

July 25, 2023

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



RE: Public Comment on FDA's 30-day Notice Regarding Quantitative Research on Front-of-Package Labeling (FDA-2023-N-0155)

Dear United States Food and Drug Administration,

[Healthy Eating Research](#) (HER), a national program of the Robert Wood Johnson Foundation (RWJF) based at Duke University, appreciates the opportunity to submit comments on the United States (U.S.) Food and Drug Administration's (FDA) procedural notice on consumer research on front-of-package labeling.

HER supports research on policy, systems, and environmental strategies that have strong potential to promote healthy eating among children, especially among population groups that are at highest risk for poor health and well-being and nutrition-related health disparities, such as families in the U.S. that are racially and ethnically diverse or have lower-incomes. Since the program began in 2005, HER has funded over 300 research studies centered on identifying the underlying causes of poor nutrition, food insecurity, and insufficient access to healthy and affordable foods, and determining policy, system and environmental changes work to improve access to healthy foods, optimal diet quality, and healthy weight and how to scale these efforts. HER research has informed the development and implementation of policies at the federal, state, and local levels. All HER funded research has prioritized the involvement of individuals and communities affected by the issues under study through all stages of the research process. HER's extensive research base, including several studies on front-of package labeling can be found [here](#). HER is directed by Mary Story, PhD, RD and Megan Lott, MPH, RD, Deputy Director.

HER applauds FDA's commitment to the development of a standardized, science-based front-of-package labeling scheme. Extensive research and case studies from countries worldwide demonstrate that front-of-package labeling can help consumers quickly and easily identify healthier food and beverage selections. HER also commends FDA's efforts to conduct a consumer study to test and explore perceptions and attitudes of front of package (FOP) labeling, which is an important step in identifying the most effective FOP label to benefit public health.

The proposed study design has several notable strengths:

Inclusion of nutrients to limit and omission of nutrients to encourage. The proposed study includes a variety of label formats that highlight nutrients to limit, specifically sodium, saturated fat, and added sugars, which research has clearly shown are linked to health harms and are overconsumed by a majority of people in the United States.¹ HER supports the inclusion of added sugars, saturated fats, and sodium as the nutrients to highlight in an FOP label, and FDA's decision to omit positive nutrients such as Vitamin C and fiber on the FOP.

¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans 2020-2025. Available at: https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

Testing of the “High In” FOP scheme. HER particularly favors the “High In” FOP scheme as it emphasizes the information most needed for consumers to make a healthy choice. Focusing on “high in” for nutrients of concern will eliminate additional information that is duplicative of what’s included in the nutrition facts label or secondary to informing consumer choice.

Increased sample size. The proposed study has a large sample of 9,000 participants to ensure adequate power to detect differences in the effects of different FOP schemes on participants’ ability to select the healthiest/least healthy product in a set.

Consistent definitions within FOP schemes. The FOP labeling schemes 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, everything in between is medium).²

Integration of qualitative methods. The study is a randomized experiment, but the agency has also incorporated qualitative research methods, including initial cognitive interviews to test whether participants understand the study questions.

Collection of demographic data. The survey instrument collects important demographic data such as nutrition knowledge, shopping habits, self-rated health, caregiver status, and nutrition literacy.

HER recommends FDA consider the following changes to improve the healthfulness of consumer choice and improve population health.

Apply and incorporate the guidelines from the Institute of Medicine Reports on Front-of-Package Nutrition Rating Systems and Symbols in designing the new FOP label. In 2009, Congress directed the Center for Disease Control (CDC) and the Institute of Medicine (IOM) to conduct a study on front-of-package nutrition rating systems and symbols. The FDA was a study sponsor and later USDA. A committee was convened in two phases to review the evidence and make recommendations to FDA on effective front-of-package labels to improve population health. Dr. Mary Story was a member of this committee. The IOM committee reports were released in 2010 and 2012.^{3,4}

The committee concluded that a single, standardized system that is easily understood by most age groups and appears on all food products would best maximize the effectiveness in encouraging consumers to make healthier food choice and purchase decisions. Their findings indicated that using simple symbols to summarize complex information about product quality is especially valuable to those with low literacy/numeracy skills or low levels of educations. The committee identified four attributes that are common to successful FOP systems: 1) simple--understanding does not require specific or sophisticated nutritional knowledge; 2) interpretive--nutrition information is provided as guidance rather than as specific facts; 3) ordinal--nutritional guidance is offered through a scaled or ranked approach; and 4) supported by communication with readily remembered names or identifiable symbols. The principles outlined in the IOM reports heavily inform Healthy Eating Research’s recommendations to FDA as plans are finalized for the forthcoming study.

² U.S. Food and Drug Administration. The Lows and Highs of Percent Daily Value on the New Nutrition Facts Label. February 25, 2022. Available at: <https://www.fda.gov/food/new-nutrition-facts-label/low-and-high-percent-daily-value-new-nutrition-facts-label>

³ Institute of Medicine. 2010. Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12957>.

⁴ Institute of Medicine. 2012. Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13221>.

Test FOP labels that do not include percent daily values and are easily understood by children and individuals with low literacy and numeracy skills. Research documents that individuals with low literacy and numeracy skills have difficulty interpreting percent daily values.^{5,6} One Australian study assessed participant preferences between the Health Star Rating system (includes an overall ranking from 1-5), a traffic light system (includes colors indicating high, medium, or low criteria), and a daily intake system (includes percent of daily values).⁷ All three labels assessed include nutritional information for calories, saturated fat, sodium, and sugars. Across all participants, the health star rating system was the most preferred, with children exhibiting the strongest preference for health star rating and least preference for daily intake labels, indicating that children might be least likely to understand FOP labels with daily values.

Increase the study sample to include children and adolescents. Evidence on the effects of FOP labels on consumer choice is largely from studies involving adults and limited studies including children. An FOP label should be designed not only for adults but also include older children and adolescents. School-aged youth have been taught to understand and use *My Plate* and the Nutrition Facts Panel and it is important to have them included as a target audience for an FOP label. A study conducted among primary-aged children in Uruguay found that children's selection of unhealthy items was significantly discouraged by a warning symbol as compared to other symbols.⁸

Consider testing additional versions of the "High In" FOP scheme. This should include versions with icons and attention-grabbing features (see, for example, the designs in Figure 1 below). An additional version of the "High In" scheme to test should be modeled after the Chilean FOP label which consists of a black octagon (i.e., variation of a warning symbol) with simple text in white describing the product as high in calories, sugars, saturated fats, or sodium. This label was designed after a mixed-method stepwise study determined it is easy to visualize, provides easily understood information, and has the ability to modify purchase behavior.⁹

Consider displaying calorie, serving size information. The IOM FOP reports makes specific recommendations that the FOP label should prominently display calories in common household measure. At present, one of the major health challenges in the United States is overweight and obesity. American consume too many calories. Energy content is arguably critical information that should be presented (along with the key nutrients to limit) as a component of an FOP system or symbol and calories should be tested along with serving size in common household measures as part of the FDA study.

Consider using the interpretation of which FOP label in a set is the healthiest/least healthy as the study's sole primary outcome. FDA has currently proposed three primary outcomes but this one is the most important. The others (speed at which participants make their decisions and whether or not participants search for more information) should be considered secondary outcomes.

⁵ Roberto CA, Ng SW, Ganderats-Fuentes M, Hammond D, Barquera S, Jauregui A, Taillie LS. The Influence of Front-of-Package Nutrition Labeling on Consumer Behavior and Product Reformulation. *Annu Rev Nutr.* 2021 Oct 11;41:529-550. doi: 10.1146/annurev-nutr-111120-094932. Epub 2021 Aug 2. PMID: 34339293.

⁶ Rothman RL, Housam R, Weiss H, Davis D, Gregory R, Gebretsadik T, Shintani A, Elasy TA. Patient understanding of food labels: the role of literacy and numeracy. *Am J Prev Med.* 2006 Nov;31(5):391-8. doi: 10.1016/j.amepre.2006.07.025. Erratum in: *Am J Prev Med.* 2017 Apr;52(4):554. PMID: 17046410.

⁷ Pettigrew S, Talati Z, Miller C, Dixon H, Kelly B, Ball K. The types and aspects of front-of-pack food labelling schemes preferred by adults and children. *Appetite.* 2017 Feb 1;109:115-123. doi: 10.1016/j.appet.2016.11.034. Epub 2016 Nov 25. PMID: 27894969.

⁸ Arrúa A, Curutchet MR, Rey N, Barreto P, Golovchenko N, Sellanes A, Velazco G, Winokur M, Giménez A, Ares G. Impact of front-of-pack nutrition information and label design on children's choice of two snack foods: Comparison of warnings and the traffic-light system. *Appetite.* 2017 Sep 1;116:139-146. doi: 10.1016/j.appet.2017.04.012. Epub 2017 Apr 18. PMID: 28428151.

⁹ Reyes, M., Garmendia, M.L., Olivares, S. *et al.* Development of the Chilean front-of-package food warning label. *BMC Public Health* 19, 906 (2019). <https://doi.org/10.1186/s12889-019-7118-1>

Consider eliminating the placement condition proposed in the Single Product Evaluation Task.

In addition to 8 FOP schemes and a no-scheme control, FDA proposes to include a tenth condition such that one tenth of participants will be randomized to view the same FOP label as one of the other schemes (the Nutrition Info label in black and white) but placed in the lower right corner of a food package (assumedly as opposed to the upper right corner where labels in the other conditions will be placed). HER encourages FDA to remove this condition because it will reduce the power and is arbitrarily applied to only one FOP scheme. HER also notes that existing research suggests that top right placement of nutrition information is optimal for capturing consumers' attention,^{10,11} and other countries including Canada and Peru require their FOP labels to be placed on the upper right part of the food package.^{12,13}

Summary

Diet-related diseases remain a pressing public health concern in the U.S. Evidence indicates that FOP food labels can play a useful role in addressing this challenge by encouraging consumers to make healthier purchases and prompting the food industry to reformulate their products to remove unhealthy nutrients. Food labels will only meet their potential to promote population health if consumers, including children and adolescents, can easily use and understand them. New FOP labels should therefore be mandatory, shown prominently on the front-of-package, interpret product healthfulness for consumers (rather than only providing numeric information), and explicitly discourage unhealthy products (rather than only promoting healthier options).

Thank you for providing the opportunity to present comments and evidence on the procedural notice on FDA's plans to conduct quantitative research on the front-of-package labels. HER would be honored to serve as a resource throughout this process.

Regards,

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¹⁰ Bialkova S & van Trijp H. What determines consumer attention to nutrition labels? *Food Quality and Preference*. 2010;21:1042-1051. doi: 10.1016/j.foodqual.2010.07.001

¹¹ Bopape M, Smith Taillie L, 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.

¹² Government of Canada. Nutrition labelling: Front-of-package nutrition symbol. June 9, 2023. Available at: <https://www.canada.ca/en/health-canada/services/food-labelling-changes/front-package.html#a5>

¹³ U.S. Department of Agriculture Foreign Agricultural Service. Global Agricultural Information Network Report: Peru Publishes Warning Manual for Processed Product Food Labels. September 27, 2017. Available at: https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Peru%20Publishes%20Warning%20Manual%20for%20Processed%20Product%20Food%20Labels_Lima_Peru_9-27-2017.pdf.

Figure 1. Variations of FDA’s High In Schemes with Additional Features to Draw Attention

Source: Center for Science in the Public Interest

