

July 17, 2023
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Comment on the FDA's Notice Regarding Quantitative Research on Front of Package Labeling
on Packaged Foods
(Docket No. FDA-2023-N-0155)**

We strongly support the FDA's pursuit of research to help select an interpretive front-of-package (FOP) labeling scheme that helps Americans make informed, healthy food choices. Peer-reviewed research demonstrates that interpretative FOP labels inform consumers. Thus, we believe it is critical that FDA conduct its research expeditiously so that consumers can reap the benefits of interpretive FOP labels without delay. We applaud the FDA for its efforts to investigate how best to design FOP labels to maximize their benefits to consumers.

The average American adult consumes 50% more sodium, 40% more added sugar, and 40% more saturated fat than daily recommendations,¹ contributing to high rates of hypertension, type 2 diabetes, and heart disease.² Reducing consumption of foods that are high in sodium, added sugar, and saturated fat could assist consumers in achieving healthier eating patterns and optimal health. However, many consumers—especially those with lower levels of education or limited English language proficiency—are not able to identify such foods using only the Nutrition Facts label,³ highlighting the need for interpretive FOP labeling to inform consumers.

The FDA has proposed conducting quantitative research on interpretative FOP labels. Their proposed study design has several strengths, including:

- The study has a large sample of 9,000 participants, sampled to mirror the US population with respect to gender, education, age, and race/ethnicity.
- The proposed label designs highlight nutrients to limit (i.e., sodium, saturated fat, and added sugar), which are linked to health harms and are overconsumed by a majority of people in the US. Importantly, the labels would highlight processed packaged foods that are high in saturated fat; this is important because the main type of saturated fat in packaged processed foods is palm oil,⁴⁻⁶ which is one of the least healthy edible oils.⁷
- The proposed label designs employ consistent definitions of “high,” “medium,” and “low” levels of nutrients, based on FDA's established criteria for interpreting the percent Daily Value (DV) of a nutrient (i.e., less than 5% DV is low, more than 20% DV is high, and everything in between is medium).
- The proposed study is a randomized experiment, allowing for causal inferences about the impact of the FOP labels on consumer understanding and product perceptions. Additionally, the agency has also incorporated qualitative research methods to inform the design of the FOP labels.
- The survey instrument collects important demographic data such as nutrition knowledge, shopping habits, self-rated health, caregiver status, and nutrition literacy.

- The FDA has conducted initial cognitive interviews to examine whether participants interpret the survey questions as intended.

We hope that FDA retains each of these strengths as they finalize the study.

We have seven recommendations for how FDA can improve the study's design and maximize the potential for interpretative FOP labels to improve consumer understanding in the US.

Recommendation 1: Evaluate additional versions of the FOP labels with icons. Examples of icons that could be included in FOP labels are depicted in **Figure 1**. Currently, only one of the proposed label stimuli uses an icon (the label with the magnifying glass), despite evidence showing that including icons and other visual elements in labels makes the labels much more effective at changing a range of desirable outcomes, including consumer understanding of product healthfulness.⁸⁻¹³ Moreover, research shows that including icons in FOP labels could be especially important for populations with limited English proficiency and with lower literacy. For example, our experimental study (n=1078, 48% Latino ethnicity, 13% limited English proficiency), which was not cited in FDA's literature review, evaluated icon-plus-text FOP food labels compared to text-only labels. We found that the icon-plus-text labels out-performed text-only labels overall.¹⁰ English proficiency moderated this effect such that the benefit of icons was larger for those with limited English proficiency compared to those with high English proficiency. These findings suggest that



Figure 1. Examples of icons that could help draw attention to front-of-package food labels

icons could make labels more effective overall and especially among people with limited English proficiency.¹⁰ It is worth noting that, based on 2020 US Census data, 25.5 million people (8.2% of

the population) in the US have limited English proficiency.¹⁴ Labels without icons or other interpretive elements could be leaving these 25.5 million people behind. Research outside of food labeling also finds that adding icons to text-based labels improves labels' ability to reach a range of consumers, including those with lower literacy. One experimental study of prescription drug labels, for example, found that participants with marginal or low literacy were better able to correctly interpret drug warning labels with icons and text compared to labels with text alone.¹² Additionally, lower literacy predicted greater misinterpretation of drug labels in this study. Thus, including icons in labels could be an important step for increasing comprehension of labels among populations with lower literacy,¹² and FDA should test additional variations of icons to determine which are most effective. FDA should also consider using contrasting colors – for the labels themselves and for the icons – as another way of heightening attention to labels, and thus increasing their ability to inform consumers about product healthfulness. Research demonstrates that black, yellow, and red are promising colors for drawing attention to FOP labels.¹⁵⁻¹⁸

Recommendation 2: Test single-nutrient, octagon-shaped labels, which evidence indicates are likely to help consumers identify products high in nutrients of concern quickly and accurately (Figure 2). As shown in Figure 2, this proposed design is similar to the octagon-shaped labels that

are now required in Chile, Mexico, Peru, Argentina, and Uruguay.¹⁹ This labeling scheme differs from the schemes FDA has proposed to test in two ways: 1) it uses an octagon shape to draw attention and quickly communicate the label's message and 2) it uses single, separated nutrient labels instead of listing multiple nutrients in one label. Our assessment of the research literature is that this label design has the strongest evidence base supporting its ability to further FDA's goals of creating a healthier food supply, establishing a healthy start, and empowering consumers.²⁰⁻²³

There are two key benefits of single-nutrient, octagon-shaped labels that identify products high in nutrients of concern. First, research shows that octagon-shaped labels are more likely to meet the FDA's goals than labels that use other shapes. For example, our experimental research manipulating shape (octagon vs. square) found that octagon-shaped labels are perceived as more effective by consumers than square-shaped labels, and also increase how much consumers consider healthfulness when they are deciding what to purchase.¹⁶ Similarly, numerous experimental studies have found that octagon-shaped labels consistently outperform other label designs,^{17,24-27} including labels with magnifying glass icons similar to those adopted in Canada and Brazil and proposed for testing by FDA.^{17,26}

The second benefit of single-nutrient, octagon-shaped labels is that they could facilitate better understanding of product healthfulness than multi-nutrient labels. Single-nutrient FOP labels take up more space on the front of product packaging for products that contain excessive amounts of several



Figure 2. Examples of single-nutrient octagon-shaped labels

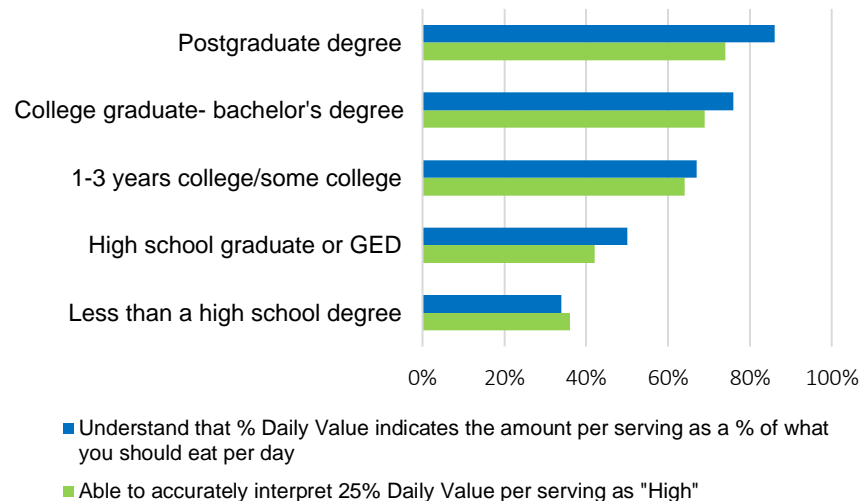
nutrients compared to products that contain excessive amounts of just one nutrient. By contrast, multi-nutrient labels take up about the same amount of space on the front of product packaging regardless of how many nutrients the product is high in. The single-nutrient labeling scheme could therefore better help consumers quickly and accurately identify when a product is high in several nutrients compared to just one or none.

For these reasons, we recommend that FDA test single-nutrient, octagon-shaped FOP labels.

Recommendation 3: Remove the conditions that include information about the percent of the daily value (% DV). Four of FDA's eight proposed label schemes provide information about the % DV of nutrients, and three of the four % DV labels do not contain icons or any other visual elements (such as color coding) to help communicate product healthfulness. These label schemes are unlikely to be effective at promoting FDA's goals because consumers (especially those with lower education levels) generally struggle to understand numerical information.^{28,29} For example, FDA's Food Safety and Nutrition Survey (FSANS),³ fielded in 2019, asked 4,398 respondents if they would consider one serving of a food with 25% DV of sodium to have a low, medium, or high amount of sodium (for reference, FDA defines "high" as 20% DV or more per serving). Only 36% of people with less than a high school degree and 42% of high school graduates with no college education were aware that this food is high in sodium, compared with 69% of college graduates and 74% of people with postgraduate degrees (**Figure 3**). These findings track closely with the results of another question in the survey assessing whether respondents could accurately interpret what it means if a product's

Nutrition Facts label shows that the product contains 7% DV for Total Fat per serving. Based on these findings, we are concerned that labels focused on the % DV could widen existing disparities in comprehension of nutritional information and recommend removing these conditions. Removing these conditions would also allow for testing of new FOP label options that have a stronger evidence base than the labels with % DV information, such as the single-nutrient, octagon-shaped labels described above.

Figure 3. Comprehension of % Daily Value, by Educational Attainment (FSANS 2019)



Recommendation 4: In the single product evaluation task in Part 2, eliminate the condition varying the placement of the FOP label. FDA proposes that one tenth of participants will be randomized to view the “Nutrition Info” label in black and white placed in the *lower right* part of the food package. The remainder of participants will see their randomly assigned FOP labels placed in the *upper right* of the food package. We encourage FDA to remove the condition varying placement because it is arbitrarily applied to only one of the FOP schemes the FDA plans to test. We also note that research suggests that nutrition information better captures consumers’ attention when it is placed in the upper right part of a food package,^{30,31} and that other countries including Canada and Peru require their FOP labels to be placed on the upper right part of the food package.^{32,33}

Recommendation 5: Use the same nutritional profiles for the “healthiest,” “middle,” and “least healthy” labels across all FOP schemes tested in the within-scheme comparison task in Part 1 of the study. Per Appendix F, it appears that the nutritional profile of the “healthiest,” “middle,” and “least healthy” labels will vary across some of the FOP schemes tested in the within-scheme comparison task. For example, in the “Nutrition Information with % Daily Value Information and Color” condition, the “middle” label shows that the product is low in saturated fat, medium in sodium, and medium in added sugar. By contrast, in the “High In” condition, the “middle” label shows that the product is high in saturated fat (vs. low) and high in sodium (vs. medium). This means that label design is confounded with the nutritional profile underlying these labels, and any differences between these conditions could be due to either differences in the label design or differences in the nutritional profile underlying these labels. Similar problems exist across other

labeling schemes. The FDA should use the same nutritional profiles across labeling schemes to avoid this harmful confounding.

Recommendation 6: Make the study’s primary outcome participants’ ability to identify when a product is high in a given nutrient. FDA states that the within-scheme comparison task will have three primary outcomes: 1) participants’ ability to identify the healthiest and least healthy products, 2) the speed at which participants make their decisions, and 3) whether or not participants search for more information to answer the question (i.e., whether they click a link to view the Nutrition Facts label). Only the first of these outcomes is directly tied to the agency’s goals of improving consumer understanding of product healthfulness. However, this outcome is still problematic because the concept of healthfulness is subjective, meaning participants could interpret this question in different ways, complicating the agency’s interpretation of results. For example, if a given FOP labeling scheme reduces the likelihood that participants select the “middle” option as the healthiest, but that same scheme fails to also increase the likelihood of selecting the “most healthy” option as the healthiest, will the FDA view this labeling scheme as effective or ineffective? The other two outcomes are likewise not inherently desirable, and therefore should be removed or treated as secondary outcomes. For example, whether we believe it is desirable for labels to increase the speed at which participants make their decisions about product healthfulness depends on whether those decisions are correct. Likewise, increasing the likelihood that participants search for the Nutrition Facts label could be desirable (if the labeling scheme spurs consumers to learn more about the product’s nutrition information and ingredients) or undesirable (if the labeling scheme is not noticeable or confusing and thus participants *need* to seek more information).

In place of the current set of primary outcomes for the within-scheme comparison task, **we strongly suggest focusing on one primary outcome that is directly tied to FDA’s goals and that is likely to change in response to the labels: a measure such as “Does this product contain high amounts of [nutrient]?”** This measure has an objectively correct answer. Moreover, this measure links to FDA’s goals of helping consumers assess healthfulness, because as previously stated, most Americans overconsume sodium, added sugar, and saturated fat and overconsumption of these nutrients is associated with increased risk of non-communicable diseases.

Similarly, we also recommend replacing the healthfulness perceptions questions in the single-product evaluation in Part 2 with questions that objectively measure consumer understanding. The question, “In your opinion, how healthy is this food product?” is not an inherently meaningful outcome. For example, if a given labeling scheme has no effect on healthfulness perceptions for a given product, will the FDA view this labeling scheme as effective or ineffective? Perhaps participants already accurately understood this products’ healthfulness, so their perceptions did not need to change, and a null effect is desirable. We suggest replacing these questions with questions for which there is an objectively correct answer (e.g., a measure such as, “Does this product contain high amounts of [nutrient]?”)

Recommendation 7: Participants should complete the between-subjects experiment before the within-subjects experiment. As proposed, it appears that participants will perform a within-subjects experiment (the within-scheme comparison task) prior to a between-subjects experiment (the single-product evaluation task). It is possible that exposure to the FOP labels in the within-subjects

experiment could interact with the experimental conditions in the between-subjects experiment, complicating interpretation of the between-subjects experiment. To avoid this possibility, we would suggest reversing the order and having participants complete the between-subjects experiment prior to the within-subjects experiment.

Thank you for considering these recommendations and for your commitment to developing an evidence-based, interpretative FOP labeling system for packaged foods in the US.

Sincerely,

Anna H. Grummon, PhD, MSPH
Assistant Professor
Department of Pediatrics and (by courtesy) Health Policy
Stanford University School of Medicine

Amanda B. Zeitlin, MPH
Project Coordinator
Department of Pediatrics
Stanford University School of Medicine

References

1. United States Department of Agriculture Agricultural Research Service. Food Patterns Equivalent Intakes from Food: Consumed per Individual, All Tables. Published 2021. Accessed July 15, 2023. <https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/fped-data-tables/>
2. Tsao CW, Aday AW, Almarzooq ZI, et al. Heart Disease and Stroke Statistics—2023 Update: A Report From the American Heart Association. *Circulation*. 2023;147(8):e93-e621. doi:10.1161/CIR.0000000000001123
3. United States Food and Drug Administration. FDA's Food Safety and Nutrition Survey (FSANS): Explorer. Accessed July 15, 2023. <https://fsans-explorer.fda.gov/>
4. Okawachi T, Sagi N, Mori H. Confectionery fats from palm oil. *J Am Oil Chem Soc*. 1985;62(2):421-425. doi:10.1007/BF02541415
5. Mba OI, Dumont MJ, Ngadi M. Palm oil: Processing, characterization and utilization in the food industry – A review. *Food Bioscience*. 2015;10:26-41. doi:10.1016/j.fbio.2015.01.003
6. Voora V, Larrea C, Bermúdez S, Baliño S. *Global Market Report: Palm Oil*. International Institute for Sustainable Development; 2020. Accessed July 15, 2023. <https://www.iisd.org/publications/report/global-market-report-palm-oil>
7. Kadandale S, Marten R, Smith R. The palm oil industry and noncommunicable diseases. *Bull World Health Organ*. 2019;97(2):118-128. doi:10.2471/BLT.18.220434
8. Brewer NT, Hall MG, Noar SM, et al. Effect of Pictorial Cigarette Pack Warnings on Changes in Smoking Behavior. *JAMA Intern Med*. 2016;176(7):905-912. doi:10.1001/jamainternmed.2016.2621
9. Noar SM, Hall MG, Francis DB, Ribisl KM, Pepper JK, Brewer NT. Pictorial cigarette pack warnings: a meta-analysis of experimental studies. *Tobacco Control*. 2016;25(3):341-354. doi:10.1136/tobaccocontrol-2014-051978
10. Hall MG, Lazard AJ, Grummon AH, et al. Designing warnings for sugary drinks: A randomized experiment with Latino parents and non-Latino parents. *Prev Med*. 2021;148:106562. doi:10.1016/j.ypmed.2021.106562
11. Grummon AH, Ruggles PR, Greenfield TK, Hall MG. Designing Effective Alcohol Warnings: Consumer Reactions to Icons and Health Topics. *American Journal of Preventive Medicine*. 2023;64(2):157-166. doi:10.1016/j.amepre.2022.09.006
12. Wolf MS, Davis TC, Bass PF, et al. Improving Prescription Drug Warnings to Promote Patient Comprehension. *Arch Intern Med*. 2010;170(1):10.1001/archinternmed.2009.454. doi:10.1001/archinternmed.2009.454
13. Acton RB, Jones AC, Kirkpatrick SI, Roberto CA, Hammond D. Taxes and front-of-package labels improve the healthiness of beverage and snack purchases: a randomized experimental marketplace. *Int J Behav Nutr Phys Act*. 2019;16:46. doi:10.1186/s12966-019-0799-0

14. United States Census Bureau. American Community Survey (ACS) 5-Year Data (2009-2021). American Community Survey. Published July 1, 2023. Accessed September 6, 2021. <https://www.census.gov/data/developers/data-sets/acs-5year.html>
15. Acton RB, Vanderlee L, Roberto CA, Hammond D. Consumer perceptions of specific design characteristics for front-of-package nutrition labels. *Health Educ Res.* 2018;33(2):167-174. doi:10.1093/her/cyy006
16. Grummon AH, Hall MG, Taillie LS, Brewer NT. How should sugar-sweetened beverage health warnings be designed? A randomized experiment. *Prev Med.* 2019;121:158-166. doi:10.1016/j.ypmed.2019.02.010
17. Goodman S, Vanderlee L, Acton R, Mahamad S, Hammond D. The Impact of Front-of-Package Label Design on Consumer Understanding of Nutrient Amounts. *Nutrients.* 2018;10(11):1624. doi:10.3390/nu10111624
18. Cabrera M, Machín L, Arrúa A, et al. Nutrition warnings as front-of-pack labels: influence of design features on healthfulness perception and attentional capture. *Public Health Nutr.* 2017;20(18):3360-3371. doi:10.1017/S136898001700249X
19. Global Food Research Program. Countries with mandatory or voluntary interpretative labels on packaged foods and drinks. Published August 2022. Accessed June 12, 2022. https://docs.google.com/viewer?url=https%3A%2F%2Fwww.globalfoodresearchprogram.org%2Fwp-content%2Fuploads%2F2022%2F08%2FFOP_Regs_maps_2022_08.pdf
20. Taillie LS, Reyes M, Colchero MA, Popkin B, Corvalán C. An evaluation of Chile's Law of Food Labeling and Advertising on sugar-sweetened beverage purchases from 2015 to 2017: A before-and-after study. *PLOS Med.* 2020;17(2):e1003015. doi:10.1371/journal.pmed.1003015
21. Taillie LS, Bercholz M, Popkin B, Reyes M, Colchero MA, Corvalán C. Changes in food purchases after the Chilean policies on food labelling, marketing, and sales in schools: A before and after study. *Lancet Planet Health.* 2021;5(8):e526-e533. doi:10.1016/S2542-5196(21)00172-8
22. Reyes M, Taillie LS, Popkin B, Kanter R, Vandevijvere S, Corvalán C. Changes in the amount of nutrient of packaged foods and beverages after the initial implementation of the Chilean Law of Food Labelling and Advertising: A nonexperimental prospective study. *PLOS Med.* 2020;17(7):e1003220. doi:10.1371/journal.pmed.1003220
23. Fretes G, Corvalán C, Reyes M, et al. Changes in children's and adolescents' dietary intake after the implementation of Chile's law of food labeling, advertising and sales in schools: a longitudinal study. *Int J Behav Nutr Phys Act.* 2023;20(1):40. doi:10.1186/s12966-023-01445-x
24. Jáuregui A, Vargas-Meza J, Nieto C, et al. Impact of front-of-pack nutrition labels on consumer purchasing intentions: a randomized experiment in low- and middle-income Mexican adults. *BMC Public Health.* 2020;20(1):463. doi:10.1186/s12889-020-08549-0
25. Jáuregui A, White CM, Vanderlee L, et al. Impact of front-of-pack labels on the perceived healthfulness of a sweetened fruit drink: a randomised experiment in five countries. *Public Health Nutr.* 2022;25(4):1094-1104. doi:10.1017/S1368980021004535

26. White-Barrow V, Gomes FS, Eyre S, et al. Effects of front-of-package nutrition labelling systems on understanding and purchase intention in Jamaica: results from a multiarm randomised controlled trial. *BMJ Open*. 2023;13(4):e065620. doi:10.1136/bmjopen-2022-065620
27. Mora-Plazas M, Aida Higgins IC, Gomez LF, et al. Impact of nutrient warning labels on choice of ultra-processed food and drinks high in sugar, sodium, and saturated fat in Colombia: A randomized controlled trial. *PLoS One*. 2022;17(2):e0263324. doi:10.1371/journal.pone.0263324
28. Bhawra J, Kirkpatrick SI, Hall MG, Vanderlee L, Thrasher JF, Hammond D. Correlates of Self-Reported and Functional Understanding of Nutrition Labels across 5 Countries in the 2018 International Food Policy Study. *J Nutr*. 2022;152(Suppl 1):13S-24S. doi:10.1093/jn/nxac018
29. Persoskie A, Hennessy E, Nelson WL. US Consumers' Understanding of Nutrition Labels in 2013: The Importance of Health Literacy. *Prev Chronic Dis*. 2017;14:E86. doi:10.5888/pcd14.170066
30. Bialkova S, van Trijp H. What determines consumer attention to nutrition labels? *Food Quality and Preference*. 2010;21(8):1042-1051. doi:10.1016/j.foodqual.2010.07.001
31. Bopape M, Taillie LS, Frank T, et al. South African consumers' perceptions of front-of-package warning labels on unhealthy foods and drinks. *PLoS One*. 2021;16(9):e0257626. doi:10.1371/journal.pone.0257626
32. United States Department of Agriculture Foreign Agricultural Service. *Peru: Peru Publishes Warning Manual for Processed Product Food Labels*. United States Department of Agriculture Foreign Agricultural Service; 2017. Accessed July 15, 2023. <https://www.fas.usda.gov/data/peru-peru-publishes-warning-manual-processed-product-food-labels>
33. Health Canada. Nutrition labelling: Front-of-package nutrition symbol. Published May 25, 2022. Accessed July 15, 2023. <https://www.canada.ca/en/health-canada/services/food-labelling-changes/front-package.html>