It’s More than a New Graphic: How the New Nutrition Facts Panel Can Impact a Food’s Labeling, Marketing and Formulation

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Guide to U.S. Food Labeling Law

August 11, 2020 at 04:58 PM EST

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The Nutrition Facts panel has become the ubiquitous part of a food's label in the United States over its 36-year history. The panel was designed to educate consumers so that they can make informed food selections based on a food's nutritional profile.

Now that the FDA has overhauled the nutrition labeling regulations for the first time, a food company must not only recognize that this is not just a technical revision, but also appreciate how the overhaul impacts the food's labeling, marketing, and even formulations.

To explore how the nutrition labeling changes can affect a food, we have selected three major revisions: (1) the nutrients required to be declared, (2) the Reference Daily Intake (RDI) and Daily Reference Value (DRV) for a nutrient, and (3) the Reference Amount Customarily Consumed (RACC) and serving size for a food.

We first summarize these changes and their impact. We then explore how the changes can impact Nutrient Content Claims (NCC) and Health Claims, other labeling claims, label design and formatting, and product formulation. Finally, we offer comments about future FDA revisions and non-FDA (litigation) considerations.

The first compliance date for the changes (Jan. 1, 2020) has come and gone for larger manufacturers, but these considerations are still important as companies verify their compliance with the new requirements and as they develop new products or rebrand existing ones.

I. Overview of Several Changes to Nutrition Labeling

A. Changes to Which Nutrients Are Required To Be Declared

While the new Nutrition Facts panel still has the same number of required nutrients, the FDA has swapped out three of them. Calories from Fat, Vitamin A and Vitamin C are no longer mandatory nutrients. They have been replaced by Vitamin D, Potassium and Added Sugars (21 C.F.R. §101.9(c)). Vitamin A and Vitamin C still may be voluntarily declared, but Calories from Fat is entirely gone and may no longer be declared.

When adding these three newly required nutrients to its Nutrition Facts labeling, a company should review its records to determine if it knows the quantity of Vitamin D, Potassium and Added Sugars in its foods. If it does not, for Vitamin D and Potassium, this can be readily determined through testing. However, depending on a food's composition, the Added Sugars declaration may require more work because of the nutrient's definition.

Beyond package sugars, Added Sugars are sugars added during food processing that are:

1. free, mono and disaccharide sugars (like sugar or fructose);
2. sugars from honey and syrups (like maple syrup or molasses); or
3. sugars from concentrated fruit or vegetable juices that have sugar in excess of what would be expected from 100 percent fruit or vegetable juice (21 C.F.R. §101.9(c)(6)(iii)).

Because not every sugar is an Added Sugar, a company assessing this declaration must analyze the food's formulation accordingly. If all the sugars in a food are Added Sugars, testing alone can be used to determine the quantity. However, when the food contains both naturally occurring sugars and Added Sugars, a company must create and maintain appropriate formulation and manufacturing records for the Added Sugars declaration.

Although Dietary Fiber is not a new nutrient, the FDA's updated regulations now define it as "nondigestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic nondigestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health" (21 C.F.R. §101.9(c)(6)(i)).

As such, isolated and synthetic nondigestible carbohydrates cannot be included in the dietary fiber quantity unless the FDA has determined that they provide a physiological effect that benefits health. If a company's food includes a mixture of recognized dietary fiber and non-dietary fibers, the company must maintain appropriate records to support the dietary fiber declaration. Therefore, the formulation of a dietary declaration must include assessing whether any or all of the "dietary fiber" meets the new definition and then declaring the compliant Dietary Fiber accordingly.

B. Changes to the RDI and DRV Values

The FDA has also updated the RDI and DRV for several nutrients (21 C.F.R. §101.9(c)(8)(iv), (9)). For example:

Nutrient	Old DRV	New DRV
Total Fat	65g	78g
Total Carbohydrate	300g	275g
Dietary Fiber	25g	28g
Sodium	2,400mg	2,300mg
Potassium	3,500mg	4,700mg
Vitamin C	60mg	90mg
Calcium	1,000mg	1,300mg

With the new RDI and DRV specifications, the daily value calculations must be verified because they may have changed. For example, if a food contains 360mg of sodium per serving, the old daily value was 15%, but now the daily value must be declared as 16% because the new value of 15.6% is rounded up under the regulations (21 C.F.R. §101.9(c)(7)(ii)).

Also, the FDA has changed the unit for several nutrients. For example, Vitamins A and D must now be declared in micrograms (mcg) instead of international units (IU). Thus, a company cannot simply copy over the old quantity declaration onto its new label, because the units will be wrong. Rather, a company must convert the old units to the new ones.

C. Changes to the Reference Amount Customarily Consumed and Serving Size

To determine a food's serving size, the analysis begins with the RACC specified in the regulations. Under the new regulations, the FDA has revised the RACC for several categories and established some entirely new ones (21 C.F.R. §101.12(b)). For example:

Category	Old RACC	New RACC
Other Candy	40g	30g
Bagels (grouped with others) (thin bagels are classified separately as "Breads (excluding sweet quick type), rolls")	55g	110g
Breakfast cereal	30g	40g
Ice cream	½ cup	2/3 cups
Muffins	55g	110g

Soda	8 fl oz	12 fl oz

Although the serving size is still determined by the relation between the RACC and the food's packaging, companies have lost some flexibility in declaring how many servings a package contains.

For example, a brownie has a RACC of 40g. If the brownie is packaged in an individual unit between 67% and 200% of the RACC (26.8g to 80g), the serving size is the whole brownie (21 C.F.R. §101.9(b)(2)(i)). Gone is the company's discretion to choose if the serving is 1 or 2 brownies when a package has >150% but <200% of the RACC.

The new regulations also have instituted a mandatory dual column format for a larger package with 200% to 300% of the RACC (for example, a brownie with a RACC of 80g to 120g) (21 C.F.R. §101.9(b)(2)(i), 21 C.F.R. §101.9(b)(12)(i)). Under the dual column format, one column lists the nutrient facts per serving (defined as the RACC), and the other lists the nutrients per package.

To comply with these new regulations, a company must assess each food and all of its packaging forms. The company must verify whether the product's RACC has changed, even if the change is relatively small. Furthermore, even if there are no changes to the RACC, a company must also verify that the serving size for each packaging is compliant

II. Impact of the Changes to the Nutrition Labeling

A. Availability of Nutrient Content Claims and Health Claims

The FDA did not modify the regulations for NCCs or Health Claims when it updated the nutrition labeling requirements. However, the changes in RACC and serving size, required nutrients and daily values can impact whether a food may qualify for an NCC or Health Claim. This was a fact acknowledged by the FDA when it established the new nutrition regulations.

With these changes, a food that once qualified for a claim may not anymore, or a food may now qualify although it previously did not. For example, for a food to make a “good source” claim, the RACC for the food must contain 10% to 19% of a nutrient’s daily value (21 C.F.R. §101.54(c)). The RACC for a beverage has increased from 8 fl oz to 12 fl oz. Thus, if a beverage had 90mg of calcium per 8 fl oz, previously it could not make a “good source” claim because it had only 9% of the daily value. Under the new regulations, the product has 135mg per 12 fl oz, which is 10% of the daily value, thereby qualifying the beverage for the claim.

However, a food can also lose its ability to make an NCC. For example, if a snack food had 8mg of Vitamin C per the RACC (30g), which is 13% daily value under the old regulation, it was eligible for a “good source” NCC. However, now that the RDI for Vitamin C has increased from 60mg to 90mg, the same snack can no longer include the “good source” NCC, because it has only 9% daily value per RACC.

B. Other Claims

Foods labels sometimes include claims beyond nutritional or health claims that are also impacted by the serving size. These claims usually relate to the quantity of a valuable ingredient or constituent — for example, “Xmg of caffeine per serving” or “X cups of juice per serving.” In those examples, if the serving size changes, the claim needs to be modified accordingly.

C. Label Design and Formatting

A food label has limited space in which to include the required information and any desired marketing claims while also presenting a brand identity. Depending on the product, that space is becoming more valuable as market demands incentivize goals like less packaging material and smaller net quantities (for example, single-serve containers) that result in less labeling space. As such, changes to the nutrition labeling regulations can impact label design and formatting in several ways.

Nutrition Facts panel size: Depending on the food, its packaging and its claims, the Nutrition Facts panel may now take up more labeling space. The most obvious new demand is the dual column format required for some foods. But claims on the food's labeling are another important consideration. For example, many food labels include NCCs related to Vitamin C content (such as "High in Vitamin C"). Previously, Vitamin C was a required nutrient, and the claim did not require any additional space in the Nutrition Facts panel. However, to retain the claim under the new regulations, the Nutrition Facts panel will need more space, because an NCC related to Vitamin C content now requires Vitamin C to be included alongside the mandatory nutrients.

***Additional Statements with NCCs*:** The change in the RACC for some foods may require a nutrient disclosure statement — the disclosure required when a food includes an NCC but has too much of a "bad" nutrient. For example, previously if a large muffin's label included a "good source of Vitamin C" claim, it did not require a disclosure statement, because the saturated fat content was below 4.0g per the muffin's RACC (55g). However, because the RACC for a muffin has increased from 55g to 110g (21 C.F.R. §101.12(b)), the large muffin now has more than 4.0g of saturated fat per RACC. Thus, under the new regulations, the label must include a saturated fat disclosure ("see nutrition information for saturated fat content"). Not only does this disclaimer take up labeling space; it is generally unattractive as well.

D. Formulation

Foods are increasingly formulated and packaged to meet certain marketing goals, such as "100 calories per serving," "low fat" or "high potassium." The changes in serving sizes, RDI and DRVs can individually or collectively impact whether a food's marketing goals are satisfied. As discussed above, the increase in the muffin serving size could result in a "low fat" muffin no longer satisfying such a claim.

Similarly, the Added Sugars declaration brings consumer attention to the product's added, nonnutritive sugar content, which is considered to be a "bad" nutrient. Previously, the FDA singled out another "bad" nutrient — trans fat — to help consumers lower their consumption of the substance. This ultimately resulted in food companies reformulating their foods to have less of this nutrient. Much as with trans fat, the FDA hopes that calling out Added Sugars will incentivize companies to reformulate their products to have less nonnutritive sugars.

III. Additional Considerations

A. Future FDA Changes

Although the FDA did not update the NCC regulations, the agency indicated that revisions to the NCC rules are likely in the future. The FDA has already been working to revise the implied NCC of "healthy," because the regulation no longer reflects current nutritional science. We can reasonably anticipate that the agency will update the disclosure requirement for the claim to incorporate either total sugar or added sugars as a consideration for deeming a food to be "healthy."

Given that previously a disclosure was required when a food contained 20% or more of the "bad" nutrient per RACC (21 C.F.R. §101.13(h)(1)), the levels for a "healthy" NCC would be as follows, assuming that the FDA continues that rule:

Nutrients	Anticipated Disclosure Level
Total Fat	15.6g
Saturated Fat	4g (the same)
Cholesterol	60g (the same)
Sodium	460mg

Added Sugar	10g

Those responsible for the marketing, formulation and compliance of a food product should remain vigilant and plan accordingly.

B. Non-FDA Considerations

The above considerations have focused only on FDA compliance obligations. However, the past two decades have witnessed an increase in consumer lawsuits against food companies for their advertising and labeling. Currently, sugar content is a litigation focus, with cases involving claims about a food's sweetness level ("lightly sweetened") or portrayals of foods as being wholesome or healthy (not necessarily the "healthy" NCC, but giving a general sense of promoting health).

Any review of food product labeling needs to consider a food's nutritional profile as it relates to current nutritional science, societal expectations and litigation trends. Litigation issues change more frequently than FDA regulations — a fact that calls for ongoing and vigilant reevaluation of products' advertising and labeling.

IV. Concluding Thoughts

The changes to the nutrition labeling are not merely technical amendments. They can affect a food's identity due to the changes' potential impact on labeling, marketing and formulation. As such, these changes need to be appreciated by a company's marketing and product development staff, as well as its regulatory compliance personnel. Having the staffs work together will help develop not only a compliant label, but also a product that fits within the company's branding and marketing objectives.