [Where Does Artificial Vanilla Flavoring Come From? Flavorists Explain \(businessinsider.com\)](https://www.businessinsider.com/where-does-artificial-vanilla-flavoring-come-from-flavorists-explain) (noting that other (natural and artificial) sources of vanillin began to replace castoreum in the 1980s, and that "As of 2009, the total U.S. consumption of castoreum was only about 292 pounds per year.").

a chemically indistinguishable vanillin. However, actual vanilla extract from vanilla beans contains many chemicals in addition to vanillin that contribute to flavor, such as glucovanillin, vanillic acid, piperonal, and anisaldehyde. Food chemists may seek to isolate and replicate some of these more subtle flavor components as well, but recreating actual vanilla will forever remain elusive, in part because of subjective differences in how much the various components in vanilla beans contribute to vanilla taste. In this respect, an actual vanilla bean’s flavor—or what many people would describe as “natural” vanilla flavor, despite the inconsistent FDA definition of that term—presents a unique value to at least some consumers.<sup>59</sup>

The current FDA rules undermine that value. By allowing manufacturers to describe foods with added flavors as “naturally flavored,” the rules sow confusion as to which foods contain an actual underlying ingredient (e.g. vanilla or vanilla extract) versus those containing a flavoring chemical (e.g. vanillin). To the extent that consumers who would prefer the real ingredients are misled into buying foods with “natural flavors” instead, selling foods without added flavors becomes that much harder, in no small part because using added flavors is so much cheaper than using the ingredients those flavors seek to imitate.<sup>60</sup>

### III.B. Legal Grounds

Under the Food, Drug, and Cosmetic Act, FDA has broad authority to prescribe how food manufacturers label ingredients. In particular, 21 U.S.C.A. § 343(i) deems a food with multiple ingredients to be “misbranded” unless its label states “the common or usual name of each such ingredient.” The statute prescribes special disclosure requirements for any food that “bears or contains any artificial flavoring, artificial coloring, or chemical preservative.” *Id.* at § 343(k). It also provides that “spices, flavorings, and [certain] colors, may be designated as spices, flavorings, and colorings without naming each.” *Id.* at § 343(i). However, nothing in the statute refers to “natural flavors” or indicates that FDA must allow food manufacturers to use that term, rather than the more informative and accurate “added flavors.”

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<sup>59</sup> Bloom *supra* note 8.

<sup>60</sup> Benavides *supra* note 58.

#### **IV. Conclusion**

FDA should revise its ingredient labeling rules to eliminate the misleading and confusing term “natural flavor.” The rules should instead direct food manufacturers to label these ingredients as “added flavors” or by their common or usual name. Doing so will help consumers avoid ultra-processed foods, create a more level playing field for food companies producing less processed foods, and reduce consumer confusion.

#### **V. Environmental Impact**

The action requested is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 and 25.32 and, therefore, does not require the preparation of an environmental assessment.

#### **VI. Certification**

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Thomas Gremillion', with a stylized flourish at the end.

Thomas Gremillion  
Director of Food Policy  
Consumer Federation of America