

## CITIZEN PETITION

August 5, 2022

Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852  
*Submitted electronically via Docket No. FDA 2013-S-0610*

**Re: Citizen petition for the U.S. Food and Drug Administration to adopt a mandatory, nutrient-specific, interpretive front-of-package nutrition labeling system for all packaged foods sold in the United States**

To Whom It May Concern:

The undersigned organizations—Center for Science in the Public Interest (CSPI), the Association of SNAP Nutrition Education Administrators (ASNNA), and the Association of State Public Health Nutritionists (ASPHN), submit this petition pursuant to 5 U.S.C. § 553(e), 21 U.S.C. § 343, and 10 C.F.R. § 10.30 requesting that the Commission of Food and Drugs amend its regulations, specifically 21 C.F.R. § 101, to require on the principal display panel of a food an easy-to-understand, standardized system that is 1) mandatory, 2) nutrient-specific, 3) includes calories, and is 4) interpretative with respect to the levels of added sugars, sodium, and saturated fat per serving.

CSPI, your food and health watchdog, is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. The organization does not accept government or corporate grants and is supported by subscribers to its Nutrition Action magazine, as well as grants from individuals and private foundations. CSPI has a long history of advocating for policies that leverage food labeling to support public health, including health warnings on alcoholic beverages, the mandatory Nutrition Facts panel, rules requiring the disclosure of allergens, calorie counts on chain restaurant menus, and more.

ASNNA is the professional organization for SNAP Nutrition Education (SNAP-Ed) administrators dedicated to improving the nutritional status of SNAP recipients and those eligible for SNAP-Ed. By utilizing comprehensive, integrated approaches to nutrition education and obesity prevention, food security, and physical activity, ASNNA works to promote communication at the state, regional, and national levels with program issues and success. ASNNA also serves as a nationwide resource for nutrition education and obesity prevention, network expertise, partnership development, and policy advocacy. ASNNA strives to advance successful practices that lead to incorporating the Dietary Guidelines for Americans, specifically among SNAP-eligible individuals and communities.

Founded in 1952, ASPHN is a non-profit membership organization that provides state and national leadership on food and nutrition policy, programs and services aimed at improving the health of our population. ASPHN's membership is composed of more than 700 public health nutritionists located throughout all 50 states, the District of Columbia and five U.S. territories. ASPHN's vision is to create new environmental norms where healthy eating and active living are the easy and natural choices for all Americans.

Americans, in general, have poor diet quality and high rates of diet-related chronic disease. Current U.S. food labeling requirements (*i.e.*, the Nutrition Facts label) and voluntary industry initiatives (*i.e.*, Facts Up Front) are insufficient to promote healthy diets. The Nutrition Facts label has low utilization, and experimental studies find that Facts Up Front does not adequately inform consumers or influence their food choices. Experimental studies in which consumers viewed Facts Up Front-style labels or other FOPNL systems found that participants who viewed Facts Up Front-style labels were less likely to accurately identify nutrients present in levels above nutritional recommendations, to identify the most healthful product within a set, or to correctly rank products according to their nutritional quality, compared to consumers who viewed other labels. More fundamentally, to our knowledge no study has shown that Facts Up Front-style labels are effective at shifting consumer behavior. Randomized experimental studies assessing the effect of Facts Up Front-style labels compared to a control condition with no FOPNL show no improvement in the overall healthfulness of actual or intended food purchases.

In contrast, experimental and real-world evidence shows that interpretive FOPNL can improve consumer understanding and encourage healthier diets. In experimental studies, nutrient warnings (which identify foods as containing high levels of overconsumed nutrients like added sugars, sodium, and saturated fat) and traffic light labels (which identify foods as containing high, medium, or low levels of overconsumed nutrients) improved participants' ability to identify foods with excess nutrients, correctly select healthier products and rank or compare products according to healthiness, assess nutrient levels, and compare product healthfulness, compared to Nutrition Facts labels alone. With respect to consumer behavior, a systematic review of experimental studies found that nutrient warning labels led to a statistically significant 26 percent increase in the overall healthfulness of purchased foods ( $p < 0.05$ ). Traffic light labels had no statistically significant effect on the overall healthfulness of purchased foods, but improved other outcomes, such as the amount of calories purchased. The same review found statistically significant 13 percent and 6 percent decreases in the total calories of purchased food when people viewed nutrient warnings and traffic light labels, respectively, compared to no labels ( $p < 0.05$ ). And after Chile adopted a mandatory nutrient warning label policy in 2016, there were statistically significant reductions in purchases of calories (-3.5%), sugars (-10.2%), saturated fat (-3.9%), and sodium (-4.7%) (all  $p < 0.05$ ).

FOPNL can also lead food companies to reformulate their products. Between 2013 (three years before Chile adopted a mandatory FOPNL policy) and 2019 (three years after), there was a statistically significant 15 percent decrease in the proportion of foods in Chile meeting the criteria for sugar warning labels ( $p < 0.05$ ).

FDA has legal authority to require interpretive, nutrient-specific FOPNL under the Nutrition Labeling and Education Act of 1990 (NLEA). Furthermore, a mandatory, nutrient-specific, interpretive FOPNL policy would be factual, non-controversial, and reasonably related to the government's interest, and thus would withstand the legal tests for acceptable compelled speech under the First Amendment of the U.S. Constitution.

Dozens of countries have already implemented interpretive FOPNL to supplement previous nutrition labeling requirements. The U.S. must learn from experiences abroad and follow the science to select a system with the greatest potential to promote equitable access to information, improve diets, promote reformulation, and advance public health.

## A. Action Requested

The petitioners request that FDA amend part 101 of title 21 of the Code of Federal Regulations to require on the principal display panel of a food an easy-to-understand, standardized system that is 1) mandatory, 2) nutrient-specific, 3) includes calories, and is 4) interpretive with respect to the levels of added sugars, sodium, and saturated fat per serving.



**Figure 1. Examples of nutrient-specific, interpretive nutrition labels implemented in Chile (left), Israel (middle), and Ecuador (right); calorie disclosures added**

The request in this petition is for any FOPNL system that meets these criteria. Examples of systems that meet these criteria include warning labels that alert consumers to high levels of nutrients, and traffic light labels that rate levels of nutrients as high, medium, or low (typically using the colors red, yellow, and green) (*see* Figure 1). Other FOPNL formats, such as Nutri-Score or Health Star Ratings, do not meet these criteria because they are not nutrient-specific and interpret the overall healthfulness of the food as opposed to the levels of specific nutrients.

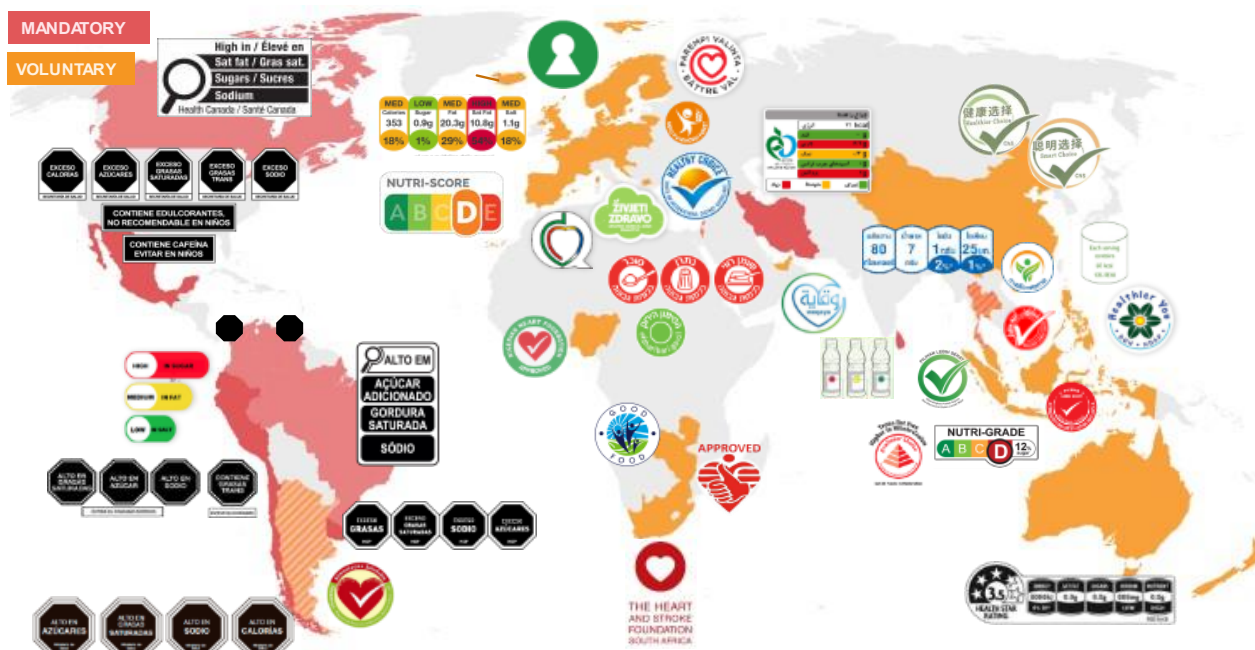
## B. Statement of Grounds

### I. General Statement of Grounds

Food labeling is an important tool to promote transparency, increase knowledge and understanding of nutrition, and support healthy diets. It has been used to assist consumers in maintaining healthy diets at least since Congress passed the NLEA. This law resulted in the adoption of the Nutrition Facts label across nearly all packaged foods and is widely regarded as a major success for public health.

Data collected by FDA in the years following adoption of the Nutrition Facts label suggest that the label had a positive impact on the healthfulness of purchased foods.<sup>1</sup> But more than three decades later, U.S. diets remain poor;<sup>2</sup> utilization of Nutrition Facts is low, especially among people with lower incomes and educational attainment;<sup>3,4</sup> and governments and public health advocates across the globe are recommending new ways of leveraging food labels to promote public health.

A recent wave of food labeling policies, collectively termed front-of-package nutrition labeling (FOPNL), aim to give consumers information about the healthfulness of foods that is clear, quick, and easy to access and understand. Dozens of government-led FOPNL systems with a wide variety of formats are already in use (*see* Figure 2).<sup>5</sup> Several countries have adopted mandatory FOPNL policies that require all qualifying foods to bear a front-of-package disclosure, while others have endorsed voluntary policies that allow food manufacturers to opt-in to presenting the government-endorsed label. Some FOPNL systems are interpretive, meaning they provide some evaluative judgment of nutrient content (*e.g.*, using colors, letters, stars, and/or words like “high” or “excess”) to assist consumers with understanding the information, while others are non-interpretive, meaning that they provide facts about nutrient content but no additional guidance on how to interpret those facts beyond what can already be found on the Nutrition Facts label (*see* Appendix A). Systems may interpret the healthfulness of a food in its entirety (*e.g.*, France’s Nutri-Score system assigns foods a letter grade A, B, C, D, or E and Australia’s and New Zealand’s Health Star Rating assigns foods 1 to 5 stars), or they may interpret the levels of specific nutrients (*e.g.*, Ecuador’s and the United Kingdom’s traffic light systems rate levels of fat, saturated fat, sugars, and sodium as high, medium, or low, and nutrient warning labels in Chile and Israel disclose when foods are high in these nutrients). Canada is the



**Figure 2. Map of countries with mandatory or voluntary interpretive labels on packaged foods and drinks, from the Global Food Research Program at University of North Carolina at Chapel Hill; available at: [https://www.globalfoodresearchprogram.org/wp-content/uploads/2022/07/FOP\\_Regs\\_maps\\_2022\\_07.pdf](https://www.globalfoodresearchprogram.org/wp-content/uploads/2022/07/FOP_Regs_maps_2022_07.pdf)**

most recent country to adopt a mandatory FOPNL policy, requiring manufacturers to place a symbol on foods that are high in saturated fat, sugars, and/or sodium with enforcement to begin in January 2026.<sup>6</sup>

The United States has not yet adopted a government-led FOPNL policy. CSPI first petitioned the FDA to adopt a FOPNL system in 2006. The petition called for a symbol on the principal display panel that would communicate to consumers the healthfulness of foods.<sup>7</sup> Shortly after, in 2007, FDA held a public hearing on the use of symbols to communicate nutrition information;<sup>8</sup> however, the agency never formally responded to CSPI's petition.

In 2010 and 2012, the Institute of Medicine (IOM, now called the National Academy of Medicine) issued parts one and two of a report on FOPNL<sup>9,10</sup> and recommended that “FDA and USDA should develop, test, and implement a single, standardized FOP system to appear on all food and beverage products.”<sup>10</sup> In response, the Food Marketing Institute and Grocery Manufacturers Association (now called the Consumer Brands Association), two food industry trade groups, developed a voluntary, non-interpretive FOPNL system called “Facts Up Front.”<sup>11</sup> Implementation of Facts Up Front began in 2012 and continues today.

Aptly named, Facts Up Front simply takes information on the calorie and nutrient content per serving from the Nutrition Facts label and places it on the front of the package. According to the Facts Up Front Style Guide for Implementers, this information must include calories, saturated fat, sodium, and sugars, and may include up to two of potassium, dietary fiber, protein, vitamin A, vitamin C, vitamin D, calcium, and iron.<sup>12</sup> Quantities must be identical to those listed in the Nutrition Facts label, and nutrients with established Daily Values (DV) must also display the percent DV.<sup>12</sup>

While Facts Up Front increases visibility of nutrition information by moving it to the principal display panel, the system does not provide consumers any guidance on how to interpret this information, beyond what was already available on the Nutrition Facts label. Moreover, it allows companies to highlight nutrients they believe show their products in a favorable light. Critics—including CSPI—have argued that this system would not do enough to influence food choice, and is instead intended to forestall regulation.<sup>13,14</sup> Studies funded by the food industry have proclaimed the system's success, but these studies only evaluated outcomes of understanding, awareness, and utilization, not the label's impact on the nutritional quality of food purchased or consumed.<sup>15-17</sup> Experimental and real-world studies examining the effects of Facts Up Front-style labels on consumer choice have found no effects, and studies comparing the effects of Facts Up Front-style labels and other forms of FOPNL on knowledge and understanding consistently find that other FOPNL systems are significantly more effective (*see* Section IV. c.).

When the system was first developed by industry, FDA indicated plans to “assess whether [Facts Up Front] is being applied in a manner that promotes public health,”<sup>18</sup> but no such assessment has been published. The U.S. government took no further action on FOPNL until 2021. In that year, FDA published a narrative review of the literature on FOPNL<sup>19</sup> and announced its intentions to develop a symbol that industry can voluntarily use to label food products that meet

the definition of the term “healthy,” a term defined in regulation, which the FDA is currently working to update.<sup>20</sup> CSPI objected to this approach to FOPNL in comments to the agency,<sup>21</sup> arguing that (1) the agency’s literature review did not systematically evaluate the relative efficacy of endorsement logos compared to other FOPNL options, (2) had the agency thoroughly reviewed the evidence, it would have found that other FOPNL systems have greater effects on diet quality, (3) a “healthy” logo could lead to a price premium on products bearing the logo, making these foods less accessible, whereas other FOPNL systems would be less likely to cause increases in prices of healthier foods, and (4) FDA has the authority to establish a mandatory FOPNL system.

Dozens of countries have implemented FOPNL, and over one hundred experimental and real-world studies have tested the effects of different FOPNL systems.<sup>5,22-23</sup> These studies find that well-designed interpretive FOPNL can significantly improve the healthfulness of foods selected by consumers and prompt product reformulation. The U.S. should learn from experiences abroad and follow the science to select a system with optimal potential to promote equitable access to information, improve diets, promote reformulation, and advance public health.

## **II. Statement of Legal Grounds**

- a. FDA has the statutory authority to require interpretive nutrient disclosures on the principal display panel

The NLEA authorizes FDA to require interpretive calorie and nutrient disclosures on the front of packages (described in regulation as the “principal display panel”).<sup>24</sup> Specifically, the law states that packaged food will be deemed misbranded if it does not include calorie information and the amount per serving of specific nutrients, some of which (including sodium and saturated fat) are listed in the statute, while others (including added sugars and *trans* fat) have been subsequently identified through FDA regulation.<sup>25</sup> FDA relied on this authority to promulgate and update the rules requiring the Nutrition Facts panel to appear on the label of packaged foods.<sup>26</sup>

Under the NLEA, calorie and nutrient disclosures must be “prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.”<sup>27</sup> Further, FDA may “require the required [nutrition] information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet.”<sup>28</sup>

Taken together, the above authority gives FDA the ability to create a labeling system that is mandatory (“required”), nutrient-specific (disclosing calories and nutrients, including added sugars, sodium, and saturated fat, which are mandated on food labels), interpretive (conveys the “relative significance” of nutrient content “in the context of the total daily diet”), and front-of-package (“prominently”).

The intent of Congress to so authorize the agency to create such an interpretive labeling system is further emphasized in the House Report for the NLEA, which states that:

In order to present nutrition information in a manner that facilitates the public's understanding, the Secretary may choose among a variety of options. . . . This could include the use of descriptive terms such as "high," medium," and "low" or use of universal symbols to indicate desirable or undesirable levels of particular nutrients.<sup>29</sup>

Thus, FDA has the authority to require interpretive front-of-package nutrient disclosures under the NLEA. These types of disclosures are consistent with Congressional intent and are a logical extension of the Nutrition Facts label.

b. Mandatory front-of-package nutrient disclosures are constitutional under the First Amendment

The First Amendment of the U.S. Constitution protects freedom of speech,<sup>30</sup> but the U.S. Supreme Court has interpreted the First Amendment as only affording commercial speech (*i.e.*, speech that concerns the potential sale of a good, such as a packaged food product) limited protection.<sup>31</sup> Indeed, disclosure requirements imposed on commercial speech, such as FOPNL, are subject to the lowest level of First Amendment scrutiny. When the government imposes a disclosure requirement in a commercial context, such as requiring food manufacturers to label the calorie and nutrient content of food, courts apply the test set forth by the Supreme Court in *Zauderer v. Office of Disciplinary Counsel of Supreme Court*.<sup>a,32</sup>

Under *Zauderer*, disclosure requirements do not violate the First Amendment if the compelled speech is 1) strictly factual and uncontroversial in its description of a commercial product, 2) reasonably related to a legitimate government interest, and 3) not unjustified or unduly burdensome.<sup>32</sup>

i. *Mandatory front-of-package nutrient disclosures can be strictly factual and uncontroversial*

The systems proposed in this petition rate levels of specific nutrients based on their objective quantities and thus can be factual and uncontroversial.

The Supreme Court has suggested that "factual and uncontroversial" information differs from opinion,<sup>32</sup> and Circuit courts have further interpreted "factual and uncontroversial" to mean not subjective.<sup>33</sup> With respect to the meaning of "uncontroversial" specifically, circuit courts have suggested that it refers to information that is factually accurate<sup>34</sup> and nonideological.<sup>35</sup>

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<sup>a</sup> If the disclosure requirement is not strictly factual and uncontroversial, then courts will apply a more rigorous test. Under that test, courts then ask if the requirement is justified by a substantial government interest, if the requirement directly advances that government interest, and if there is a reasonable fit between the government's goal and the requirement (*Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 563-4 (1980)).

Additionally, the Supreme Court identified abortion as a controversial topic that ruled out the use of *Zauderer* for accessing a disclosure requirement related to that topic.<sup>36</sup>

Courts have already held that both nutrient warnings and calorie disclosures are factual and uncontroversial. In 2017, a New York appellate court determined that New York City's requirement for sodium warnings on chain restaurant menus did not violate the First Amendment.<sup>37</sup>

This law requires chain restaurants to display a black and white triangular saltshaker icon next to menu items with more than 2,300 milligrams of sodium.<sup>38</sup> At the point of purchase, chain restaurants must also conspicuously post disclosures explaining that the icon "indicates that the sodium (salt) content of this item is higher than the total daily recommended limit (2,300 mg). High sodium intake can increase blood pressure and risk of heart disease and stroke."<sup>38</sup> Regarding the sodium warning icon and disclosure, the court wrote that the "weight of the scientific evidence in the record shows that it is factual, accurate and uncontroversial"<sup>39</sup> that high sodium intake carries the stated medical risks. Philadelphia introduced similar legislation requiring sodium warnings for chain restaurant menus in 2018<sup>40</sup> and has not faced a constitutional challenge.



**Figure 3. Warning icon required for chain restaurant menu items that exceed 2,300 milligrams of sodium in New York City**

Additionally, in 2009, the Second Circuit Court of Appeals found that New York City's chain restaurant menu calorie disclosure requirement (which the Patient Protection and Affordable Care Act's national standard has since preempted) did not violate the First Amendment.<sup>41</sup> In that case, although the New York State Restaurant Association challenged the requirement, it did not dispute that calorie disclosures are factual.<sup>42</sup>

Based on the legal precedent set by court cases upholding the constitutionality of existing calorie disclosure and nutrient warning label policies, FOPNL in the form of calorie disclosures or mandatory disclosures signaling levels of nutrients (*i.e.*, "high" or "high/medium/low") can satisfy this first prong of the *Zauderer* test. These labels can accurately convey a food's caloric and nutrient content relative to other foods, and in the context of the total daily diet, based on widely accepted Daily Values. Because "high" or "high/medium/low" nutrient disclosure levels would be tied to established, science-based Daily Values, they would not be controversial, and courts are unlikely to characterize them as ideological or opinion-based.

*ii. Mandatory front-of-package nutrient disclosures are reasonably related to legitimate government interests*

In order to withstand the *Zauderer* test, the government needs to identify only a legitimate interest to which the disclosure requirement is reasonably related.<sup>32</sup> In the New York State and New York City cases discussed above, the courts upheld calorie and nutrient disclosure requirements based on the government's interests in improving consumer knowledge of potential health risks,<sup>39</sup> and reducing consumer confusion and deception in light of what New York City



termed an “obesity epidemic.”<sup>43</sup> In other cases applying the *Zauderer* test to compelled disclosures, circuit courts have found that USDA’s mandatory country-of-origin labeling on meat and Vermont’s required labeling of light bulbs containing mercury were reasonably related to government interests in ensuring that consumers are better informed.<sup>34,44</sup>

By introducing FOPNL to better inform consumers about the relative levels of nutrients in foods, and to increase consumers’ awareness of the health risks related to overconsumption of calories, added sugars, sodium, and saturated fat, FDA could readily establish that it is pursuing a legitimate government interest.

*iii. Mandatory front-of-package nutrient disclosures are not unjustified or unduly burdensome*

The final prong of the *Zauderer* test requires a showing that the disclosure is not unjustified or unduly burdensome. To show that a disclosure requirement is not unjustified, the government must present evidence that the problem it is attempting to address is “real and not purely hypothetical.”<sup>45</sup> However, a disclosure need not definitively address the problem.<sup>46</sup> A requirement that is not unduly burdensome is one that does not extend any further than reasonably necessary, and therefore does not risk “chilling” protected speech.<sup>45</sup> An unjustified or unduly burdensome mandatory disclosure “drowns out” an advertiser’s message and “effectively rules out the possibility” of having an advertisement in the first place.<sup>47</sup>

High rates of diet-related disease in the United States justify FOPNL, and such labeling can be designed in a manner that would not unduly burden food manufacturers. There is a robust body of scientific evidence indicating that diet-related disease is a serious public health problem. And growing evidence indicates that FOPNL may lower diet-related disease rates by changing consumer behavior and spurring product reformulation. Furthermore, FOPNL could be a small enough presence on the front-of-package that it would not drown out other messages that food producers place there. Circuit courts have upheld a tobacco warning taking up 50 percent of the back and front of cigarette packages<sup>48</sup> and mandatory solicitation disclosures applicable to loan lenders that are required to be in the same or larger font as other lender information.<sup>49</sup> The Court of Appeals for the Ninth Circuit, sitting *en banc*, struck down San Francisco’s sugar-sweetened beverages warning that would have taken up 20 percent of advertising space, but only because evidence cited by the City’s own expert indicated that the City’s goal could be accomplished by a warning half of that size.<sup>50</sup> Regardless, FOPNL could take up substantially less than 20 percent of the principal display panel for many foods, and can be designed to leave ample room for food producers’ other messaging.

A mandatory, nutrient-specific, interpretive front-of-package labeling system is not likely to face a successful challenge on First Amendment grounds because the disclosures will be factual and noncontroversial, the system will be reasonably related to a legitimate government interest concerning public health and consumer awareness, and it will not be broader or more burdensome on industry than necessary to address that interest.

### III. Statement of Factual Grounds

#### a. Americans have poor diets and high rates of diet-related disease

Despite decades of public health efforts to improve the American diet, people in the United States continue to have generally poor diet quality and high rates of diet-related chronic disease. According to data from the National Health and Nutrition Examination Survey (NHANES), the average Healthy Eating Index-2015 score for all Americans, ages 2 years and older, was 58 out of 100 in 2015-2016 (the most recent data available) and has remained relatively stable over the past decade (*see* Figure 4).<sup>2</sup> The U.S. Department of Agriculture (USDA) Food and Nutrition Service interprets this to mean that “Americans do not align their eating choices with the Dietary Guidelines.”<sup>2</sup>



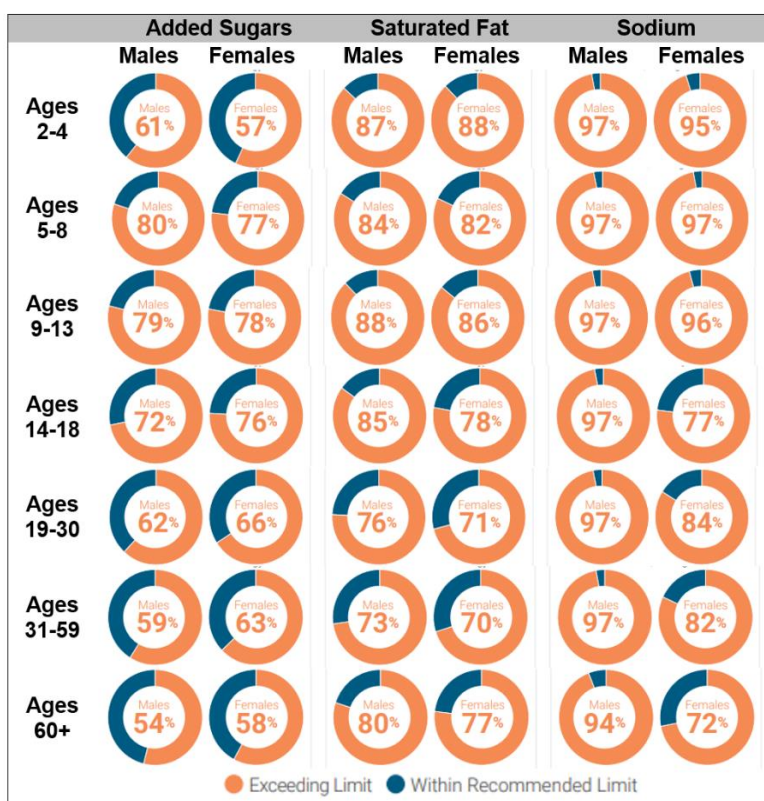
**Figure 4. Adherence of the U.S. Population, Ages 2 and Older, to the Dietary Guidelines for Americans over Time, as Measured by Average Total Healthy Eating Index-2015 Scores (Source: Dietary Guidelines for Americans, 2020-2025)**

While about 10.5 percent of U.S. households experienced food insecurity at some time during 2020,<sup>51</sup> putting them at risk of nutrient insufficiency,<sup>52,53</sup> the primary contributor to low diet quality in the United States is overnutrition rather than undernutrition. The vast majority of Americans exceed recommended nutrient limits (*see* Figure 5).<sup>54</sup> The average sodium intake among adults is 3,530 milligrams per day (1.5 times the recommended daily limit of 2,300 milligrams); the average added sugars intake among adults is 17 teaspoons per day (1.4 times the recommended daily limit of 12 teaspoons); and the average saturated fat intake among adults is 28.7 grams per day (1.4 times the recommended daily limit of 20 grams).<sup>55,56</sup>

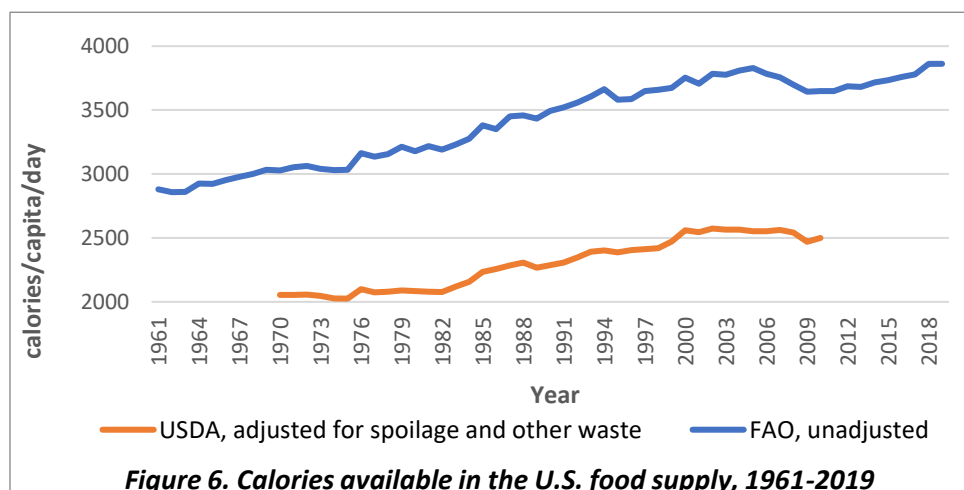
People in the U.S. also consume excess calories. Between 1970 and 2010, there was an increase in estimated average caloric intake per capita per day from 2,054 to 2,501, and more recent data suggests this has likely remained steady or even increased (*see* Figure 6; for reference, 2,000 calories a day is used by FDA for general nutrition advice).<sup>57</sup>

Meanwhile, U.S. adults consume an average of only 0.9 cup per day of fruit (compared to the recommended daily intake of 1.5-2.5 cups), 1.6 cups per day of vegetables (recommended daily intake is 2-4 cups), and 0.8 ounces of whole grains (recommended daily intake is 3-5 ounces).<sup>54,55</sup>

Diet quality is closely linked to one's risk for developing chronic diseases such as heart disease,<sup>58,59</sup> type 2 diabetes,<sup>60</sup> certain cancers,<sup>61</sup> and stroke.<sup>58</sup> These are among the top ten leading causes of mortality in the United States.<sup>62</sup> A study by researchers at the University of Washington Institute for Health Metrics and Evaluation found that dietary risks accounted for an estimated 529,299 U.S. deaths in 2016<sup>63</sup> (equal to nearly one in five U.S. deaths in 2016<sup>64</sup>), a powerful argument for new interventions to improve diet quality in the United States.



**Figure 5. Percent of U.S. Children and Adults Exceeding Limits of Added Sugars, Saturated Fat, and Sodium based on NHANES 2013-2016, 2 Days of Dietary Intake Data, Weighted (Source: Dietary Guidelines for Americans, 2020-2025)**



**Figure 6. Calories available in the U.S. food supply, 1961-2019**

In this petition, we request that FDA implement a FOPNL system that includes interpretive disclosures with respect to levels of added sugars, saturated fat, and sodium. Interpretive nutrient labeling is needed to assist consumers in understanding which foods may lead them to exceed daily recommended limits for these overconsumed nutrients.

We also request that FDA implement a system that includes non-interpretive calorie disclosures. This information is needed on the front of package of all foods (not only foods that are high in calories) because consumers are interested in knowing about calories in the foods they consume, but generally lack knowledge of the caloric content of different foods. In a 2019 survey by FDA, when respondents were asked “Which of the following do you usually look for when looking at a Nutrition Facts label?,” the most commonly-selected response was “Calories” (60% of respondents).<sup>65</sup> In the same survey, when asked “How confident are you that you know how many calories are in the foods you eat?,” only 16 percent responded “Very” or “Extremely” confident (33 percent said “Somewhat” confident and 50 percent said “Not at all” or “Slightly” confident).<sup>65</sup> And when asked “In general, do you think that you consume too few, too many, or about the right amount of calories?,” 44 percent of respondents responded “Too many calories” (only six percent responded “Too few”).<sup>65</sup>

Ensuring that consumers are informed about calories in foods is important because excess caloric intake can lead to weight gain, which is linked to increased risk of type 2 diabetes, cardiovascular disease, certain cancers, and other adverse health outcomes.<sup>66</sup> Furthermore, increased access to calorie information can support consumers looking to count calories, which a systematic review of weight management interventions found to be the most effective behavioral tool for weight management in people with overweight or obesity.<sup>67</sup>

b. Current food labeling requirements are insufficient, resulting in low utilization

When it was introduced three decades ago, the Nutrition Facts label was a major step forward in promoting transparency, facilitating nutrition education, and improving diets. But research over the years has found that only a minority of consumers regularly utilize the label. Data from NHANES 2017-2018 show that only 41 percent of adults ages 20 years and older report using the Nutrition Facts panel “always” or “most of the time” when deciding to buy a food product (*see* Table 1).<sup>68</sup>

Low utilization of the Nutrition Facts label may be attributable to the time and attention required to review the complex label. With increasing reliance on fast-paced digital and social media, consumers are looking to take in information quickly and have limited attention spans.<sup>69</sup> Consumers tend to use shortcuts when processing nutrition information and rely on heuristic cues that enable quick decisions to preserve their cognitive resources.<sup>70</sup> This means that instead of using the Nutrition Facts label, which is usually placed on the back or side of the package, consumers may rely on more prominent labeling attributes, such as nutrition-related claims on the front. The need to convey important information more quickly and succinctly has

According to the 2014 FDA Health and Diet Survey, 31 percent of consumers report that they often use front-of-package claims such as “low sodium” or “rich in antioxidants” when deciding to buy a product.<sup>4</sup> Unfortunately, such claims can mislead consumers. A 2018 study by FDA found that the presence of nutrient content claims related to vitamins and minerals on snack foods decreased the perceived sugar content and increased the perceived healthfulness, perceptions of the presence of healthful nutrients, and intentions to consume the product.<sup>71</sup> A 2022 study by researchers from University of North Carolina and CSPI found that nutrition-related claims on fruit-flavored drinks containing added sugar made parents more likely to incorrectly believe these drinks contained no added sugar and were 100 percent juice, and more likely to select those products over actual 100 percent juice products.<sup>72</sup> Systematic reviews of earlier studies examining the impacts of health and nutrition related claims reveal that other studies have had similar findings.<sup>73,74</sup>

**Table 1. Regular use of Nutrition Facts panel on food labels by income, education, and language of interview (NHANES 2017-2018, adults ≥20 y)**

	<b>Always or Most of the time</b>	<b>Sometimes, Rarely, or Never</b>	<b>p-value</b>
Total, weighted	41%	59%	
<b>Income level</b>			<i>p &lt; .0005*</i>
Below FPL	34%	66%	
100%-199% FPL	37%	63%	
200%-299% FPL	36%	64%	
300%-399% FPL	46%	54%	
≥400% FPL	44%	56%	
<b>Educational attainment</b>			<i>p &lt; .0005<sup>#</sup></i>
Less than HS	26%	74%	
High school	35%	65%	
Some college	42%	58%	
College and above	49%	51%	
<b>Language used in interview</b>			<i>p &lt; .0005<sup>†</sup></i>
English	41%	59%	
Spanish	35%	65%	

\*Cramer’s V = 0.063, p <0.005

<sup>#</sup> Cramer’s V = 0.105, p <0.005

<sup>†</sup> Cramer’s V = 0.037, p <0.005

In addition to overall low utilization, there are also statistically significant differences in utilization of the Nutrition Facts label by income level, educational attainment, and language (p<0.0005).<sup>68</sup> Only 34 percent of people with household incomes below the federal poverty level (FPL), 26 percent of people with less than a high school education, and 35 percent of people who were interviewed in Spanish reported regularly using the Nutrition Facts label, compared with 44 percent of people with household incomes above 400 percent of the FPL, 49 percent of people who completed college, and 41 percent of people who were interviewed in English.

Potential reasons for these differences in label utilization are that the label requires prior nutritional knowledge, English proficiency, literacy, and numeracy skills to interpret. In a 2006 study, 200 adults were given a survey to evaluate their understanding of the Nutrition Facts label. They were asked open-ended questions where they had to interpret food labels, such as determining carbohydrate or caloric content of a certain amount of a food, and questions where they selected which of two foods had more or less of a certain nutrient. They also answered

validated questionnaires assessing health literacy and numeracy skills. The study found significantly lower rates of correct responses among those with lower versus higher literacy (51% vs 75%,  $p<0.0001$ ) and lower versus higher numeracy (61% vs 84%,  $p<0.0001$ ).<sup>75</sup> Higher performance on the survey was also significantly correlated with higher income and higher education ( $p<0.001$ ).<sup>75</sup>

The fact that current nutrition labeling provides less benefit to sociodemographic groups with less social privilege (*i.e.*, lower incomes and less education) is particularly concerning given that these same groups have lower quality diets and poorer health. In 2011-2012, 58 percent of people in the United States with less than a high school education and 53 percent of people with only a high school education had poor quality diets (defined as <40% adherence to the American Heart Association's recommendations for consumption of fruits and vegetables, fish and shellfish, sodium, sugar-sweetened beverages, and whole grains), compared with 33 percent of people with a college degree.<sup>76</sup> Likewise, 61 percent of people with incomes less than 130 percent of the FPL had poor quality diets, compared with 36 percent of people with a family income exceeding 300 percent of the FPL.<sup>76</sup> Meanwhile, the prevalences of diabetes, stroke, and obesity are higher among U.S. adults with less education compared to those with more education. Among adults with no high school degree, 5% have had strokes and 13% have diabetes, compared with 3% and 8% of those with more than a high school education.<sup>77,78</sup> Likewise, 40% of people with a high school degree or less have obesity compared to 28% of college graduates.<sup>79</sup> Additionally, the prevalences of diabetes, stroke, heart disease, and obesity are higher among U.S. adults with incomes lower than the FPL (19%, 5%, 12%, and 44%, respectively) compared to those with incomes at least 400 percent of the FPL (11%, 2%, 10%, and 38%, respectively).<sup>77,80,81</sup>

Nutrition interventions that disproportionately benefit groups that already experience better outcomes related to diet and health may improve population health but serve to exacerbate health disparities. Although food labeling interventions cannot remove the structural barriers that produce dietary differences and health disparities, food labels can be designed to enhance equal access to nutrition information.

One way to make nutrition information on food labels more accessible is through interpretive labeling. Whereas noninterpretive labels like the Nutrition Facts label only display facts about the nutrient content of a food with no additional guidance on how to interpret those facts (aside from the percent Daily Value, which remains difficult for many consumers to understand<sup>65</sup>), interpretive labels assist consumers in judging the healthfulness of foods with indicators such as 'high in' statements or colors (*e.g.*, red, yellow, and green) that refer to the amounts of nutrients relative to a standard. Leveraging automatic associations (*e.g.*, red = stop; green = go) can help people process information more quickly and easily. Interpretive labels are well-suited to consumer tendencies to rely on heuristic cues to evaluate the nutritional quality of foods,<sup>70</sup> and researchers have suggested that they may also be easier to understand by people with less education, lower literacy or numeracy, limited English, and youth.<sup>5</sup>

Another way to make nutrition labels more accessible is by requiring that they appear on the front of the food package. Placing nutrition information on the front of the food package could decrease the time and attention required to access this information. Furthermore, front-of-package nutrition labels that highlight when products have high levels of added sugars, sodium, and saturated fat could help counteract the misleading effects of current front-of-package marketing claims.

- c. Voluntary actions by industry have been insufficient because they fail to influence consumers' food choices

As described in the Introduction section, the Food Marketing Institute and Grocery Manufacturers Association (now the Consumer Brands Association) introduced a voluntary FOPNL system called “Facts Up Front” in 2012. Later in this petition, we describe the evidence that voluntary FOPNL is, overall, a flawed and insufficient approach to providing front-of-package nutrition information. Here, we will discuss the specific shortcomings of Facts Up Front.

Like the Nutrition Facts label, Facts Up Front is noninterpretive. Because it provides no new tools for consumers to make healthier decisions, it is not surprising that Facts Up Front-style labels have performed less well than other FOPNL systems in experimental studies.

While industry-funded research has demonstrated that Facts Up Front may increase consumer knowledge of the nutritional quality of foods compared to no FOPNL,<sup>15,17</sup> other studies have demonstrated that the Facts Up Front labels are less effective at increasing consumer knowledge than other forms of FOPNL. Studies in which consumers viewed Facts Up Front-style labels or other FOPNL systems found that participants who viewed Facts Up Front-style labels were statistically significantly less likely to accurately identify nutrients present in levels above-nutritional recommendations, to identify the “most healthful” product within a set, or to correctly rank products according to their nutritional quality, compared to consumers who viewed other labels including traffic lights, nutrient warning labels, or Nutri-Score (*see* Table 2) ( $p < 0.01$ ).<sup>82-85</sup>

More fundamentally, to our knowledge no study has shown that Facts Up Front-style labels are effective at shifting consumer behavior. Randomized experimental studies assessing the effect of Facts Up Front-style labels compared to a control condition with no FOPNL show no improvement in the overall healthfulness of actual or intended food purchases.<sup>86-88</sup> And a real-world study of a Facts Up Front-style label implemented in the United Kingdom found no generalizable effect of the label on healthier choice behavior.<sup>89</sup>

In contrast, a large body of research has determined that other FOPNL systems are effective at nudging consumers to purchase or select foods with lower levels of nutrients such as saturated fat, sodium, and sugar. This points to the need for FDA to issue regulations mandating a more effective FOPNL system that will generate greater health and nutrition benefits. We now turn to that evidence.

**Table 2. Studies comparing effects of Facts Up Front-style labels and other front-of-package nutrition labels on consumer knowledge**

Study	N	Outcome	Label Condition	Result
<b>Deliza et al (2020)</b>	1,932	Average number of correct responses to 6 questions about whether the product's content of sugar, saturated fat, or sodium was higher than recommended levels	FUF-style	2.1
			Traffic light	2.8
			Nutrient warning	3.4-3.7, depending on color/shape/icon format
<b>Egnell et al (2019) in <i>Nutrients</i></b>	1,032	Odds that participants correctly ranked products according to their nutritional quality, OR [95% CI]	FUF-style	(ref)
			Health star rating	1.20 [0.82, 1.75]
			Traffic light	1.31 [0.90, 1.90]
			Nutrient warning	1.23 [0.84, 1.81]
			Nutri-Score	3.60 [2.48, 5.24]
<b>Egnell et al (2019) in <i>Ernaehrungs Umschau Intl</i></b>	1,000	Odds that participants correctly ranked products according to their nutritional quality, OR [95% CI]	FUF-style	(ref)
			Health star rating	1.20 [0.80, 1.80]
			Traffic light	2.15 [1.44, 3.21]
			Nutrient warning	1.10 [0.73, 1.65]
			Nutri-Score	2.72 [1.83, 4.05]
<b>Arrua et al (2017)</b>	387	Average percentage of correct responses to questions assessing whether participants could identify the most healthful product within a set of 2 or 3 products	FUF-style	67%
			Traffic light	83%
			Nutrient warning	82%

FUF=Facts Up Front

- d. Experimental and real-world evidence finds that interpretive, nutrient-specific FOPNL systems benefit public health
  - i. *Experimental studies show that nutrient warnings and traffic light labels improve the healthfulness of food purchases*

Multiple systematic reviews and meta-analyses have summarized the experimental evidence testing the effects of FOPNL on diet quality, and concluded that interpretive, nutrient-specific systems have positive effects on consumer behavior.

The most recent meta-analysis is by Song et al (2021), who summarized the evidence on four types of FOPNL: nutrient warnings, traffic light systems, Nutri-Score, and health warnings.<sup>22</sup> The first two of these four systems are interpretive and nutrient-specific, and thus most relevant to this petition (*see* Section II, Statement of Legal Grounds, for details on why this petition specifically requests an interpretive, nutrient-specific label). The detailed findings on nutrient warnings and



traffic lights are described in Table 3, and a higher-level comparison of the efficacy of all four systems is presented in Table 4.

Song et al. assessed the effects of labels on seven behavioral outcomes: 1) probability of choosing less healthful options (defined as products requiring nutrient warnings or red traffic lights); 2) probability of choosing more-healthful options (defined as products not requiring nutrient warnings or red traffic lights); 3) overall healthfulness of selected foods (measured using models such as the modified version of the British Food Standards Agency's Nutrient Profiling System); and purchase or selection of 4) calories, 5) sugar, 6) saturated fat, and 7) sodium.<sup>b,22</sup> The study found that nutrient warnings had statistically significant effects on five out of these seven outcomes: nutrient warnings significantly decreased the probability of choosing less-healthful options (OR=0.65), significantly increased the probability of choosing more-healthful options (OR=3.61), significantly increased the overall healthfulness of purchased/chosen foods by 26%, and significantly decreased the total calories and saturated fat of chosen foods by 13% and 16%, respectively (but not total sugar or sodium), compared to no front-of-package label (see Table 3).<sup>22</sup> The same review found that traffic light labels had statistically significant effects on three of these outcomes: traffic light labels significantly increased the probability of choosing more-healthful options (OR=1.5) and significantly decreased the total calories and saturated fat of purchased foods by 6% and 13%, respectively.<sup>22</sup> Across studies that directly compared the effects of nutrient warnings and traffic light labels, there were no significant differences between the two labels for any of the seven outcomes. However, network estimates produced by Song et al. (which include "direct estimates" of the comparative effects of two labels from studies that examined both labels, combined with "indirect estimates" that compare the effects of two labels but are produced based on studies that examined either one or the other label, but not both) found that nutrient warnings produced a statistically significant 6% greater reduction in total calories and a significantly greater reduction in the probability of choosing less-healthful options (OR=0.81) compared to traffic light labels.

Another meta-analysis by Croker et al (2020) summarized the evidence on five types of FOPNL (nutrient warnings, traffic lights, Nutri-Score, health star rating, and Facts Up Front-style labels). Again, only the first two of these systems are both interpretive and nutrient-specific. Croker et al found that nutrient warnings had statistically significant effects on three of four outcomes: nutrient warnings significantly decreased the calories, sugar (grams), and sodium (milligrams) per 100g of food purchased (but not saturated fat per 100g), compared to no label (all  $p < 0.05$ ).<sup>23</sup> Traffic light labels had statistically significant effects on one of these outcomes: they significantly decreased the sodium per 100g of food purchased.<sup>23</sup>

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<sup>b</sup> The individual studies in this meta-analysis varied in their designs (*e.g.*, online versus in-store settings, types of foods included, and types of food selection tasks) but were considered by the authors to be sufficiently homogenous to be combined for the purpose of meta-analysis.

**Table 3. Summary of findings from Song et al (2021) and Croker et al (2020) comparing effects of interpretive, nutrient-specific FOPNL systems on purchasing outcomes**

Outcome	Nutrient warning vs. control		Traffic light vs. control		Nutrient warning vs. Traffic light	
	Direct Estimate	Network Estimate	Direct Estimate	Network Estimate	Direct Estimate	Network Estimate
	<b>Song et al (2021)</b>					
	<b>Odds Ratio [95% CI]</b>		<b>Odds Ratio [95% CI]</b>		<b>Odds Ratio [95% CI]</b>	
Probability of choosing less healthful options	0.62 [0.49, 0.79]	0.65 [0.54, 0.77]	0.90 [0.76, 1.07]	NA	0.94 [0.74, 1.20]	0.81 [0.67, 0.98]
Probability of choosing more healthful options	3.61 [2.82, 4.63]	NA	1.50 [1.20, 1.87]	NA	0.81 [0.60, 1.08]	NA
	<b>Relative Mean Difference [95% CI]</b>		<b>Relative Mean Difference [95% CI]</b>		<b>Relative Mean Difference [95% CI]</b>	
Overall healthfulness of selected foods (%)	26 [17, 35]	NA	3 [-2, 9]	NA	0 [0, 0]	NA
Calories (%)	-13 [-18, -8]	-13 [-18, -8]	-6 [-11, -2]	-6 [-11, -1]	-2 [-11, 7]	-6 [-13, 0]
Sugar (%)	-7 [-21, 6]	-7 [-20, 6]	-3 [-16, 10]	-3 [-16, 10]	-5 [-31, 21]	-4 [-21, 12]
Saturated fat (%)	-12 [-24, 0]	-16 [-27, -5]	-14 [-24, -5]	-13 [-22, -4]	-2 [-20, 16]	-3 [-16, 10]
Sodium (%)	-8 [-17, 1]	-8 [-18, 2]	No data	No data	0 [0, 0]	-1 [-10, 8]
	<b>Croker et al (2020)</b>					
	<b>Effect Size [95% CI]</b>		<b>Effect Size [95% CI]</b>			
Calories (kcal/100g)	-4 [-9, 0]		-4 [-11, 3]			
Sugar (g/100g)	-0.7 [-1.1, -0.3]		-0.3 [-0.6, 0.1]			
Saturated fat (g/100g)	-0.2 [-0.5, 0.1]		-0.2 [-0.4, 0.0]			
Sodium (mg/100g)	-34 [-59, -8]		-35 [-59, -11]			
Note: Network estimate says “NA” for comparisons in Song et al (2021) if the direct and indirect effects were significantly inconsistent ( $p < 0.05$ ), meaning the network estimate may violate the assumption of consistency and transitivity of the network meta-analysis						

The experimental evidence on efficacy also generally favors an interpretive, nutrient-specific approach over other types of FOPNL that rely on summary scores or non-interpretive systems. Croker et al found that Nutri-Score (a summary system), health star ratings (also a summary system), and Facts Up Front-style labels (which are nutrient-specific but noninterpretive) had no significant effects on any of the examined purchasing outcomes.<sup>23</sup> In Song et al, Nutri-Score and health warnings had similar effects as nutrient warnings and traffic lights, but nutrient warnings had a greater effect on total calories when compared to both Nutri-Score and health warnings, and a greater effect on overall healthfulness of purchased or chosen foods compared to Nutri-Score (*see* Table 4).<sup>22</sup>

Overall, the experimental evidence strongly supports the implementation of nutrient-specific, interpretive FOPNL. The evidence favors nutrient warnings over traffic light labels for most outcomes, but both approaches would have a positive effect on consumer behavior. FDA has the authority to implement a mandatory policy requiring nutrient warnings or traffic light labels on packaged foods, and both systems would be factual, non-controversial, and reasonably related to the government's interest, and thus constitutional under the First Amendment.

**Table 4. Summary of statistically significant findings from Song et al (2021) comparing effects of different interpretive FOPNL systems on purchasing outcomes**

<b>Outcome</b>	<b>Nutrient Warning vs Traffic Light</b>	<b>Nutrient Warning vs NutriScore</b>	<b>Nutrient Warning vs Health Warning</b>	<b>Traffic Light vs NutriScore</b>	<b>Traffic Light vs Health Warning</b>
<b>Probability of choosing less healthful options</b>	NW → lower probability	No difference	No difference	No difference	HW → lower probability
<b>Probability of choosing more healthful options</b>	No difference	NS → higher probability	NW → higher probability	No difference	No difference
<b>Overall healthfulness of purchased/ chosen foods</b>	No difference	NW → greater effect	No data	No difference	No data
<b>Total calories</b>	NW → fewer calories	NW → fewer calories	NW → fewer calories	No difference	No data
<b>Total sugar</b>	No difference	No difference	No difference	No difference	No data
<b>Total sodium</b>	No difference	No difference	No data	No difference	No data
<b>Total saturated fat</b>	No difference	No difference	No data	No difference	No data

NW = nutrient warnings; NS = Nutri-Score; HW = health warnings

ii. *Experimental studies show that nutrient warnings and traffic light labels improve consumer knowledge and understanding*

One of the mechanisms by which nutrient warnings and traffic light labels improve the healthfulness of consumers' food choices is by improving consumers' understanding of the healthfulness of foods, typically defined by their levels of added sugars, saturated fat, and sodium. In experimental studies that assessed objective understanding among participants who viewed products with only a Nutrition Facts label versus a Nutrition Facts label plus nutrient warnings or traffic light labels, nutrient warnings and traffic light labels outperformed Nutrition Facts labels for most of the examined outcomes (*see* Table 5).<sup>90-95</sup> Nutrient warnings and traffic light labels improved participants' ability to identify foods with excess nutrients, correctly select healthier products, and rank or compare products according to levels of unhealthy nutrients.

**Table 5. Studies comparing effects of traffic light and nutrient warning labels plus nutrition facts labels (NFL) versus NFL only on consumer knowledge**

Study	N	Outcome	Nutrient Warning + NFL	Traffic Light + NFL	NFL Only
<i>Andrews et al (2021)</i>	711	Mean number of correct responses to questions asking if consuming 5 servings of a product in a day would be more or less than the recommended amount for: saturated fat, sodium, fat, cholesterol, and calories (out of 6)	3.33	3.64	3.31
<i>Bandeira et al (2021)</i>	2,400	Average percentage of correct responses to "In your opinion, does this product contain nutrients at higher levels than recommended for a healthy diet?" across 9 products	59.5-62.4%	55.0%	41.3%
<i>Vanderlee et al (2021)</i>	1,997	Percentage that correctly selected the healthiest* of 5 products	36%	52%	27%
		Percentage that correctly selected the least healthy* of 5 products	32%	46%	24%
		Mean number of correct responses in task ranking 5 products according to healthiness*	1.7	2.3	1.3
<i>Hobin et al (2015)</i>	2,010	Percentage of correct responses to "Does this product contain a lot, a moderate amount, or a little sodium?"	NA	55.5%	43.8%
		Percentage of correct responses to "Which product is the best option for someone who is trying to reduce their risk of high blood pressure by lowering sodium intake?"	NA	74.3%	63.7%

		Percentage of correct responses to “How do these two products compare for sodium?”	NA	23.6%	28.0%
<i>Watson et al (2014)</i>	4,357	Mean number of correct responses to “Which of these products do you think is healthier*?” (out of 9)	NA	7.5 (SD 2.0)	5.6 (SD 2.8)
<i>Jones &amp; Richardson (2007)</i>	92	Mean error in perceived healthiness rating compared to actual SSAG/1 health score*	NA	1.77 (SD .76)	2.22 (SD .77)

\*SSAG/1 = Simple Scoring System, Group A nutrients, per 100g, see Rayner, Scarborough, & Stockley (2004)<sup>96</sup>

*iii. Real-world evidence shows that interpretive FOPNL can influence consumer and industry behavior*

There is also real-world evidence of the efficacy of interpretive, nutrient-specific FOPNL systems from countries that have implemented them.

Chile’s Food Labeling and Advertising Law<sup>97</sup> required labels stating “alto en [calorias/azúcares/grasas saturadas/sodio]” (which translates to “high in [calories/sugars/saturated fat/sodium]”) starting in June 2016. A study of purchasing data from 2,381 Chilean households found statistically significant declines in daily per capita calories (-3.5%), calories from sugar (-10.2%), calories from saturated fat (-3.9%), and milligrams of sodium (-4.7%) purchased from packaged foods, comparing actual post-policy purchases from July 2016 through December 2017 with a counterfactual scenario estimating expected post-policy purchases based on pre-policy trends.<sup>98</sup> Another study that looked specifically at beverage purchases in the same study population found a statistically significant 7.5 percent decrease in daily per capita calories from beverage purchases, driven by a 27.5 percent decline in calories from beverages with ‘high in’ labels (primarily ‘high in’ sugar), but partially offset by an increase in purchases of calories from healthier beverages.<sup>99</sup> A third study analyzed scanner-level data from Walmart-Chile, one of the country’s largest supermarket retailers. This study found that sugar content of Walmart purchases decreased from 27.3 grams to 24.9 grams per dollar spent, and calorie content decreased from 488 to 457 calories per dollar.<sup>100</sup> Thus, while studies have not yet evaluated the impact of Chile’s nutrient warning label policy on overall diet quality, purchasing data point to positive effects.

Studies have also found that the food industry reformulated products following the implementation of Chile’s Food Labeling and Advertising Law, assumedly to avoid nutrient warnings. A serial cross-sectional study that looked at thousands of packaged foods and beverages sold in Chile found a statistically significant decrease in the proportion of foods and beverages requiring at least one “high in” label, from 51 percent to 44 percent, several months after the country’s warning label law took effect.<sup>101</sup> The most frequent reductions were found in the proportion of ‘high in’ sugar and ‘high in’ sodium products, but there were also decreases in ‘high in’ saturated fat and calories products in certain food categories.<sup>101</sup> A longitudinal evaluation looked at a smaller sample of 476 packaged foods commonly consumed in Chile and found a statistically significant 15 percent decrease in the proportion of foods meeting the criteria

for ‘high in’ sugar labels from 2013 to 2019 ( $p=0.001$ ), as well as smaller (nonsignificant) declines in the proportions of foods meeting criteria for ‘high in’ calories (-3.9%), saturated fat (-1.5%), and sodium (-9.2%) labels.<sup>102</sup> These studies suggest that policies requiring interpretive labels that indicate when foods contain high levels of specific nutrients may lead to reductions in those nutrients across the packaged food supply.

A few smaller studies have also assessed the effects of Ecuador’s law requiring traffic light labels,<sup>103</sup> which took effect in 2014 (note, however, that Ecuador’s traffic light labels are not required on the front of the food package and often appear on the back). One study examined the purchases of carbonated soft drinks and found a downward trend from January 2013 through December 2015, although the difference in average purchases before and after implementation of the traffic light policy (1.72 liters per capita per month versus 1.63 liters per capita per month) did not reach statistical significance at  $p<0.05$ .<sup>104</sup> Another study also found no significant effect on purchases of high-sugar beverages between January-August 2014 versus September 2014-December 2015 or on the sugar content of high-sugar soft drinks sold in Ecuador during this period,<sup>105</sup> but two popular beverages (Fioravanti Fresa and Inca Kola) reduced their sugar content enough to result in a color change on the traffic light label from yellow or red to green.<sup>105</sup> A qualitative study in which researchers conducted key informant interviews with nine representatives of companies that manufacture and market processed foods found that some companies reported reducing levels of added fat, sugar, or sodium in their products in order to replace red bars with yellows or greens.<sup>106</sup>

Finally, natural experiments have examined the effects of traffic light labels in the United Kingdom and Australia. One study used data from more than 360,000 food purchases (20,707 households) and compared sales at retailers that used traffic light labels on their store-brand products with sales at retailers that opted not to use traffic light labels. The study found that traffic light labels were associated with statistically significant reductions of 588 calories, 14 grams of saturated fats, 7 grams of sugar, and 0.8 milligrams of sodium in monthly household purchases from labeled, store-brand foods (all  $p<0.01$ ).<sup>107</sup> Other studies in the United Kingdom and Australia found no statistically significant effects associated with traffic light labels, but these studies were substantially smaller, shorter-term, and looked at a limited range of product categories as opposed to the total shopping basket.<sup>108,109</sup>

*iv. Some evidence suggests that interpretive, nutrient-specific FOPNL could promote equal access to nutrition information*

Current evidence is limited and mixed, but some studies suggest that interpretive FOPNL are at least as accessible for people with lower versus higher levels of education and income. If FDA designs a FOPNL system that is equally accessible across these demographic groups, this could help narrow the current gaps in understanding and utilization of nutrition information.

One experimental study of health and nutrient warning labels on sugar-sweetened beverages in the United States with a sample of 1,360 adults found no differences in perceived message effectiveness by income or education level.<sup>110</sup> Another experimental study with a sample of 300

adults from Uruguay found that while participants with low incomes generally perceived ultra-processed foods to be significantly more healthful than did middle- and high-income participants ( $p < 0.05$ ), traffic light labels had a greater effect on reducing perceived product healthfulness and perceived recommended consumption frequency of various ultra-processed foods for respondents with low incomes compared to those with middle and high incomes.<sup>111</sup> Similarly, a study of nearly 2,000 Canadian adults found that those with lower health literacy tended to perceive products as more healthful than participants with adequate health literacy, but interpretive FOPNL (particularly nutrient warnings and health star ratings, with a weaker effect from traffic light labels) helped close the gap in perceived healthfulness by health literacy level.<sup>112</sup> A large experimental study of 11,617 adults from Canada, the United States, Australia, and the United Kingdom found that participants with less education were less likely to respond correctly to questions asking whether a food had low, moderate, or high levels of sugar or saturated fat than those with more education, even when nutrient warnings were present, but this study did not assess whether nutrient warnings improved understanding of the levels of nutrients in foods among people with lower levels of education (*e.g.*, by comparing rates of correct responses among this group when warnings were or were not present).<sup>113</sup>

In countries that have implemented interpretive, nutrient-specific FOPNL, consumers across levels of education and income have reported benefits. Data from Ecuador's 2018 National Health and Nutrition Survey found that 21 percent of respondents reported that the country's traffic light labels helps them "some" or "a lot" with food purchase decisions, and such self-reported utility of the label did not differ by level of educational attainment, although a higher level of education was associated with increased odds of reporting awareness and understanding of the labels (as noted above, traffic light labels in Ecuador may be placed anywhere on the food package; they are not required to be placed on the front).<sup>114</sup>

In Chile, consumers at all household asset levels experienced declines in overall calories purchased from foods and beverages, and calories purchased from "high-in" foods and beverages, after the country's nutrient warning label policy was implemented.<sup>98</sup> The greatest declines were in households with the lowest assets (5% decrease in overall calories purchased and 25% decrease in calories from "high-in" products).<sup>98</sup> However, when assessing the data by level of educational attainment, declines in overall calories and calories from "high-in" products were greatest among consumers with the highest level of education.<sup>98</sup> Specifically looking at beverage purchases, high-educated and low-educated households showed similar absolute reductions in purchases of "high-in" beverages (approximately 27 mL per capita per day,  $p < 0.001$ ), although this reflected a larger relative decline for high-educated versus low-educated households, as low-educated households had higher consumption of these beverages at baseline.<sup>99</sup>

As FDA considers which FOPNL to require on packaged foods sold in the United States, the agency should test several options to identify the system that will maximize understanding and utilization across all sociodemographic groups. A system designed with particular attention to the populations benefiting less from previous nutrition labeling initiatives could help promote more equitable access to nutrition information.

- e. Experience from other countries indicates FOPNL systems should be mandatory

This petition calls for FDA to implement a mandatory FOPNL system because mandatory labeling policies are more effective than voluntary policies. Voluntary FOPNL policies tend to have inconsistent uptake by food manufacturers. For example, Australia adopted a voluntary FOPNL policy in June 2014. Five years later, the voluntary health star rating label appeared on less than half of eligible products (41%).<sup>115</sup> France adopted a voluntary Nutri-Score label in 2017, and the label only appeared on brands accounting for 50 percent of sales volume in 2020.<sup>116</sup> Endorsement logos such as the Scandinavian Keyhole and Choices logo have also faced low uptake by industry, leading the World Health Organization Regional Office for Europe to recommend that countries implementing FOPNL “explore ways to overcome issues with uptake of the FOPL system in the marketplace, including through mandatory implementation.”<sup>117</sup>

FOPNL is inherently less useful when inconsistently applied across the food supply. When FOPNL is missing from some products, consumers cannot use the information to guide their decisions and cannot be certain of the reason behind its absence. This is particularly true for endorsement logos, which are intended to appear on the healthiest packaged foods. With voluntary endorsement logo policies, consumers have no way of knowing whether foods lack endorsement logos because they are not sufficiently healthy, or because the manufacturer has not opted to apply the label. CSPI raised this concern in comments on FDA’s proposal for a voluntary “healthy” logo.<sup>21,118</sup>

Furthermore, when front-of-package summary rating systems are voluntary, companies may selectively apply labels to products that will look more appealing with the label. In Australia, products displaying the voluntary health star rating label had a statistically significantly higher average score compared to products not displaying the label (3.4 stars versus 2.6 stars,  $p < 0.001$ ).<sup>115</sup> In France, 73 percent of products from national brands using the label had Nutri-Score ratings of A or B (as opposed to C, D, or E) compared with only 37 percent of products from retailer brands, which appeared to be using the label less selectively.<sup>116</sup> Given the critical goal of addressing overconsumption of sodium, added sugars, and saturated fat in the United States, FOPNL needs to appear on all foods, not only the healthiest foods.

- f. Other considerations

- i. *FDA must decide which foods will be required to bear FOPNL*

When countries develop FOPNL systems, they must determine which packaged food products will be required to bear labels. In Chile and Mexico, only foods and beverages that contain added sugars, added sodium, or added fat are eligible for FOPNL.<sup>119,120</sup> Similarly, the Pan American Health Organization has developed a nutrient profiling model used only to rate foods that meet definitions of “processed” or “ultra-processed.”<sup>119</sup> Conversely, the National Health Surveillance Agency in Brazil rates all foods, with some exempted categories, including fruits and vegetables, meats, baby foods, and a few others.<sup>119</sup> As FDA develops a FOPNL system for the United States, it should carefully consider which food categories to include or exclude. For example, if FDA



selects a traffic light system, the agency should consider including non-packaged products such as fresh fruits and vegetables and bulk grains in the Notice of Proposed Rulemaking and ensuring that these products will also be labeled (*e.g.*, through shelf tags or signage) to avoid the unintended effect of implying that packaged foods with green labels are healthier than non-packaged foods with no labels.<sup>121</sup> If FDA selects a traffic light system, the agency will also need to decide on cutoff points that will constitute high, medium, or low levels of nutrients. FDA should be sure to set the low cutoff points such that only foods with truly low levels of these nutrients will be eligible to bear green labels.

- ii. *FDA should ensure the selected FOPNL system will not have detrimental effects on people with or at risk of developing eating disorders*

In this petition, we request that FDA implement a FOPNL system that includes calories. However, some research suggests that labels emphasizing calorie content may have adverse effects for people with—or at risk of developing—eating disorders. Research on this topic has only examined the effects of calorie labels on restaurant menus as opposed to packaged foods. One study found no negative outcomes of calorie labels for participants with high risk for eating pathologies,<sup>122</sup> but two studies produced concerning findings. Haynos & Roberto (2017) found that when women were randomly assigned to view restaurant menus with calorie labels, hypothetical orders by participants with anorexia nervosa and bulimia nervosa had significantly fewer calories and hypothetical orders by participants with binge eating disorder had significantly more calories than when menus had no calories listed.<sup>123</sup> Larson et al (2018) found that self-reported use of calorie labels on restaurant menus to limit calorie intake was higher among participants using unhealthy weight control behaviors, such as taking diet pills or smoking more cigarettes, compared to participants using healthy weight control behaviors, like exercising and watching portion sizes.<sup>124</sup>

The context of FOPNL on packaged foods differs from calorie labeling on restaurant menus in that consumers already have access to calorie information in the Nutrition Facts label. Nevertheless, in designing a FOPNL system for Israel, the country’s Ministry of Health opted not to include calories “out of concern for the possibility of encouraging eating disorders.”<sup>125</sup> As FDA designs a FOPNL system for use in the United States, we recommend that the agency select a system with the greatest overall benefit while avoiding harm for vulnerable groups.

To conclude, there is a pressing need for novel interventions to improve diet quality of the U.S. population. FDA has the authority to implement mandatory, interpretive, nutrient-specific FOPNL. Evidence shows that such a system could improve diets and promote equitable access to nutrition information.

We ask that FDA act in the interest of public health and issue regulations establishing a simple, standard front-of-package labeling system that is mandatory, nutrient-specific, includes calories, and is interpretive with respect to the levels of added sugars, sodium, and saturated fat per serving, for all packaged foods sold in the United States. Although both nutrient warnings and

traffic light labels meet these criteria, we emphasize again that nutrient warnings appear to have superior efficacy at improving diets and are therefore more likely to improve population health.

### **C. Environmental Impact**

Under 21 C.F.R § 10.30(3), petitioners must provide an environmental impact assessment or claim a categorical exclusion from such requirement. The action requested herein is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 (h) and 25.30(k), and therefore does not require the preparation of an environmental assessment. Further, the undersigned believe that the actions requested in this petition would have no environmental impact.

### **D. Economic Impact**

Under 21 C.F.R § 10.30(3), upon request by the Commissioner following review of the petition, petitioners must submit “a statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.”

The Commissioner has not requested a statement of the economic impact of the requested action in this instance. However, the petitioners are providing a brief analysis because we believe that while this petition will result in some cost increases to industry, government, and consumers, one of the factors identified in 21 C.F.R § 10.30(3), the benefits will outweigh the costs.

Studies modeling the effects of previous food labeling and reformulation efforts have found that the benefits outweighed the costs. In 2018, FDA estimated that the 2016 changes to food and supplement labeling, including to the Nutrition Facts Label, would cost \$4.8 billion and produce \$33.1 billion in cost savings over 20 years.<sup>126</sup> Another study modeling the effects of the new “added sugars” line on the Nutrition Facts label estimated net health care cost savings of \$31 billion.<sup>127</sup> A third study predicted that implementing traffic light labels in Australia would cost \$AU81 million annually following initial implementation, and concluded that the policy would save more than it cost.<sup>128</sup> And a study evaluating the impact of Chile’s 2016 nutrient warning label policy found no effect on employment or wages.<sup>129</sup> These findings suggest that the cost savings produced by FOPNL would far outweigh the costs.

The fact that food manufacturers already know the amount of calories, added sugars, sodium, and saturated fat used in their products will mitigate costs. Companies have established methods for calculating and printing nutrition information for calories and the above nutrients on the Nutrition Facts label to comply with the existing labeling requirements. For many, if not all, manufacturers these methods include using nutrition analysis software, such as the ESHA food processor database.<sup>130</sup> Furthermore, major food producers frequently redesign their labels, sometimes every year.<sup>131</sup> Any additional costs associated with a new front-of-package labeling requirement are likely to be negligible for companies that regularly update their labels anyways,

and would therefore be unlikely to impact price, employment, or the other factors identified in the economic impact statement.

### **E. Certification**

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

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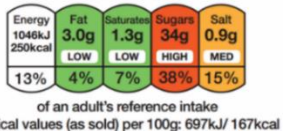
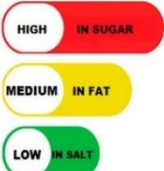


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## Appendix A. Examples of different front-of-package nutrition labeling systems

Example	Type	Country	Mandatory or Voluntary?	Interpretive or Non-Interpretive?	Appears on Healthiest, Less Healthy, or All Foods?	Summary or Nutrient-Specific?	Includes Calories?
	Endorsement Logo	Denmark, Iceland, Lithuania, Norway, Sweden	Voluntary	Interpretive	Healthiest	Summary	No Calories
	Nutri-Score	Portugal, Spain, Austria, France, Belgium, Germany, Luxembourg, Switzerland	Voluntary	Interpretive	All	Summary	No Calories
PER 1/2 CUP 	Facts Up Front	USA (industry-led, not government-endorsed)	Voluntary	Non-Interpretive	All	Nutrient-Specific	Calories
	Health Star Rating	Australia/ New Zealand	Voluntary	Interpretive	All	Both	Calories
Each serving (150g) contains 	Traffic Light	United Kingdom	Voluntary	Interpretive	All	Nutrient-Specific	Calories
	Traffic Light	Ecuador	Mandatory (but not required on the front of package)	Interpretive	All	Nutrient-Specific	No Calories
	Nutrient Warning	Chile	Mandatory	Interpretive	Less healthy	Nutrient-Specific	Calories
	Nutrient Warning	Israel	Mandatory	Interpretive	Less healthy	Nutrient-Specific	No Calories

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