



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

Submitted via Regulations.gov

RE: Docket No. FDA-2023-N-0155: Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods

March 27, 2023

To Whom It May Concern:

We appreciate the opportunity to provide comments on proposed consumer research regarding a front of package (FOP) labeling scheme to identify the nutrient profile of foods and beverages. IDFA believes that FOP schemes should facilitate consumer understanding and therefore, research on how consumers use and understand FOP labeling is vital to ensure that the scheme has the desired impact on consumer food and beverage choices, and to avoid any confusion and/or unintended consequences.

The International Dairy Foods Association (IDFA), Washington, D.C., represents the nation's dairy manufacturing and marketing industry, which supports more than 3.3 million jobs that generate \$41.6 billion in direct wages and \$753 billion in overall economic impact. IDFA's diverse members make 90 percent of the milk, cheese, ice cream, yogurt and cultured products, and dairy ingredients produced and marketed in the United States and sold throughout the world. Safe, nutritious, affordable, and sustainable, dairy foods offer unparalleled health and consumer benefits to people of all ages.

It is vital that any FOP nutrition labeling scheme be science-based, factual, understandable, and actionable by consumers. Any potential change to a product label should not be undertaken without fully comprehending how consumers will understand and react to such a change in order to avoid misleading or confusing label information.

To that end, IDFA supports the consumer research the Agency has been, and will be conducting, and encourages the Agency to leverage this research to guide and inform the development of any FOP scheme. It will be important for any FOP scheme to be well-understood by consumers and not unintentionally provide misleading interpretations of the safety, health value, or nutritional role of the food in the overall diet.

Principles for FOP Labeling Systems

IDFA believes that, if used, FOP labeling should reflect a complete picture of the food and its role in a healthy diet, including both nutrients to limit and nutrients to encourage. In keeping with this overall position, IDFA supports the following principles in the building of FOP systems:

- Any FOP nutrition labeling scheme should not conflict with regulatory and trade obligations.
- Any FOP nutrition labeling scheme should be grounded in scientific evidence.
- Any FOP nutrition labeling scheme should be voluntary, clear, simple, and flexible.
- FOP nutrition labeling should facilitate consumer understanding of the nutritional composition of a food and how it fits into an overall recommended dietary pattern.

FOP Labeling Should be Voluntary and Complementary to Existing Labeling and Nutrition Information

Labeling is one key method for consumers to understand the nutritional value provided by the foods they consume. Nutrition information is already available to consumers through the recently updated Nutrition Facts Label and defined claims based on Reference Amounts Customarily Consumed, which have also been recently updated. Along with the Nutrition Facts Label and other labeling, FOP schemes have the potential to provide important nutrition information to consumers quickly. However, it is important that any FOP scheme be aligned with FDA's current claims structure and required nutrition labeling. To that end, IDFA requests that FDA exempt foods for special dietary uses, medical foods, and foods with insignificant nutritional and caloric content, as well as food specifically formulated for infants through 12 months and children 1-3 years of age from FOP labeling. To support the goals of FDA's Nutrition Innovation Strategy, FOP labeling schemes should help consumers quickly and easily identify foods that can help them build healthy eating patterns and come closer to achieving the recommendation of the Dietary Guidelines for Americans (DGA).

Finally, any scheme or graphic that the Agency develops should be allowed to be *voluntarily* displayed on the front of food labels. The cost of making changes to food and beverage labels is significant and any potential change to a product label, including voluntary changes, should not be undertaken without fully comprehending how consumers will understand and react to such a change to avoid misleading or confusing label information. We agree that this planned consumer research is important to undertake and analyze prior to releasing FOP labeling schemes.

Results of FDA's Past Research Should Be Made Publicly Available

In order to make informed comments on FDA's request for input on the planned consumer research, as well as to consider potential future label changes, it is important for the public to be able to review the results of past surveys and consumer research that FDA has conducted. In the request for comment, FDA refers to the literature review conducted in 2022 related to FOP labeling schemes. This literature review was made public in the Federal Register, permitting members of the public to look at the information identified, the conclusions drawn by FDA, as well as identifying any relevant research that may have been overlooked.

Part of the findings of this literature review will be particularly useful as considering the design of the consumer study and the schemes to be tested. Some of the key learnings included a consumer preference for a positive, summary FOP scheme as opposed to warning-style labels. This literature review also showed that there is limited research on what type of scheme has the most merit.¹ This aligns with other recent review of food purchases and other outcomes related to FOP schemes, which showed that FOP schemes are minimally effective in prompting consumers to make healthier food purchases and have limited effect on improving diet quality. Like the FDA literature review, no single FOP scheme was identified as more effective than others.² As consumer research is designed, we encourage FDA to search for and consider the design of previously conducted research on FOP schemes.

The request for comment also refers to focus group consumer research regarding FOP that was conducted, including some schemes that were tested and the mocked-up food labels presented to research participants. However, the results of these focus groups were not shared with the public. These results are even more vital because the current research that is the focus of this request for comment will be based upon the results of the earlier focus groups. The request indicates that the future quantitative research will use some, but not all of the schemes tested in the early focus groups. Therefore, it is impossible to provide comment on the future research if the results of the past research, including the schemes to be tested, are unknown.

Success Metrics and “Practical Utility” Should Be Defined Prior to the Consumer Research

FDA asked for public input on “...whether the information [collected from the consumer research] will have practical utility.” More information is needed to be able to make this assessment. Specifically, FDA needs to be clear on its definition of “practical utility” for labels and needs to clearly define the primary outcome of their quantitative consumer research so that questions and research design can be developed to address the intended goal. For example, if the intended practical utility is that consumers understand the nutrient content of a food, that would require different study design and questions than a study intended to identify the practical utility of consumer purchase behavior or consumption intent.

Prior to conducting the quantitative study, FDA should identify the key metrics for successful consumer understanding in order to evaluate the effectiveness of each FOP labeling scheme. These metrics may include product perception, label perception, purchase intent or consumption intent. Knowing the main outcome of the study against which the success of the different FOP schemes will be assessed is necessary to guide the study design and interpretation of the results. If the main outcome is not clear, the study risks losing practical value. Setting these metrics for success prior to the study will permit both FDA and the public to better interpret the results.

Commenting on Time Burden is Impossible Without Further Details of Proposed Consumer Survey

Among the comments requested by FDA is information regarding the time burden of the planned quantitative study. However, the time burden is impossible to estimate and comment on if the design and other details of the quantitative survey are unknown to the commenters.

¹ Verrill L, Wu F, Weingaertner D, Oladipo T, and Lubin L (2021). *Healthy Symbol Literature Review*. Food and Drug Administration. <https://www.regulations.gov/document/FDA-2021-N-0336-0002>

² Braesco V and Drewnowski A. (2023). Are Front-of-Pack Nutrition Labels Influencing Food Choices and Purchases, Diet Quality and Modeled Health Outcomes? A Narrative Review of Four Systems. *Nutrients*, 15, 205. <https://doi.org/10.3390/nu15010205>

The number of questions estimated to be asked, as well as specifics on these questions, is necessary information to make an estimate of time and the burden on the participants. Additionally, it would be important to know which FOP labeling schemes will be tested and with what testing variables.

For example, if FDA chooses to present a scheme in quantitative testing that was shown to be confusing to a focus group of consumers, the presentation and testing of this particular scheme may be a waste of time and testing resources that would best be applied to schemes that were more comprehensible in the focus groups. Additionally, if in an effort to reduce the time burden on consumers, only a few schemes were tested and there was insufficient variation between these schemes, the research may not be able to identify a FOP scheme that is clear and useful to consumers if it was excluded from the research.

Additionally, clearly identifying a primary outcome will allow for the appropriate calculation of a sample size estimate, ensuring that the study is sufficiently powered to determine both the burden of the proposed collection of information and the practical utility. Conducting an under-powered study would waste resources and could provide uninterpretable results or worse, findings that are misinterpreted.

Survey Populations Should Reflect the Diversity of the US Population

As the US population continues to grow in diversity, nutrition labeling in general and FOP schemes specifically need to be understandable and actionable for a diverse population of consumers. We agree with FDA's intention that the consumers surveyed should be "balanced to reflect the U.S. Census on gender, education, age and ethnicity/race." We appreciate that these factors will be considered, along with a measure of health literacy.

Recognizing that there are additional individual characteristics that could affect selection of food, there are other attributes that should be considered to comprehend how consumers understand and use a potential FOP scheme. This could include health status, particularly for conditions that are related to nutrition, such as diabetes, weight status and hypertension. It is also important to identify how a FOP scheme would be understood by parents, both for themselves and for providing foods and beverages to their minor children. We agree that a wide variety of ages should be included in the study because different age groups may have very different reactions to FOP labeling. English language literacy and the method of administration of the test would also be important variables to consider within the study population. Also, the panel should be representative of primary shoppers. Additionally, surveyed consumers should span across socio-economic status, as research suggests that the use and understanding of nutrition labeling, potentially including FOP labeling, may be conceptually different for those with varying levels of income.

Consumer Studies Should be Designed to Avoid Unintended Consequences

Additional areas of inquiry may be needed to ensure that the consumer studies provide the most helpful information on schemes that consumers understand and act upon. For example, additional or different categories of food, such as vegetables or snack foods, may need to be tested to understand how consumers react to schemes on those food items, which may be very different from how they react to FOP labeling on other foods.

Schemes that are Tested Should Reflect the Full Nutrient Profile of Foods

The FOP labeling schemes that are tested should include not only nutrients that are recommended for limited intake by the DGA, but also nutrients that are encouraged in American diets. This will provide the

full nutrient profile of the labeled foods and beverages. These schemes must accurately reflect the full nutrient profile of a food, and consumer research should ensure that consumers will understand this.

IDFA requests that fact-based, Guideline Daily Amount (GDA) schemes without interpretive elements are included in the test as well as interpretive schemes to help understand the benefits and limitations of the schemes. The schemes tested should also include some that are presented in black and white and others with color to identify if color should be used or permitted in FOP labeling schemes. Moreover, additional schemes may need to be included in the test to gain insights on category specific, pack-size specific considerations such as the “calories only” scheme used by voluntary, industry-led schemes for foods and beverages in small packages.³

Further, Facts Up Front (FUF) is already widely adopted and used by industry. Therefore, any newly proposed scheme should be tested against FUF with a clear primary outcome that is well-defined prior to the initiation of the study. This will ensure that any newly proposed FOP nutrition label offers a benefit beyond what is already widely available to consumers and used by industry.

Additional Questions to Include in the Quantitative Research Survey

IDFA supports FDA including the following questions in the quantitative research survey to gain a thorough comprehension of consumer attitudes and understanding of different types of FOP schemes on packaged foods. Some additional questions that FDA should pose to survey participants include:

- 1) What are consumers looking for on packaging that helps them select products that are appropriate for their nutritional needs?
- 2) Will the symbol or scheme imply to the consumer that the product is organic, bioengineered, natural, simply made, or non-GMO for example? (use the most prevalent symbols in the market to illustrate this example)
- 3) Do you think the food with the symbol or scheme will taste better or worse than another food? Similarly, would the food with the symbol be more or less expensive than another food?
- 4) How do consumers view front of pack labeling in general, including schemes currently in use on food products sold in the U.S.?
- 5) Do consumers view the scheme as an endorsement vs. as a claim?
- 6) Do consumers view a scheme as being more credible with or without the words "FDA" being in the symbol?
- 7) Would consumers prefer getting information on nutrient content from the government versus the food industry?
- 8) What does this symbol mean as compared to other labeling or claims on the package?

IDFA believes that these questions play a vital role in understanding consumer perception and understanding of a FOP labeling schemes on packaged foods.

Conclusion

IDFA supports FDA’s consumer research on an FOP labeling scheme. We believe it is important to provide nutrition information to help consumers make food choices that align with the Dietary Guidelines’ goal of consuming healthy diets. However, prior to research on these schemes, it is important to understand consumer comprehension and behavior to ensure that the intended study of

³ American Beverage Association. “Putting Calorie Info Up Front” <https://www.balanceus.org/industry-efforts/putting-calorie-info-up-front/>

Facts Up Front. “Interactive Label” <http://www.factsupfront.org/AboutTheIcons.html>

the schemes has the intended effect of providing insights into consumer behavior that would allow for the increased consumption of healthy foods, without unintended consequences.

Sincerely,

A handwritten signature in black ink that reads "Joseph Scimeca". The signature is written in a cursive, slightly slanted style.

Joseph Scimeca, PhD
Senior Vice President, Regulatory and Scientific Affairs