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Client Alert

FDA and Life Sciences

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FDA Releases Proposed Front-of-Package Nutrition Labeling Rule

On January 16, 2025, the U.S. Food and Drug Administration ("FDA") published a highly anticipated proposed rule on front-of-package ("FOP") nutrition labeling ("proposed rule").[i]

If finalized, the proposed rule would require a new informational box ("Nutrition Info box") containing information on three "nutrients to limit" — saturated fat, sodium, and added sugars—to be placed on the principal display panel ("PDP") of most food packages and the labeling of foods sold to consumers from bulk containers.

The proposed Nutrition Info box, which is visually similar to the existing Nutrition Facts Panel ("NFP"), is interpretive in nature and intended to provide complementary information to help consumers more easily identify foods that are "Low" (5% DV or less), "Med" (6% to 19% DV), or "High" (20% DV or more) in saturated fat, sodium, and added sugars. The proposed rule also includes conforming amendments to related nutrient content claim regulations.

Comments on the proposed rule are due May 16, 2025.

JUSTIFICATION FOR THE REGULATION

FDA cites to the general food and nutrition labeling authorities found in the U.S. Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990, to support FDA's statutory authority to mandate FOP labeling.[ii]

Given the rising rates of diet-related chronic diseases amongst the U.S. population, the preamble explains that FDA's goal is to "provide consumers, including those who have lower nutrition knowledge, with interpretive nutrition information that can help them quickly and easily identify how foods can be a part of a healthy diet."[iii] FDA believes that FOP nutrition labeling "could help improve consumer awareness of

nutrients to limit by providing a more accessible description of certain information contained in the Nutrition Facts label."[iv]

POLICY HISTORY

FDA has been considering options for FOP nutrition labeling schemes for nearly twenty years. Throughout this period, the agency sought comment from interested stakeholders through public hearings and stakeholder meetings, and it evaluated different FOP labeling schemes through literature reviews, focus group testing, and other experimental research.

FDA has not been alone in this interest. In 2011, in the United States, industry launched its own voluntary labeling program known as "Facts Up Front."[v] Internationally, there has been rising global interest in both mandatory or voluntary FOP nutrition labeling, including some schemes that function essentially as warning labels or where a letter grade is used to represent the healthfulness of a food's nutrient profile.[vi]

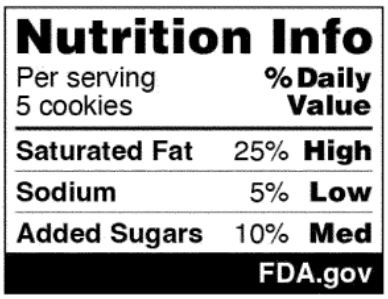
In parallel, Congress and other stakeholders have periodically prodded federal public health agencies to evaluate potential FOP labeling. In 2009, Congress directed the Centers for Disease Control and Prevention to commission a study by the Institute of Medicine to provide recommendations regarding FOP nutrition symbols.[vii] In August 2022, the Center for Science in the Public Interest, the Association of SNAP Nutrition Education Administrators, and the Association of State Public Health Nutritionists submitted a citizen petition asking that FDA amend its regulations to require standardized FOP nutrition labeling, including calories, added sugars, sodium, and saturated fat.[viii] In September 2022, as part of the White House Conference on Hunger, Nutrition, and Health, the Biden Administration previewed plans to issue FOP rulemaking. And, in 2024, members of the Senate Committee on Health, Education, Labor, and Pensions introduced legislation that would require that FDA impose warning labels on certain food and beverages, and the committee convened a hearing at which FDA senior leadership were asked repeatedly about the agency's plans to require FOP nutrition labels.[ix]

UPDATED RESEARCH SUPPORTING PROPOSED RULE

To develop the scheme ultimately proposed in the rule, FDA considered the various recommendations and approaches that had emerged over the past two decades, and it embarked on new research to test specific FOP concepts and labels. Through focus groups, FDA tested variations on four FOP nutrition labeling schemes, with a total of 41 variations tested. These schemes included presentation of nutrients to limit, nutrients to encourage (e.g., fiber, calcium), numerical (e.g., %DV) and interpretive (e.g., Low, Med, High) information, and both black-and-white and color schemes.[x] Building on information learned from the focus groups, FDA performed a controlled, randomized study of more than 9,000 U.S. adults, which tested three FOP scheme categories with various features (e.g., with and without %DV), for a total of eight FOP schemes. Finally, FDA performed a second round of focus groups to better understand consumer reaction to FOP nutrition labeling on beverage products.[xi]

PROPOSED FRONT-OF-PACKAGE LABELING SCHEME

Based on findings from FDA's literature reviews, focus group testing, and experimental study, FDA has proposed a mandatory "Nutrition Info" box to appear on the FOP of food packaging, unless exempt. The Nutrition Info box would identify the serving size and include three nutrients to limit—saturated fat, sodium, and added sugars—along with both the %DV and an interpretive designation of "Low," "Med," or "High" for each nutrient.



Notably, the proposed scheme does not include either calories or various nutrients to encourage, which are currently incorporated in industry's Facts up Front scheme. FDA explains that it highlighted only these three nutrients, "given their significance in building healthy dietary patterns, the scientific research on FOP nutrition labeling [including that consumers find simpler schemes easier to understand], and the current food labeling landscape, in which consumers report being familiar with a wide variety of industry claims."[xii] As discussed below, FDA does provide an option for manufacturers voluntarily to add calorie information to their FOP nutrition label.

The scheme also does not include the use of colors (e.g., red, yellow, green) as an interpretive signal, although colors are commonly required by FOP schemes in other countries. FDA explained that, while some existing evidence suggests that color coding can lead to improved understanding of nutrition labeling, the results from FDA's study indicated that colors provided no clear upside (neither significantly increasing the utility of the Nutrition Info box nor increasing understanding of the interpretive information provided) and they introduced downsides in the form of challenges for individuals with colorblindness as well as increased costs of the rule.

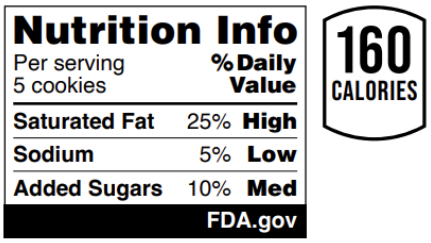
FDA proposed a range of 5% DV or less for "Low," 6% to 19% DV for "Med," and 20% DV or more for "High." FDA specifically invites comment on any alternative criteria for the interpretive descriptions. In explaining its thinking behind including both %DV and interpretive signals, FDA cites results from its recent research, which showed that presenting both the quantitative %DV and the interpretive descriptions may help consumers better understand why a serving of food has the interpretive description it does and would better inform consumers about where certain foods fall within the ranges of each term.[xiii]

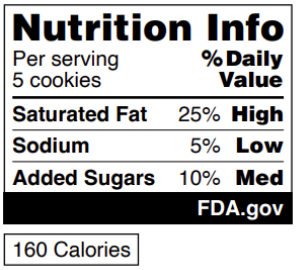
If finalized, the Nutrition Info box must appear on the upper third of the principal display panel (on the left or right side). The font must have a minimum type size of at least 8-point font and must not be any smaller than the size of the required net quantity of contents declaration.[xiv]

For foods sold from bulk containers, which do not have a principal display panel, FDA proposes that the labeling display the Nutrition Info box plainly in view of the customer at the point of purchase, an approach that is more prescriptive than currently required for the NFP.[xv] FDA specifically invites comments on this approach.

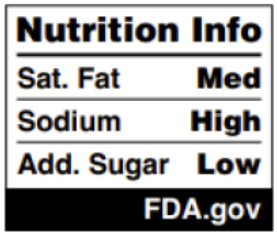
ALTERNATIVE FORMATS

FDA has also provided several alternative formats for the Nutrition Info box.[xvi] FDA has stated that manufacturers may voluntarily include a calorie statement on the FOP (e.g., to comply with vending machine calorie labeling requirements at 21 C.F.R. § 101.8(c)(2)(ii)):

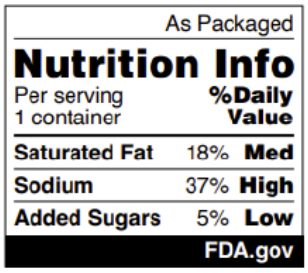




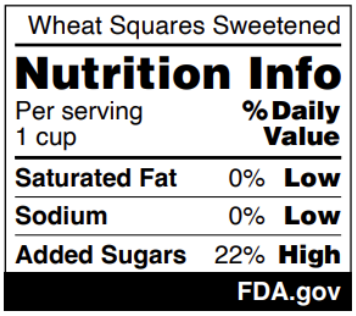
Additionally, for intermediate-sized food packages (40 or fewer square inches available to bear labeling), a condensed version of the Nutrition Info box can be used:

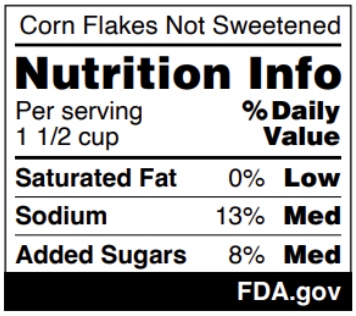


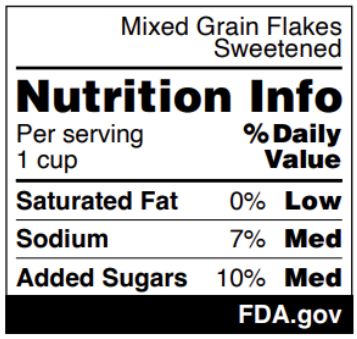
There is also an option for a Nutrition Info box reflecting "as packaged" nutrition information for products presenting a dual-column Nutrition Facts label that shows "as packaged" and "as prepared" nutrition information:



Finally, for products that use an aggregate display for the Nutrition Facts label (i.e., products that contain two or more separately packaged foods intended to be eaten individually), FDA has proposed the following format:







PROPOSED EXEMPTIONS

A Nutrition Info box would be required for all foods covered under 21 C.F.R. § 101.9 (nutrition labeling of food) that is marketed for people ages 4 and older, unless the food is otherwise exempt from nutrition labeling. Dietary supplements labeled in accordance with the special nutrition labeling provisions in 21 C.F.R. § 101.36 are exempt.

FDA has also proposed exemptions for:

- Food in small packages that have a total surface area available to bear labeling of less than 12 square inches, unless nutrition information, such as a claim, is presented on the label;
- Outer packaging of products marked as gifts that contain a variety or assortment of foods; and
- Unit containers in a multiunit retail food package, so long as the unit containers fall under the exemption for Nutrition Facts labeling in accordance with 21 C.F.R. § 101.9(j)(15).

CONFORMING AMENDMENTS TO NUTRIENT CONTENT CLAIM REGULATIONS

FDA has proposed certain conforming amendments to existing nutrient content claim regulations. For example, FDA is proposing adjustments to the following regulations regarding low sodium and low saturated fat nutrient content claims:

- 21 C.F.R. §§ 101.61(b)(4)(i)(A) and (b)(4)(i)(B): A food other than a meal product or main dish product may bear a low sodium nutrient content claim if a serving of the food contains 115 mg or less sodium per RACC rather than 140 mg or less sodium per RACC;
- 21 C.F.R. § 101.61(b)(5)(i): Meal products and main dish products may bear a low sodium nutrient content claim if a serving of the food contains 115 mg or less sodium per 100 g rather than 140 mg or less sodium per 100 g; and
- 21 C.F.R. §§ 101.61(b)(4) and (5) and 101.62(c)(2) and (3): Food subject to the proposed rule would be required to display ‘‘Low’’ in accordance with 21 C.F.R. § 101.6 for sodium or saturated fat in the Nutrition Info box to qualify for a low sodium or low saturated fat nutrient content claim, respectively.

PREEMPTION

The proposed rule contains an express preemption provision in 21 C.F.R. § 101.6(d) stating that “a State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this section for the Nutrition Info box.” Notably, FDA recognizes in the preamble to the proposed rule that preemption also may arise “regarding other FOP nutrition labeling if a state requirement is found to obstruct the federal purpose articulated in this rule.”[xvii]

COMPLIANCE DATE

The proposed rule, if finalized, would establish a compliance date of three years after the final rule’s effective date for businesses with $10 million or more in annual food sales, and a compliance date of four years after the effective date for businesses with less than $10 million in annual food sales.

KEY CONSIDERATIONS

The proposed rule was issued shortly before the change in Administration, and it is unclear if finalizing the proposed rule will be a top priority for new political leadership in the Administration, HHS, and FDA. However, as detailed above, the proposed rule reflects a milestone almost two decades in the making. The concept of FOP nutrition labeling is commonplace internationally and has garnered bipartisan interest in the U.S. at various points throughout the years. Given this history, and a current national focus on issues related to health, nutrition, and addressing the rise in diet-related chronic diseases, the topic of FOP nutrition labeling is likely to retain momentum. Accordingly, interested stakeholders are encouraged to review and comment on the proposed rule to FDA. Comments can be submitted to the docket (Docket No. FDA-2024-N-2910) until May 16, 2025.

FDA's preliminary estimate of economic impacts of the rule anticipates costs to implement the rule, over ten years, to be $3.2 billion (undiscounted), reflecting $1 billion in relabeling costs and $2.2 billion in reformulation costs which, although voluntary, are an anticipated effect of the proposed High/Med/Low interpretive scheme. To the extent that stakeholders have information relevant to FDA's estimate of the costs and benefits of the proposed rule, these comments would also help inform the contours of any final rule.

Finally, it is worth considering the details of any FOP nutrition labeling requirement in the broader context of other information that food packages may contain about the relative healthfulness of products. For instance, only a few weeks prior to releasing the FOP proposed rule, FDA also issued a final rule updating the definition of the implied nutrient content claim "healthy."[xviii] While manufacturers' use of this claim is voluntary, FDA also championed this effort as a means for consumers to identify healthier food choices at a quick glance. The agency is also exploring development of a "healthy" symbol, and is presumably still considering finalizing its draft guidance on the use of Dietary Guidance Statements (e.g., "Make half your grains whole grain") on food packages.[xix] It will be important for stakeholders and the agency to further consider how the details of a mandatory FOP nutrition labeling scheme are complementary to, and not in competition with, these and other messages to consumers.

For nearly a century, King & Spalding has been on the front lines of nearly every major issue affecting the food and beverage industry, helping clients understand how these issues can affect their businesses, and identify the best path to achieve their objectives. For questions about how this proposed rule may affect your products, please contact the authors of this article or your King & Spalding contact.

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[i] 90 Fed. Reg. 5426 (Jan. 16, 2025).

[ii] *Id*. at 5428.

[iii] *Id.* at 5427.

[iv] *Id.* at 5430.

[v] *See* FDA, Letter of Enforcement Discretion to GMA/FMI re "Facts Up Front" (Dec. 13, 2011), https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/letter-enforcement-discretion-gmafmi-re-facts-front (accessed Jan. 27, 2025).

[vi] *See* University of North Carolina-Chapel Hill, "Front-of-Package Labels Around the World," Global Food Resource Program (2023), GFRP-UNC_FOPL_maps_2023_02.pdf (accessed Jan. 27, 2025).

[vii] H. Appropriations Comm., 111th Cong., "Omnibus Appropriations Act, 2009 (H.R. 1105; Public Law 111-8): Division F—Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009," at 1398 (Comm. Print 2000), https://www.govinfo.gov/content/pkg/CPRT-111JPRT47494/pdf/CPRT-111JPRT47494-DivisionF.pdf (accessed Jan. 27, 2025); H.R. Rep. No. 111-366, at 1021 (2009) (Conf. Rep.), https://www.govinfo.gov/content/pkg/CRPT-111hrpt366/pdf/CRPT-111hrpt366.pdf (accessed Jan. 27, 2025).

[viii] Citizen Petition from Center for Science in the Public Interest, the Association of SNAP Nutrition Education Administrators, and the Association of State Public Health Nutritionists, FDA-2022-P-1832 (Aug. 5, 2022), https://www.regulations.gov/document/FDA-2022-P-1832-0001 (accessed Jan. 27, 2025).

[ix] *See* What Is the FDA Doing to Reduce the Diabetes and Obesity Epidemics in America and Take on the Greed of the Food and Beverage Industry?, 118th Cong. (2024), https://www.help.senate.gov/hearings/what-is-the-fda-doing-to-reduce-the-diabetes-and-obesity-epidemics-in-america-and-take-on-the-greed-of-the-food-and-beverage-industry (accessed Jan. 27, 2025).

[x] 90 Fed. Reg. at 5432.

[xi] *Id*. at 5433.

[xii] *Id*. at 5441.

[xiii] *Id*. at 5445.

[xiv] *Id.* at 5446.

[xv] *Id*. at 5452.

[xvi] *See* FDA, Examples of FDA Proposed Nutrition Info Boxes, https://www.fda.gov/media/185015/download?attachment (accessed Jan. 27, 2025).

[xvii] 90 Fed. Reg. at 5457.

[xviii] 89 Fed. Reg. 106,064 (Dec. 27, 2024).

[xix] 88 Fed. Reg. 39,256 (June 15, 2023); FDA, Draft Guidance for Industry: Questions and Answers About Dietary Guidance Statements in Food Labeling (Mar. 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-about-dietary-guidance-statements-food-labeling.