

July 14, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Food Labeling: Front-of-Package Nutrition Information, A Proposed Rule by the Food and Drug Administration (Docket No. FDA-2024-N-2910)

We are academic researchers who study the effects of food labels on consumer knowledge and behavior, including how to design food labeling policies to best inform consumers about a food's nutrient profile and health risks. We appreciate the FDA's continued commitment to educating consumers about the nutritional content of their food by requiring front-of-package nutrition labels. **We strongly support the FDA's proposal to:**

1. Adopt a front-of-package nutrition labeling system.
2. Mandate front-of-package nutrition labels, rather than proposing a voluntary labeling system.
3. Interpret nutrition information for consumers, rather than providing solely numeric information.
4. Highlight high amounts of the most important nutrients to limit (added sugars, sodium, and saturated fat), rather than including nutrients to increase (e.g., dietary fiber).

We suggest several amendments to the proposed rule, which would help consumers more easily use and understand the labels. These include:

5. Adopt a High In labeling scheme, which would display labels only on products high in added sugars, sodium, or saturated fat.
6. Incorporate visual elements that make the labels easier to see and understand (e.g., the color red, an exclamation mark, a triangle shape, a contrasting background so the label stands out from the rest of the packaging).
7. Mandate front-of-package nutrition labels on all packaged food and drinks, including those marketed to infants and toddlers.
8. Mandate a non-sugar sweetener disclosure that would accompany the front-of-package labeling rule.
9. Require a multi-label scheme in which products carry a distinct label for each excess nutrient (e.g., a product high in added sugars and sodium would carry one "High In Added Sugars" label and one "High In Sodium" label).
10. Use a nutrient profile model like Canada's, which sets stricter thresholds for foods served in smaller portions. This ensures that snack foods, which are unlikely to exceed 20% DV thresholds due to their small size but are often high in sugar, sodium, and saturated fat *density*, receive the appropriate designation as "High In."

1. We support the FDA’s proposal to adopt a front-of-package nutrition labeling system.

Currently, U.S. consumers must rely on the Nutrition Facts label for information about the nutritional content of products. Although this label is an important tool that should remain on products, it is infrequently used and poorly understood. An FDA study with a nationally representative sample of 4,398 Americans found that only 20% reported consistently using the Nutrition Facts label when buying a food for the first time, and 1 in 8 said they *never* look at these labels.¹ Even when consumers look at the Nutrition Facts label, systematic reviews show they often have difficulty understanding its content.² Moreover, use and understanding of the Nutrition Facts label are lower among groups with lower income and educational attainment.²⁻⁴ Even among adults with a college degree, nearly half cannot correctly interpret one or more aspects of the label.⁴

In contrast to the low use of the Nutrition Facts label, many consumers use information presented on the front of food and beverage packaging.⁵⁻⁷ Eye tracking studies confirm the importance of front-of-package labels for drawing attention to nutrition information, finding that when products display both front-of-package labels and Nutrition Facts labels, consumers pay more attention to the front-of-package labels than the Nutrition Facts labels.^{8,9} Eye tracking studies have also found that when front-of-package food labels are added to products, consumers are more likely to notice nutrition information, find nutrition information more quickly, and pay attention to that information for longer, compared to when only the back-of-package Nutrition Facts label is present.¹⁰ In-person laboratory studies and real-world natural experiments confirm that adding front-of-package labels to products can improve food purchase behavior.¹¹⁻¹⁷ Thus, there is a clear need for a front-of-package nutrition label in addition to the Nutrition Facts label.

2. We support the FDA’s proposal to mandate front-of-package nutrition labels, rather than adopt a voluntary labeling system.

Research consistently demonstrates that mandatory food labeling systems are more effective than voluntary systems. Evidence from other countries, including Belgium, France, Germany, Australia, and New Zealand, shows that voluntary labels are applied to only a small portion of the food supply.¹⁸⁻²³ For example, only 28% of products displayed voluntary labels three years after New Zealand adopted the voluntary Health Star Rating (HSR) system.¹⁸ By contrast, Chile’s mandatory front-of-package labeling policy has resulted in almost perfect compliance, with 93% of products displaying the required labels.²⁴ Furthermore, voluntary labels are more frequently displayed on healthier products.^{18,20,21,25} This selective application can mislead consumers²⁶⁻²⁸ and undermine the goal of providing accurate, easily comparable nutritional information across products.^{29,30}

In addition to guiding consumers, mandatory front-of-package labels can also incentivize manufacturers to reformulate products to reduce the amount of nutrients of public health concern.³¹ Voluntary labeling systems, however, have been found to spur only very small changes to the food supply.^{29,30,32-34} For example, within a few years of the voluntary implementation of the Health Star Rating system, the sodium content of labeled products declined by only 1.4% in Australia and 4% in New Zealand.³⁵ By contrast, within a few years of

Chile's mandatory implementation of nutrient warning labels, the number of products classified as 'high in sodium' dropped by 63% and those classified as 'high in sugar' dropped by 25%.³⁶

Front-of-package nutrition labels can also facilitate other policies to improve dietary behaviors, but only if the labels are mandatory. For example, Chile's Law of Food Labeling and Marketing required front-of-package warning labels on products high in calories and other nutrients of concern. Products with warning labels cannot be promoted to children under 14 and cannot be served in schools.³⁷ This mandatory labeling system made it easy for schools to identify prohibited products.³⁸ This unified suite of policies also reinforced the message that consumption of labeled products should be limited.³⁹

3. We support the FDA's proposal to interpret nutrition information for consumers, rather than providing solely numeric information.

The current back-of-package Nutrition Facts label and voluntary front-of-package Facts Up Front labeling system display only numeric information about a product's nutritional profile. By contrast, interpretive labeling systems use words, colors, symbols, and/or icons to communicate nutrition information to consumers simply and quickly. The National Academy of Medicine recommended an interpretive labeling system over a decade ago,⁴⁰ and considerable research supports using interpretative labels over numeric labels.⁴¹⁻⁴⁴ Studies from several countries demonstrate that interpretative labels perform better than numeric labels at improving consumers' understanding of products' healthfulness.⁴⁵⁻⁵³ Studies that examine consumers' purchase behaviors also find that interpretative labels improve the overall healthfulness of people's choices compared to numeric labels.^{45,46,51,54-58} Many studies show that consumers prefer interpretive labeling systems to numeric ones.^{56,59-61}

4. We support the FDA's proposal to highlight high amounts of the most important nutrients to limit (added sugars, sodium, and saturated fat), rather than including nutrients to increase (e.g., dietary fiber), on the front-of-package label.

Highlighting high amounts of added sugars, sodium, and saturated fat on the front of food packages is consistent with the 2020-2025 Dietary Guidelines for Americans (DGAs) recommendations.⁶² To support healthy dietary patterns, the DGAs recommend limiting saturated fat to less than 10% of calories, limiting added sugars to less than 10% of calories, and limiting sodium to less than 2,300 mg/day (and even lower in some population subgroups). Most Americans exceed the recommended intake limits for these nutrients, significantly contributing to chronic diseases, including heart disease, stroke, and type 2 diabetes. Ten other countries currently require front-of-package labels highlighting high amounts of sodium, saturated fat, and added sugars,⁶³ and such policies have been associated with healthier food purchases.^{14,17}

Of note, the FDA's proposed labels do not include information about nutrients to encourage (e.g., dietary fiber, vitamin D, calcium, iron, and potassium), finding that their focus group participants were confused by labels including both nutrients to encourage and those to avoid.⁶⁴ This is consistent with studies of the voluntary Facts Up Front-style labels, which include both nutrients to encourage and avoid, and show no impact on consumer food choices.^{56,65-67} Food companies already highlight nutrients to encourage on the front of food packages (e.g., "Good source of

Vitamin D”), and will likely continue to do so voluntarily. Additionally, the FDA’s “healthy” nutrient content claim will already allow companies to alert consumers to healthier products. Therefore, we support the FDA’s proposal not to allow nutrients to encourage in the Nutrition Info box.

5. The FDA should adopt a High In labeling scheme, which would display labels only on products high in added sugars, sodium, or saturated fat.

The Nutrition Info box was selected as the preferred label design based on the FDA’s experimental study results.⁶⁸ In that study, 9,200 U.S. adults were randomized to view one of eight front-of-package labeling schemes in an online survey, complete two sequential tasks, and answer questions about the labels they viewed. In the first task, participants viewed three nutrient profiles of a single labeling scheme and selected the most and least healthy profile. In the second task, participants viewed labels on the front of a food package and answered questions about the product’s healthfulness and nutrient content. Although the Nutrition Info box performed better than the High In labels on measures of perceived nutrient content and overall nutritional profile, the experimental design did not capture how people interact with food labels in the real world.

When asked to closely examine labels in a controlled setting, it is intuitive that labels with more interpretive information (like the Nutrition Info box) will be more helpful to consumers than labels with less information (like the High In labels). In the real world, however, consumers are flooded with distracting information on store shelves and product packaging, often relying on simple visual cues to quickly judge a product’s healthfulness.⁶⁹ While the FDA’s study participants spent about 30 seconds responding to questions in the agency’s survey, consumers shopping in a grocery store can make product decisions in as little as a third of a second.⁷⁰ Similarly, while the FDA study directed consumers to look at only a few food packages at a time, consumers in a real grocery store are confronted with dozens of packages at once for a given food selection. Studies that evaluate front-of-package labeling systems in the real world, and in contexts that better reflect a real shopping experience (e.g., an online store) provide evidence that High In labels are associated with healthier food choices.^{14,17,71-86} By contrast, real-world evidence for the effectiveness of the Nutrition Info box or similar multiple traffic light labels is extremely limited.

High In labels are preferable to the Nutrition Info box because they communicate a simple message – products carrying a label are less nutritious than those without a label. Research from Chile, which mandates High-In-style labels on packaged products, supports this assertion.³⁹ One study found that parents relied on the labels as a “quick shortcut” for identifying healthier products. In that study, even young children could interpret High-In-style labels, telling their parents not to buy them snacks with labels because they weren’t allowed in school. High In labels clearly delineate less healthful foods from more healthful ones when applied to the U.S. food supply. A recent study found that approximately 49% of products purchased at a supermarket chain would be required to carry a High In label under the FDA’s scheme.⁸⁷

In contrast to High In labels, consumers cannot rely on the presence or absence of a Nutrition Info box to make a quick decision about a product because all products would carry a label. Instead, they must read the label, interpret the information, and weigh the relative importance of

each nutrient. In fact, recent experiments comparing the Nutrition Info box to High In schemes found that the Nutrition Info box yielded slower evaluations of products' nutrient profiles and nutrient contents.^{88,89} This process of interpretation is particularly burdensome if labels send mixed signals – how does a consumer assess the nutritional profile of a product that is high in sodium, but low in added sugar? It has been estimated that approximately 40% of U.S. packaged foods would carry severely mixed labels – labels in which at least one nutrient is “low” and another is “high”.⁸⁷ The FDA's experiment did not test consumer responses to severely mixed labels, despite prior experimental research consistently showing that severely mixed labels confuse consumers.^{26,80,83} Furthermore, the Nutrition Info box may mislead consumers into thinking that harmful products, such as sugar-sweetened beverages, are healthy because their labels display only one “high” nutrient (added sugar) with two “low” nutrients (sodium and saturated fat).⁸⁹ For these reasons, we strongly recommend that the FDA adopt a High In labeling scheme over the Nutrition Info box.

6. The FDA should amend the proposed rule to incorporate visual elements into the label design.

The FDA's experimental study found that including a magnifying glass icon did not meaningfully affect U.S. consumers' attention to or use of the Nutrition Info box.⁶⁸ However, the FDA's study was conducted in a highly controlled online setting where consumers were asked to view and spend time interpreting each nutrition label. In the real world, food companies go to great lengths to reduce the salience of nutrition labels so consumers will not notice them, for example, by adding health claims, nutrient-content claims, or other front-of-package marketing.^{90,91} Therefore, eye-catching visual cues, including borders or a black and white color scheme that stands out from the rest of the packaging, are critical for ensuring the FDA's labels are seen by consumers.

The FDA's finding conflicts with a large body of scientific literature showing that visual elements, including icons and symbols, improve the effectiveness of front-of-package labels and are more easily understood by populations with lower literacy.^{75,92-94} Experimental studies across many countries also show that shapes and colors associated with danger, such as octagons, triangles, black, white, red, and yellow, outperform more neutral shapes and colors.^{82, 96, 98-101} Additionally, a recent eye-tracking study with US adults found that front-of-package nutrient warnings with images attracted more attention than control labels.¹⁰² To improve consumer attention to and understanding of nutrition information, the FDA should incorporate visual elements into its label design. This could be achieved by including a prominent exclamation mark icon on High In labels, next to “high” nutrients in the Nutrition Info box, or by highlighting “high” nutrients using a red background with white text. A recent experiment found that modifying the Nutrition Info box to highlight “high” in red and removing %DV increased accurate assessments of product nutrient profiles and nutrient contents and perceptions that the label was easy to understand and use. However, both the modified and unmodified Nutrition Info boxes resulted in higher perceived healthfulness of unhealthy products with mixed nutrient profiles (e.g., beef jerky, candy, and soda) relative to High In labels.⁸⁸

7. The FDA should amend the proposed rule to require front-of-package nutrition labels on all packaged foods and drinks, including those marketed to infants and toddlers.

Commercially prepared baby food and follow-up formula are among the first foods with added sugar that are introduced to young children. Evidence from several countries shows that many commercially prepared baby foods and follow-up formulas are high in added sugars and sodium.¹⁰³⁻¹⁰⁶ For example, a 2015 study of the U.S. food supply found that most commercial toddler meals, cereal bars, breakfast pastries, and infant-toddler snacks and desserts had high sodium content or contained added sugars.¹⁰³ Furthermore, health claims are common on follow-up formula packages, and studies suggest that such claims can mislead parents and increase product appeal.¹⁰⁷⁻¹¹¹ Front-of-package labels could help parents identify products high in nutrients of concern and correct misperceptions caused by misleading health claims.

The FDA cited inconsistency between the Daily Reference Values (DRVs) for children aged 1-3 years and the 2020-2025 Dietary Guidelines for Americans as the rationale for including only foods intended for consumption by people four years of age and older. The DRVs should be updated, and the FDA should require front-of-package nutrition labels on products marketed for children under 4 based on the DRVs and resultant percent Daily Values (DVs) that are required on the Nutrition Facts labels of such foods. The FDA should apply the same % DV cutoffs for determining when a food is high in (or high, medium, and low in) added sugars, sodium, and saturated fat as apply for foods marketed for individuals 4 years and older. If the FDA is unable to quickly update the DRVs and DVs for children, the Agency could later expand the rule to include products marketed for this population.

8. The FDA should mandate a non-sugar sweetener disclosure to accompany the front-of-package labeling rule.

Under a mandatory front-of-package labeling scheme, food companies may replace added sugars with non-sugar sweeteners to maintain sweetness and avoid carrying a “High In Added Sugars” label. Following the implementation of Chile’s front-of-package labeling law, the proportion of sweet foods and beverages containing non-sugar sweeteners significantly increased.¹¹² These changes in the Chilean food supply translated to dietary behaviors, with significant increases in purchases and consumption of non-sugar sweeteners, including among children.¹¹³

The increasing use of non-sugar sweeteners in the food supply is a significant public health concern, as these substances are not recommended for children. The long-term health effects of consuming large amounts of these substances are still unknown. Additionally, early exposure to non-sugar sweeteners increases sweet taste preferences and may influence future dietary patterns.^{62, 114-118} Research has shown that many U.S. parents try to avoid purchasing products containing non-sugar sweeteners for their children, but are confused by product labels.¹¹⁹⁻¹²¹ To educate consumers and prevent excess intake of non-sugar sweeteners among children, the FDA should mandate clear disclosures on products containing non-sugar sweeteners stating that they are not recommended for children, consistent with mandatory labeling regulations in Mexico and Argentina.⁶³ In experimental studies, such disclosures have increased parents’ understanding of product ingredients, decreased perceived healthfulness, and lowered intent to purchase sweetened fruit drinks.¹²²

9. The FDA should amend the proposed rule to require that products carry a distinct label for each excess nutrient.

Evidence from countries with mandatory front-of-package labeling policies shows that food companies increase front-of-package marketing to make nutrition labels less visible to consumers.^{90,91} The FDA could make its labels more salient by requiring that products carry a distinct label for each excess nutrient (e.g., a product high in added sugars and sodium would carry one “High In Added Sugars” label and one “High In Sodium” label).⁸⁸ In a recent study, 3,931 US adults were randomized to view one of five front-of-package labeling systems: FDA’s High In label, three kinds of High In labels with icons, and a High In labeling system in which each excess nutrient carried a distinct label, also with icons (“multiple”). Compared to all other conditions, participants viewing the multiple labels were better able to identify high-sodium and high-saturated-fat items (78% vs. 68-72% and 85% vs. 76-80%, respectively, all $p < .05$). Another recent study of 13,929 US adults compared a multiple label High In scheme (Multiple High In) to the FDA’s High In scheme, the Nutrition Info box, a modified Nutrition Info box (no %DV and “High” highlighted red), and a no-label control.⁸⁹ The Multiple High In significantly outperformed the Nutrition Info box, helping participants correctly identify the least healthy nutrient profiles and correctly assess product nutrient content as high. The Multiple High In labels also helped people make the quickest product evaluations, while the Nutrition Info box produced the slowest evaluations. Multiple High In was more effective than the other labels and the control in reducing selection of a high-in product in a hypothetical shopping task, helping consumers recall label content, and encouraging label use (all $p < 0.001$).

Requiring a label for each excess nutrient would also send a clear message to consumers – products with more labels have worse nutrient profiles than products with fewer labels. Research from Chile, which mandates one High-In-style label for each excess nutrient, supports this point.³⁹ One study found that parents used the Chilean labels to set limits for their children on what could be purchased, telling them to “look for the cookies that have the fewest labels”. Similarly, teachers used the multiple-label format to promote healthier foods in schools, telling parents not to “bring food with more than two labels” into the classroom. By requiring one label for each excess nutrient, the FDA could make its labels more visible while making it easier for both consumers and institutions to set simple food rules.

10. The FDA should use a nutrient profile model for “High In” that ensures that all products high in sugar, sodium, and saturated fat are indicated as such, regardless of portion size.

Nutrient profile models (NPMs) are definitions comprised of nutrients and nutrient thresholds that determine which product receives what label. Best practices¹²³ for developing NPMs for front-of-package labeling systems suggest that NPMs should 1) align with health goals; 2) consistently identify “High In” foods across food categories and portion size; and 3) be based on scientific evidence, including analyses of the current food supply. NPMs that are too lax run the risk of not adequately identifying all foods and beverages high in nutrients of concern, while NPMs that are too stringent may limit a labeling system’s utility to guide consumers to healthier choices (since most or all products may carry a label).

The FDA has proposed using a 20% daily value (DV) model based on precedent established in the 1993 Nutrition Labeling and Education Act of using 20% DV to declare a product “High In” any nutrient (including nutrients of benefit). To our knowledge, the FDA has not studied the coverage of this NPM on the current US food supply nor compared its performance against other NPMs, a critical step towards ensuring a labeling system meets health goals. In fact, a recent paper found that compared to other international NPMs, including those of Canada, Chile (the first country to have a mandatory High In nutrient labeling system), and the Pan American Health Organization, the proposed FDA model would require the fewest products to carry a High In label.¹²⁴ This issue was particularly pronounced in categories that tend to be served in small portions (e.g., salty snacks, bars).

To address this issue, we recommend using an NPM similar to the one used by Canada for their High In nutrient labeling system. Canada’s model sets thresholds for High In labels that are dependent on “reference amount” or serving size. While the official method of calculation for the Canadian NPM involves adjusting nutrients to align serving sizes with reference amounts for each product category, roughly, this corresponds to: $\geq 10\%DV$ for products with reference amount 30 g or 30 mL or smaller, $\geq 15\%DV$ for products with reference amount over 30 g or 30 mL, and $\geq 30\%DV$ for main dishes. This approach would maintain comparability with the previously proposed approach of 20% while more accurately designating products served in smaller portions with high amounts of added sugar, sodium, and saturated fat as “High In”.

In conclusion, and as highlighted in this comment, we strongly support the FDA’s proposal for the US to adopt a mandatory, interpretive front-of-package nutrition labeling system that solely highlights key nutrients to limit, but we urge FDA to improve this rule in several ways to ensure it will maximally improve health for the entire US population. We urge federal agencies to act quickly on these recommendations to enable consumers to access the information they need to make healthy choices for themselves and their families.

Sincerely,

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Note: The views expressed in this comment letter are those of its authors only. This letter is not submitted on behalf of The University of North Carolina at Chapel Hill, University of Pennsylvania, University of California, University of Connecticut, or University of Washington.

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