Public Comment on Docket No. FDA-2021-N-0336 for ‘‘Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on a Voluntary Symbol Depicting the Nutrient Content Claim “Healthy” on Packaged Foods”

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Introduction

FDA has requested comments on a proposed set of studies related to developing a “healthy” symbol for food packaging. We organize our reply below in five sections: objectives, participants, procedures, measures, and data analysis. We conclude with additional evidence about “healthy” symbols more generally.

Objectives

As stated in Docket No. FDA-2021-N-0336, FDA is planning three studies on “healthy” symbols to achieve the goals of the 2018 Nutrition Innovation Strategy (NIS). The overarching objective of the NIS is for FDA to “reduce the burden of chronic disease through improved nutrition and advance its public health mission.”

We support FDA’s goal of reducing the burden of chronic disease through improved nutrition. We also see front-of-package labels, which can quickly communication information about nutritional quality, as a promising way to improve consumer understanding of the nutritional quality of food products. However, we are concerned that voluntary labeling to highlight “healthy” foods will not be the most effective way to achieve these goals based on prior evidence from other countries that have implemented similar labels. As described in the “additional comments section,” research suggests that other labeling systems such as nutrient warnings or graded summary indicator systems are likely to be more effective at improving the

healthfulness of consumers' food purchases compared to endorsement logos like the proposed "healthy" symbol Moreover, evidence suggests that endorsement logos do not meaningfully improve consumer understanding of product healthfulness and may lead to overestimation of the product's nutritional value.

We believe FDA should focus instead on a mandatory front-of-package labeling strategy that informs consumers about high levels of unhealthy nutrients linked to chronic diseases, rather than a voluntary logo that may be used selectively by industry. In the "additional comments" section, we present more evidence about some of these other systems that FDA may consider examining.

Participants

In the main experiment, FDA plans to recruit 5,000 US adult members from an online consumer panel. It is unclear whether these participants will be drawn from a nationally representative sample. We recommend using quota samples to match the demographic breakdown of the US population with respect to gender, age, race/ethnicity, income, and education. FDA should also consider oversampling from certain groups at highest risk for dietary-related disparities. This is important to ensure that the proposed healthy symbol works well among all populations, and in particular lower-education groups who may be less likely to use or understand the Nutrition Facts Panel.

Procedures

1. It was not clear how many study arms are planned and what stimuli will be evaluated. We would recommend a four-arm between-subjects experiment with following study arms: a no-symbol control, a healthy logo, a summary indicator system that includes both positive and negative ratings (e.g., similar to the Nutriscore system that gives all products a letter grade, from A to E, with an associated color coding), and nutrient warnings similar to the ones first implemented in Chile and now also implemented in Mexico, a key trading partner and food importer to the US.
2. We recommend switching the order of the studies so that the two smaller studies/samples are used to pre-test symbols first, before the final symbols are tested in the main experiment. This is the process we have used several times in our own front-of-package labeling experimental work.[1-3] Refining the symbols after conducting the experiment (as FDA proposed) could be problematic if the subsequent studies are not powered to examine changes in the primary outcome/s of interest.
3. For all of the food product categories used as stimuli in the experiment, it is important to ensure that there is a variety of healthier and less healthy products within each category,

such that there will be a range of products that do and do not receive the experimental labels.

4. We recommend including beverages in the list of food product categories since some consumers hold misperceptions about the healthfulness of certain beverage types, including sugar-sweetened fruit drinks and sports drinks,[4] and because sweetened beverages are an important contributor to chronic disease in the US.

5. The proposed experiment involves exposure to products via images in an online survey. We recommend that the FDA employ a naturalistic online store for the study, rather than a simplistic choice experiment. A simplistic choice experiment could show that healthy symbols help consumers identify which products are "healthier," but the external validity of these findings will be uncertain. It is possible that the results from a choice experiment may not be replicated in a real-world food environment, where consumers are evaluating many more products at once and have very limited time to make food purchasing decisions. By contrast, a naturalistic online store will heighten realism and external validity. The online store method has been used successfully in prior studies[5-8] and allows participants to shop for products in a setting that mimics online grocery shopping (which has become increasingly common since the COVID-19 pandemic).[9]

6. The purpose of evaluating a URL alongside the healthy symbol was unclear and a URL would not function in a brick-and-mortar retail setting.

Measurement

1. The primary outcome was not clear. We recommend selecting a primary outcome that is strongly predictive of longer-term behavior change, such as actual selection of products or intentions to purchase products, with the goal of designing a symbol that is likely to improve healthfulness of consumers' purchases. In the context of a naturalistic online store, it could be valuable to measure the healthfulness of products purchased using a scientifically-driven nutrient profile model (see Labonte et al. for a systematic review of nutrient profile model options).[10] It could also be valuable to assess the number of "healthier" products purchased overall and within each category, as well as shifts from ultra-processed foods to whole/fresh foods.

2. As described further below, we share concerns raised by other researchers and advocates that a healthy symbol might lead consumers to believe that processed foods are healthier than they are in reality, especially if the definition of "healthy" is too broad. Thus, it will be important to measure a variety of potential unintended consequences. It would be useful to assess perceived healthfulness of packaged products that receive the "healthy" symbol compared to whole/fresh fruit and vegetable counterparts to evaluate whether consumers incorrectly believe that the processed foods are as healthy as fresh produce, for example.

3. Participants' own ratings of believability and trustworthiness of the label are generally not strong predictors of how people will behave in the real world.[11] If FDA chooses to

measure these constructs, we would not suggest using them to evaluate which label is most likely to help people make healthier dietary choices.

4. One possible (intended or unintended) consequence of front-of-package labels is product reformulation. Manufacturers may reformulate their products in order to meet the criteria to carry a positive endorsement label or avoid having to carry a warning label. Measuring reformulation in the context of an experiment is not possible, but it will be important for FDA and researchers to study the real-world reformulation effects of any new front-of-package labels.

Analysis

Docket No. FDA-2021-N-0336 did not include details about the studies' predictions, analytic plan, or power calculations. We strongly suggest that FDA pre-register critical details about the study including: primary outcome and all secondary outcomes, any hypotheses or predictions, the analytic plan, and the power analysis used to arrive at the target sample sizes. These pre-registration details could be submitted via AsPredicted.org or ClinicalTrials.gov depending on the nature of the study.

Additional comments

We wish to make several additional points about research on "endorsement" labels (i.e., labeling schemes designed to indicate healthier product options, similar to what FDA is proposing to develop), as described below:

1. **Existing evidence suggests that the impact of voluntary "endorsement" labeling systems on healthfulness of *food purchases* is limited**. In a randomized-controlled laboratory study of the effects of the "Smart Choices" label, which was previously used in the US to indicate healthier products, Roberto et al. found no difference in amount consumed or purchase intentions between labeled cereal products and unlabeled controls.[12] Two studies testing the impact of New Zealand's Health Star Rating labels also found no effect on the healthfulness of food purchases compared to controls.[13,14] Assuming the goal of the "healthy" symbol is to help consumers make healthier product choices, these studies suggest it may not achieve that goal. By contrast, other types of labels, including nutrient warning labels, have been more consistently associated with reduced purchases or purchase intentions of less healthy products.[15-17] In a trial of three types of labels (star rating, high sugar and health warning), Acton et al. found no overall effect of labeling on sugary drink selection, although there was a trend toward reduced likelihood of selecting a sugary drink in the "high sugar" label condition.[18] In a direct comparison of the effects of different labeling systems, a French study found that the "Green Tick" endorsement system out-performed a control, but was outperformed by the "5-Color Nutrition Labels" system when it came to the nutritional quality of participants' final shopping cart.[19]

2. **Evidence for the effects of "endorsement" labels on increasing consumer understanding is mixed.** In France, two studies comparing several types of labels found the "Green Tick" endorsement system to be the least effective in improving participants' understanding of nutritional quality of products. The Guideline Daily Amounts (GDA) system, the Multiple Traffic Lights (MTL) system, and the 5-Color Nutrition Labels system all outperformed the "Green Tick."[20,21] Similarly, a nationally representative study in Great Britain testing the impact of four labels against a no-label control found that all the labels improved consumer ability to correctly rank product healthfulness, but that Nutri-Score and MTL system had the largest impact, while the Positive Choice tick performed worst.[22]

Other studies have found "endorsement" labels to be effective in impacting consumers' perception of a product's healthfulness. However, such studies also identify sources of concern related to such perceptions. Andrews et al. found that a product with the "Smart Choices" label was perceived as healthier than a product with the same nutritional profile that carried a traffic light label - which allows for more nuance, and thus reflected the product's considerably higher levels of cholesterol and sodium, unlike the "Smart Choices" label.[23] Roberto et al. found that the Dutch "Choices" label also led to greater perceived healthfulness of products in their study, but worse understanding of their nutritional content.[24] The researchers point out that the label sometimes made it more difficult for participants to identify the healthier among similar products, since those that met Choices' specific nutrient thresholds were not necessarily healthier overall.[24] Therefore, by oversimplifying information about nutritional quality, "endorsement" labels may create a distorted perception of products' overall healthfulness, especially when not attached to strict nutrient standards.

3. **The use of positively framed labels in general, and "healthy" specifically is a potential cause for concern**, as the "healthy" designation may be interpreted as a blanket endorsement to consume as much of a product as desired, or to exclusively consume products with this label.[25,26] Health "halo effects," which may encourage overconsumption, can be stronger for "seal of approval" labeling systems.[27] Furthermore, "healthy" implies that a product is good for you in absolute, rather than relative, terms, which could be misleading for consumers.[28] The Academy of Nutrition and Dietetics recommends against labeling foods "in an overly simplistic manner as 'good foods' and 'bad foods'" because such emphasis on specific foods can cause confusion and/or act as barriers to adopting healthy dietary patterns.[29] For additional information about the potential unintended consequences of a "healthy" vs. "unhealthy" dichotomization in labeling, please see Julia et al (2021), appended to this public comment.[25]

Since "healthy" labels are voluntary and unlikely to be applied to fresh produce and items that are not pre-packaged or ultra-processed, they may not encourage products that consumers should eat more of (e.g., fruits and vegetables).[28] Nestle et al. point out that "'healthier' processed foods are not necessarily healthy. Manufacturers can manipulate snack food ingredients by replacing fat or sugar with refined starch, yielding a higher rating score with little meaningful improvement in nutritional quality."[30] The definition of "healthy" also varies widely

across labeling systems. For example, an evaluation of the “Smart Choices” label found that 64% of products with the label would not meet the Nutrient Profile Model criteria (an objective scoring system designed by independent scientists) for “healthy” products.[31]

In sum, the evidence about endorsement labeling systems is mixed and suggestive of potential unintended consequences related to “health halo” effects. Moreover, evidence suggests that other labeling systems, such as summary indicator systems or warning labels, are likely to be more effective than endorsement logos for improving consumer understanding and increasing healthfulness of food purchases. For this reason, we urge FDA to consider evaluating a “healthy” symbol against alternative labeling systems with a stronger evidence base, with the long-term goal of developing a front-of-package labeling system that informs consumers and leads to healthier food purchasing behavior with minimal unintended consequences.

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