AMERICAN FROZEN FOOD INSTITUTE

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July 17, 2023

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

Re: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods; Docket No. FDA-2023-N-0155

Dear Sir or Madam,

The American Frozen Food Institute (AFFI) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) second procedural notice regarding quantitative research on front of package (FOP) labeling on packaged foods. From manufacturers to distributors to suppliers to packagers, AFFI is proud to represent publicly traded and family-owned companies who help produce frozen foods and beverages for today's food service and retail marketplace and serve as economic pillars within their communities throughout the U.S. The frozen food industry contributes approximately $65.1 billion to U.S. GDP and accounts for 670,00 U.S. jobs. In addition to our members' strong role in economic growth, AFFI members share a commitment to food safety and transparently communicating information about the nutritional profile of the foods they produce and sell.

AFFI continues to have a significant interest in the agency's work in investigating a standardized front-of-pack nutrition labeling (FOPNL) scheme, having submitted detailed comments on the agency's initial 60-day notice of its proposed collection of information on this important topic. We appreciate the additional information the agency shares in this second procedural notice, including the overall study design, mock product labels, and planned FOPNL schemes for testing. Given the importance of the planned study, and its significance in shaping any future standardized FOPNL scheme, however, we urge the agency to continue to incorporate feedback from stakeholders to maximize the utility of the study and ensure it produces truly actionable information that furthers public health goals. To that end, we offer additional thoughts on three key areas of concern for AFFI members raised by the second procedural notice:

1. **FOPNL schemes to be tested**: AFFI appreciates FDA sharing the eight different FOPNL schemes that will be included in the study. However, AFFI is both surprised and disappointed that the schemes do not include (1) the widely adopted Facts Up Front scheme, currently in use across a wide swath of the packaged food supply; (2) any scheme that includes information about calories, a critical component of the additional context consumers need to quickly identify foods that can fit in a healthy dietary pattern; and (3) one or more schemes that incorporate positive nutrients or otherwise takes a positive interpretative approach (e.g., stars, check boxes).

2. **Short timeframe for comment:** AFFI appreciates that the second procedural notice includes more information about the planned study, as well as the results of the agency's review of the literature on the effectiveness of other FOP schemes adopted around the world. This transparency is important because the study results are likely to have a tremendous impact on FDA's choice of a standardized FOPNL, should it proceed to choose one. However, given the high stakes and the complexity of the information, a 30-day comment period is not sufficient to understand the information fully or formulate the kind of detailed, study-specific feedback that will help the agency strengthen the design and enhance the utility of the results in advancing its public health goals.

3. **First Amendment considerations**: In our comments on the agency's initial 60-day notice, we acknowledged that the planned consumer study is only a first step in exploring FOPNL schemes. However, before moving forward to propose a mandatory approach to FOPNL, we urged the agency to consider carefully whether it has the requisite legal authority to do so and whether doing so might draw legal challenges. We reiterate our caution on that point now, in particular because seven of the eight schemes to be tested take an interpretive rather than informational approach, which heightens concerns about adherence to First Amendment requirements.

Detailed Comments

1. **The FOPNL Schemes to Be Tested Should Include Schemes that Are Already in Wide Use, Display Calories, and Account for Positive Nutrient Contributions**

AFFI appreciates that the current study design includes eight different iterations of six different schemes, and the cost and complexity of any study increases as the number of schemes to be tested increases. That said, it is critically important that the study examine a range of possible schemes to understand and evaluate their relative effectiveness in helping consumers quickly identify foods that can fit into a healthy dietary pattern.

AFFI is particularly concerned that the planned schemes do not include Facts Up Front (FUF) or something that closely approximates it. As FDA knows, Facts Up Front provides consumers with rapid access to information on calories, nutrients to limit, and positive nutrients in a standardized format. It was developed over ten years ago and has been in wide use across the U.S. since that time. Despite its widespread adoption, familiarity to consumers, and calls for inclusion in the study, FDA omits it, commenting only that the planned schemes "include attributes" of Facts Up Front. Respectfully, AFFI believes FUF (or a very close approximation) should be one of the tested schemes. Without its inclusion, the planned study does not "test a variety of schemes reflecting those currently found in the marketplace," as FDA promises, nor can it provide insight as to whether the other schemes are more effective or otherwise offer any incremental value over FUF. In short, because FUF is already used widely and expanding its use could be accomplished quickly and cost effectively, it is necessarily a key baseline, against which other schemes must be evaluated.

AFFI is also confused and disappointed by FDA's apparent decision not to include information on calories in any of the schemes to be tested. The agency states repeatedly that FOPNL is intended to compliment the Nutrition Facts Panel "by giving consumers

additional context to help them identify healthier food selections." Absent information about calories, consumers will not have that context. A healthy dietary pattern necessarily involves making food selections that deliver essential nutrients while staying within calorie limits. If calories are exceeded, overweight and obesity may result, undermining the value of nutrient-dense selections and exacerbating the public health burden of diet-related chronic disease. Calories are an essential piece of the "context" any FOPNL must provide. The fact that calories are now displayed more prominently on the full, updated Nutrition Facts Panel (NFP) does not address the concern. Indeed, by omitting calories from a standardized FOPNL, FDA could inadvertently increase the likelihood that consumers ignore calorie information and make selections based only on the information contained in what appears on the front-of-the package. Unless one or more of the tested schemes includes calorie information, the study will provide no insight on the likelihood of this unfortunate but nonetheless very plausible outcome.

AFFI has similar concerns about the absence of positive nutrients from the tested schemes. Although eight iterations are planned, none includes any information – directly or indirectly (via stars or checkmarks) – about the positive nutrient contribution of a food, again leaving stakeholders struggling to understand how the tested schemes can be described as delivering "additional context" or enhancing consumers' understanding of food's total nutritional contribution. In response to concerns, FDA states that it chose the schemes to be tested "based on our literature review and the feedback we collected through our focus group research, which indicate the simpler schemes are easier for consumers to understand." While AFFI appreciates that the prior focus group research provides important information, it was a qualitative study. It did not measure the impact of including positive attributes/nutrients to encourage in achieving the stated goals of a standardized FOPNL. Moreover, unless a scheme that includes positive nutrients is included, the study will shed no light on the cost/benefit of including positive information relative to other tested schemes.

FDA also states that "consumers often already have access to information about nutrients to encourage on the front of food packages." But this is a separate point. The issue is not whether companies may make voluntary claims about positive nutrients, but rather whether they should or could be included in a potentially mandatory standardized FOP labeling scheme to provide a more complete picture of how the food fits into a healthy dietary pattern.

2. The Complex Nature of the Subject Being Studied Warrants Additional Time for Comment

AFFI acknowledges the agency's effort in providing additional detailed information about the planned study. In addition to the FOPNL schemes to be tested, FDA provides mockups of the product labels, a list of the research questions to be answered, a general description of the overall study design, and an 82-page summary of its literature review. We appreciate the information and the transparency it brings to the process. At the same time, however, we feel strongly that the 30-day timeline for comments is not sufficient given the complexity of the material and the consequential nature of the agency's work.

Although there are several concerns raised by the planned study design that are immediately evident, and discussed in Section 1 of our comments, we are concerned that others are less evident and will go unaddressed. Without more time to study the materials and consult with experts skilled at measuring the impact of label information on consumer perception and decision making, FDA will not get the type of detailed, deeply reflective feedback needed to optimize the study. Certainly, at a minimum, the opportunity for input at this stage of the process, when the agency's plans are further advanced and more information is available, should be at least as long as the time provided for input at the outset of the process, when little to no information was available to stakeholders about the schemes to be tested or how (i.e., under what conditions) those schemes would be assessed. Now that this information is available, stakeholders need at least as much time, and likely more, than FDA provided at the outset (i.e., 60 days plus).

In addition to its concern about the short timeframe for comments, AFFI believes it is important to emphasize that the value of the planned research relative to the agency's broader public health goals is limited by what it measures. As we pointed out in our initial comments, the study will not test actual behavior, only what consumers say they will do, and prior research indicates those are often two very different things. As a result, whether any of the tested FOPNL schemes, including whichever one the study judges most effective, will actually affect consumer purchase and consumption behavior in a positive way will remain unclear. On a related note, because of the limitations of the design, the study will not assess how FOPNL affects consumer perceptions and choices across product categories, only within the limited number of chosen categories (i.e., frozen meal, breakfast cereal, and canned soup). Moreover, even within the chosen categories, the study will provide insight only as to consumers' ability to distinguish the most healthful from middle and least healthful options, not how FOPNL would affect their choice when confronted, as expected in the real world, with products in the same category that bear the same or similar FOP symbols. For example, would consumers look beyond the FOPNL to the full NFP for information about positive nutrients to "break the tie"?

3. The Interpretive Nature of the FOPNL Schemes Chosen for Testing Heightens the First Amendment Concerns Associated with the Agency's Broader Initiative

AFFI recognizes that the planned quantitative study on FOPNL is a first step in the agency's exploration of FOP labeling as a tool to help consumers make healthier food choices. However, for the reasons discussed in AFFI's initial comments and which are incorporated by reference here, FDA should carefully assess whether it has the requisite legal authority under the Act to mandate FOPNL before moving forward to propose it. 1/

Caution is also warranted on First Amendment grounds and that caution is heightened by the particular FOPNL schemes FDA has chosen for testing. As outlined in our initial comments, food labels are a form of commercial speech, and commercial speech is entitled

1/ Congress was quite specific in the authority it granted to FDA for nutrition labeling when it passed the Nutrition Labeling and Education Act in 1990. It has not expanded that authority since that time. Moreover, the evolution of Supreme Court jurisprudence in the intervening years reinforces the need to proceed cautiously, given the Court's view that regulatory agencies must have *clear direction* from Congress – rather than a broad delegation of power – if a proposed regulatory implicates the "major question doctrine," as would seem to be the case with a brand new, across-the-board labeling requirement that effectively characterizes foods as "good" or bad" based on a narrow subset of the comprehensive set of nutrients Congress mandated be included on the label.

to protection under the First Amendment. *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980). Although the Supreme Court recognizes that compelled speech like mandatory label requirements can be consistent with the demands of the First Amendment if it is "reasonably related to the State's interest in preventing [consumer] deception," in order to meet that standard, the speech must be "strictly factual and uncontroversial." *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). With one exception, all the schemes FDA has chosen to test are interpretive. They go beyond simply providing information, choosing instead to characterize that information and send a normative message to consumers through colors and words like high/medium/low, even though consumers' dietary requirements and preferences vary, and nutrition science and dietary guidance have long been areas that are recognized as continually evolving, with little that is settled and clear.

Moreover, FDA would need to show that the proposed compelled speech corrects an omission that would otherwise be deceptive. The type of showing that would be required here sets a high bar indeed and we are not aware of any information that would suggest that to omit information on the front panel of all food labels of the type FDA is proposing to test is deceptive.

For these reasons, we question whether any of these schemes could meet the First Amendment's demand for information that is purely factual and uncontroversial. Our doubts in this regard are enhanced by the balance of the *Zauderer* test, which requires not only that compelled speech be factual and uncontroversial but also that it "reasonably relate" to the government's interest and not be unduly burdensome. There are serious questions about the effectiveness of FOPNL in resulting in meaningful, long-term behavioral changes. Further, with so many other tools available to the agency to encourage healthier food choices by consumers (e.g., consumer education campaigns; voluntary claims, including an updated "healthy" claim and associated on-pack symbol; the contents of the Nutrition Facts Panel and the emphasis brought to certain elements through choices involving type size and bolding), and that do so in a simple, less burdensome, and cost effective way, the reasonable relationship between mandatory FOPNL and healthier food choices by consumers that *Zauderer* would call for is hard to articulate.

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AFFI greatly appreciates the opportunity to provide input on the agency's updated plans to conduct a quantitative study of various FOPNL schemes. Our members have a longstanding commitment to ensuring consumers have access to the information they need to make informed purchase decisions that contribute to an overall healthy diet. However, in moving forward both with the study and the agency's broader initiative relating to FOPNL, we urge the agency to remain open to feedback from the full range of stakeholders and cognizant of the limitations of its legal authority. Please do not hesitate to contact us if we can provide further information.

Sincerely,

Donna M. Garren, PhD
Executive Vice President, Science and Policy