The Proposed Nutrition Label: 10 Tips for Assessing Change

By Steven B. Steinborn and Veronica Colas

For the first time in over 20 years, the Food and Drug Administration (FDA) is proposing major revisions to the nutrition facts panel (NFP) that appears on nearly every label of packaged food. Although it is anyone's guess what shape the finals rule will take, gaining an understanding now of the proposals and the potential impact on how food companies communicate with consumers via the food label is vital to long-term regulatory success.

In March 2014, FDA unveiled two proposed rules that would make significant changes to the nutrition labeling and serving size regulations. Importantly, no label changes will be required until at least two years after the effective date of the final rule.[1] The proposed changes are technical and require great attention to detail. Beyond submitting comments to FDA, savvy companies are well-served by formulating the right questions and evaluating the answers carefully. Regulatory success means understanding how the proposed changes could impact brands and specific products and planning accordingly. To assist, we have developed the "Top 10 Self-Assessment Questions" to help companies assess the likely impact of the new requirements across their product portfolio.[2]

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1. Would any of your products now labeled as two servings be required to be labeled as one serving?

FDA is proposing to amend the definition of a single-serving container so that all containers with less than 200 percent of the reference amount customarily consumed (RACC) would be labeled as "1 serving." This would remove the current flexibility for products with a RACC of 100 g or 100 mL or larger, under which manufacturers may decide whether a package with 150 to 200 percent of the RACC will be labeled as one or two servings.

2. Would your products be affected by the proposed expansion of dual column labeling?

Under the proposed rule, any containers with between 200 and 400 percent of the applicable RACC would require dual-column labeling on a per serving and per container basis. Only a few categories of products falling within the relevant range would be exempt.[3] At present, dual column labeling is only allowed in a few instances specified by regulation (e.g., on an "as packaged" and "as prepared" basis). The vast majority of products contain a single column showing nutritional values on a per serving basis. Beyond requiring more label space, consider what impact dual-column labeling will have in terms of how consumers understand the NFP and the role of foods labeled with a dual column in the total diet.

The amount of information that must be included in the second column, and in what format, is uncertain. Under the option proposed by the agency, both quantitative amounts and percent daily values (DVs) would be declared for each column. Under the two alternative formats FDA is considering, only certain nutrients (i.e., calories; or calories, saturated fat, and sodium) would need to be declared on a dual-column basis with the remaining information listed on a per serving basis in a single column.

3. Would the RACC for any of your products change?

FDA requires food companies to determine the stated serving size for purposes of nutrition labeling based on the applicable RACC. The proposal includes a number of changes to the current RACCs based on updated consumption data. These changes could have a direct impact on the nutritional values declared on the Nutrition Facts panel. Examples of proposed changes include:

- Increasing the RACC for "Beverages: Carbonated and noncarbonated beverages, wine coolers, water"; and "Beverages: Coffee or tea, flavored and sweetened" from 240 mL to 360 mL;
- Decreasing the RACC for "Yogurt" from 225 g to 170 g; and
- Revising the RACC for "Ice Cream, Bulk" from ½ cup to 1 cup.

The agency would also establish new RACC categories or add new foods to existing RACC categories. In some cases, the proposed changes would result in changes to the number of labeled serving sizes. For example, ice cream in a 1 pint container is currently declared as 4 servings but would now contain 2 servings. In contrast, yogurt in a 24 oz container currently contains 3 servings and would now contain 4 servings. A change in the declared serving size would have a significant impact on the declared values for calories and other nutrition information. Companies should assess whether any of their product serving sizes would change based on the proposed changes to RACCs.

4. Would your products remain eligible for existing claims if the serving size changes?

If the serving size for any of your products would change, either in light of the proposed single-serving container definition or due to any of the proposed RACC changes, the next question to ask is whether your products would still qualify for existing nutrient content claims or other claims; or would be eligible for any additional claims. For example, to revisit the proposed changes for ice cream, if FDA finalizes the proposed increase in RACC and corresponding increase in serving size, most pints of ice creams would become eligible for a "good source of calcium" claim, but some low fat ice creams may no longer qualify for a "low fat" claim as the declared amount of fat would double.

5. Will existing nutrient content claims be required to include proposed explanatory statements?

For products that would be subject to the proposed dual column labeling requirements, FDA has stated that nutrient content claims would need to clarify for consumers whether the claim is made on the basis of the RACC or the container. If a product does not qualify for the claim on a "per container" basis, the claim would need to include language explaining that the claim is made on a "per serving" basis only. FDA gives the following example of the explanatory language: "good source of calcium"; "a serving of __ oz of this product contains 150 mg of calcium." In the specified circumstances the proposal would significantly lengthen what are

now simple claims (e.g., "good source of calcium," "low fat").

6. Would your products be disqualified from making existing nutrient content claims due to proposed changes to percent DVs?

FDA has proposed to update many of the daily reference values (DRVs) and reference daily intakes (RDIs) based on current dietary recommendations. For example, the DRV for sodium would decrease from 2,400 mg to 2,300 mg. The percent daily values (DVs) for fiber and calcium would increase from 25 to 28 g, and 1,000 to 1,300 mg, respectively. Nutrient content claims such as "good source" and "excellent source" are tied to the percent DV. Proposed changes to the DVs could mean that some products that currently qualify for a "good source" of fiber or calcium claim, for example, may no longer qualify. Nearly every percent DV would change slightly, so companies should review the full proposed rule and evaluate products that currently bear claims tied to a DV.

7. Would your declared values for fiber or claims regarding fiber change based on the proposed more restrictive definition of fiber?

In addition to the proposed increase to the percent DV for dietary fiber, FDA would also define the term "dietary fiber" in a way that restricts the ability to count certain added fibers towards the declared value. Specifically, the term dietary fiber would include naturally occurring fibers (i.e., non-digestible carbohydrates and lignin that are intrinsic and intact in plants), as well as those added fibers that have been determined by FDA to have a physiological effect that is beneficial to human health. This effect can be established either by virtue of an FDA-authorized health claim, such as those for beta-glucan soluble fiber or barley beta-fiber; or by submitting a petition to the agency regarding the beneficial effects of the fiber source.

If finalized, this provision would mean that added fiber sources could not be counted as dietary fiber unless pre-authorized by FDA. Companies should assess whether fiber claims and declarations could be maintained under this proposed definition. If not, products would have to be reformulated or the fiber claim would need to be removed from the food label.

8. Do your products contain "added sugars" that, for the first time, would be included in the Nutrition Facts panel (if the proposed rule is finalized as written)?

One of the most significant elements of the proposed rule is the addition of added sugars as a mandatory nutrient to declare. FDA would define added sugar as "sugars that are either added during the process of foods or are packaged as such." FDA recognizes that no reliable analytical methods exist to distinguish between added and intrinsic sugars in foods, and therefore proposes that the amount of added sugars must be verified through maintenance and review of records. The agency does not prescribe the specific types of records that must be maintained, but states that the manufacturer will be in the best position to know which of its records substantiate the declared values.

9. If the "added sugar" requirement is adopted, along with recordkeeping requirements for other nutrients that lack a valid analytical method, will you be able to document and substantiate for FDA the levels of those nutrients in your products?

Aside from the threshold questions of whether FDA should require added sugars to be declared on the label and what should count as "added sugar," if this provision is finalized, industry will need to assess its ability to accurately measure and document the amount of sugars added to foods during processing. These types of records would also be required for other nutrients for which there is no reliable analytical method, including (1) added fiber that does not meet the proposed definition of dietary fiber, (2) added sugars that undergo fermentation, (3) Vitamin E (when a food contains both *RRR*-α-tocopherol and all *rac*-α-tocopherol acetate), and (4) folate (when a food contains both folate and folic acid). Companies should determine the extent to which these values can be measured and documented for specific products, whether additional information would be needed from suppliers, and what other challenges should be addressed.

10. Is information on potassium and vitamin D content, and quantitative values for vitamins and minerals generally, currently available?

In place of Vitamins A and C, FDA is proposing to require the mandatory declaration of potassium and Vitamin D, which the agency finds are nutrients of public health significance. Companies should assess whether they currently have access to information on the potassium and vitamin D content of their foods or ingredients, or whether such information would need to be specifically requested from suppliers and the amount of time needed to obtain that information.

FDA also proposes to require quantitative declarations for vitamins and

minerals (e.g., "90 mg" and "100% DV" Vitamin C instead of simply "100% DV"). It would be prudent to evaluate whether this information is readily available for vitamins and minerals. If not, consider how this information can be obtained in an efficient and reliable manner.

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The final rules are more than a year away and FDA will allow several years for companies to implement the requirements before enforcement begins. Food companies can readily get a sense of the likely impact now by taking an inventory of their products and label claims. Preparing for the sweeping changes contemplated by the proposed rules will position companies well to understand and respond to the final rules once published. Planning ahead is crucial to regulatory, and ultimately business, success.

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1. FDA has proposed a compliance date of two years after the effective date, which is 60 days after the final rule is published in the *Federal Register*. The agency has requested comments on this compliance period.
2. The proposed rule also includes requirements for the Supplements Facts Label and for foods for children under 4 years and pregnant and lactating women. These provisions are outside the scope of this Article.
3. Proposed exemptions include: bulk products used as ingredients or for multi-purposes (e.g., flour, sweeteners, shortenings, oil, eggs, butter, margarine); multipurpose baking mixes; labels that qualify for the tabular or linear NFP format; and products that require further preparation or are commonly consumed in combination with other foods and voluntarily use two columns, such as macaroni and cheese kits, pancake mixes, and cereal and skim milk.