

by Neil H. Mermelstein

Gearing up for New Nutrition Labels

Nutrition labeling of foods and beverages has been required in the United States since 1994 and Canada since 2007. The products bear the familiar Nutrition Facts label with slight differences by country. The Nutrition Facts label was followed several years later by a similar Supplement Facts label on dietary supplements. Earlier this year, the U.S. Food and Drug Administration (FDA) and Health Canada decided that the labels were due for updating to help consumers make better food choices.

FDA Labeling Proposals

In the March 3, 2014, *Federal Register*, the FDA proposed two rules to update the labeling regulations: a labeling proposal and a serving-size proposal. In the labeling proposal, "Food Labeling: Revision of the Nutrition and Supplement Facts Labels," the FDA proposed, among other things, to update the list of nutrients required or permitted to be declared; update the Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs); and revise the format of the Nutrition Facts label. In the serving-size proposal, "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments," the agency proposed, among other things, to amend the definition of a

single-serving container; require dual-column labeling for certain containers; update several reference amounts customarily consumed (RACCs); and add RACCs for several food products and categories.

The deadline for comments on both proposals was initially June

The FDA proposed an effective date of 60 days after publication of a final rule in the Federal Register and a compliance date two years later to give industry time to analyze products.

2, 2014, but was extended to August 1, 2014. Dani Schor of the FDA's communications and public engagement staff said that the labeling proposal received 287,874 comments and the serving-size proposal received 558 comments but noted that some of the comments may be duplicates. She said that although the agency does not have specific numbers, the topics of greatest interest included added sugars, the label format, and dietary fiber. The FDA proposed an effective date of 60 days after publication of a final rule in the *Federal Register* and a compliance date two years later to give industry time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the labels, and print new labels. Schor said that the agency is analyzing the comments received but has no estimate for when a final rule will be issued.

The FDA estimated that the two proposals taken together would affect about 27,890

manufacturers or packagers, would require about 345,241 products to be relabeled, and would cost \$2,873 per universal product code for a total estimated capital cost of \$992 million. The benefits, the agency said, would far outweigh the costs: the one-time cost to the industry of labeling,

Amount Per Serving	
Calories 230	Calories from Fat 72
% Daily Value*	
Total Fat 8g	12%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	12%
Dietary Fiber 4g	16%
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g

This is the current Nutrition Facts label.

Gearing up for New Nutrition Labels continued...

PROPOSED LABEL / WHAT'S DIFFERENT

Servings:
larger,
bolder type

Updated Daily Values

% DV comes first

New: added sugars

Change of nutrients required

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per 2/3 cup	
Calories	230
% DV*	
12%	Total Fat 8g
5%	Saturated Fat 1g
	Trans Fat 0g
0%	Cholesterol 0mg
7%	Sodium 180mg
12%	Total Carbs 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	Vitamin D 2mcg
20%	Calcium 260mg
45%	Iron 8mg
5%	Potassium 235mg


* Footnote on Daily Values (DV) and calories reference to be inserted here.

Serving sizes updated

Calories: larger type

Actual amounts declared

New footnote to come



This is the proposed Nutrition Facts label.

reformulating, and initial recordkeeping would be \$2.3 billion, but the cumulative benefits over 20 years would be \$21.1 billion to \$31.4 billion. The following are brief descriptions of some of the proposed changes to the Nutrition Facts label. Some of the changes also apply to the Supplement Facts label.

- Including the declaration of “Added Sugars,” indented beneath “Sugars” on the label so that consumers can easily determine the amount of sugars added to a product. The FDA said that many experts recommend consuming fewer calories from added sugar because it can decrease the intake of nutrient-rich foods while increasing calorie intake.

- Updating the daily values for such

nutrients as sodium, dietary fiber, and vitamin D. Daily values are used to calculate the percent daily value (%DV) listed on the label, which helps consumers understand the information in the context of a total daily diet.

- Changing the units for vitamins A, E, and D from international units to milligrams or micrograms and declaring the amounts of vitamins and minerals as well as the %DV.

- Requiring declaration of the amount of potassium and vitamin D because they are new nutrients of public health significance, which are under-consumed nutrients that are associated with the risk of chronic disease. Calcium and iron would continue to be required. Vitamins

A and C would no longer be required but could be included on a voluntary basis since deficiencies are uncommon.

- Removing “Calories from Fat” but continuing to require “Total Fat,” “Saturated Fat,” and “Trans Fat” on the label because research shows that the type of fat is more important than the amount.

- Changing serving-size requirements to reflect how people eat and drink today. The current serving sizes were based on reference values from surveys conducted 1977–1978 and 1987–1988. More recent data show that about 27 of the 158 current RACCs should be changed and 25 RACCs should be added. Packages containing 150%–200% of the RACCs would no longer be labeled as more than one serving. Packages containing 200%–400% of the RACC would require dual-column labeling, but packages containing more than 400% would not.

- Making calories and serving sizes more prominent to emphasize parts of the label that are important in addressing current public health concerns such as obesity, diabetes, and cardiovascular disease.

- Shifting the %DV to the left of the label to make it more prominent.

- Highlighting caloric content by increasing the type size and boldfacing the number of calories and servings per container.

- Changing the amount per serving to the amount per common household measure (e.g., amount per 1 cup).

- Changing the footnote to more clearly explain what %DV means.

The Health Canada Proposal

Nutrition labeling of foods and beverages became mandatory in Canada in December 2007. In early 2014, Health Canada asked for comments regarding ways to improve the nutrition information on food labels. As a result of the feedback received and a technical review, Health Canada conducted a pre-regulatory consultation on proposed changes to nutrition labeling with a deadline of September 11, 2014 for comments.

Health Canada’s proposal included making serving sizes more consistent among similar food products and basing

the serving sizes on the most current information on the amounts of food that Canadians actually eat in one sitting, making changes to the list of nutrients that must be declared and updating the daily values to reflect the most recent dietary recommendations, changing the way the sugar content of food is presented on the label, changing the appearance of the Nutrition Facts table and the list of ingredients, and creating an optional information box highlighting the presence of certain bioactive components, such as caffeine.

According to Sylwia Krzyszton, senior advisor, media relations, at Health Canada, the feedback received from consumers and stakeholders is being reviewed and analyzed. This feedback will be taken into consideration when developing final recommendations for proposed changes that will be published in *Canada Gazette, Part I* for further consultation. »»

This graphic illustrates the proposed changes to serving sizes.

FOOD SERVING SIZES GET A REALITY CHECK

Serving Size Changes

What's considered a single serving has changed in the decades since the original nutrition label was created. So now serving sizes will be more realistic to reflect how much people typically eat at one time.

CURRENT SERVING SIZE	PROPOSED SERVING SIZE
1 PINT (4 SERVINGS) 200 CALORIES	1 PINT (2 SERVINGS) 400 CALORIES

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Packaging Affects Servings

Package size affects how much people eat and drink. So now, for example, both 12 and 20 ounce bottles will equal 1 serving, since people typically drink both sizes in one sitting.

12 OUNCES 120 CALORIES	20 OUNCES 200 CALORIES
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1 SERVING PER BOTTLE FOR EITHER BOTTLE SIZE

Gearing up for New Nutrition Labels continued...

The FDA regularly discusses issues of mutual interest with Health Canada, including labeling, but did not consult with Health Canada in developing the FDA proposals, Schor said. Nevertheless, the proposed changes to the two labels are fairly similar, Krzyston said, particularly with respect to the scientific update.

Software Companies Gear Up

Ever since nutrition labeling began, companies have been offering software programs that can prepare Nutrition Facts labels and help develop formulations that provide the desired values for presentation on the label. How are some of these companies preparing for the issuance of final nutrition labeling regulations?

- **Axxya Systems.** Shazia Nathoo (snathoo@axxya.com), chief executive officer at Axxya Systems, Redmond, Wash. (www.nutritionistpro.com), said

that the company is participating in various industry conferences and speaking with industry leaders about the new labeling rules to determine the changes needed in its *Nutritionist Pro*[™] food labeling and formulation software to accommodate its clients. The company, she said, will continue to stay abreast of the new guidelines and as soon as the final rules are issued will make the necessary changes. The company offers its clients two software updates per year but will offer an earlier release as soon as the changes are put into effect.

The software has been on the market since the 1980s, she said, and has gone through several labeling changes. So changing the software is not challenging, but it will involve changes to each label to accommodate the new format. The proposed regulations may require some reformulations and more processes for record keeping, she said, and efforts

must also be made to make sure that consumers are able to understand and use the label correctly.

- **ESHA Research.** Elizabeth Braithwaite, research and content manager at ESHA Research, Salem, Ore. (www.esharesearch.com), said that more than 80% of the top 100 food manufacturers in the United States, as well as many consultants and laboratories, have used ESHA's *Genesis*[®] R&D food formulation and labeling software to produce Nutrition Facts labels. She said that the company is following the proposed regulations closely and its highest priority is to implement the final rules in the software. Once the program has been updated, current customers will need to install the new version of the program. In the meantime, the company has added the proposed label format to the current program so customers can compare the old and new labeling formats. ESHA will

update its software to accommodate changes in Canadian labeling regulations as well. Braithwaite said that she does not see major problems in the software implementation but that one of the challenges for manufacturers will be deciding whether to reformulate their products to maintain health and nutrient content claims and make their products more attractive to consumers.

• **FoodCalc.** Lucy Logan, chief executive officer of FoodCalc, San Francisco, Calif. (www.foodcalc.com), said that the company is waiting for the regulations to be finalized before revising its *LabelCalc* nutrition labeling software. The company has been working behind the scenes with the old label format and the proposed format but will wait until the final regulations are issued to make final changes to the platform. Since the software is Web-based, she said, changes can be made within 24 hours, as occurred with changes to labeling regulations in previous years. All feature changes are made ahead of time and tested with focus groups to ensure proper usability. The company has a set protocol for making changes to its platform, which begins with initial programming changes made and tested in house and then presented to high-usage clients for feedback and any necessary further changes before issuing the revised software to its clients. This same process will be followed with the new label changes.

The tricky part of the proposed regulations, Logan said, relates to added sugars. The company has gone through its ingredients database to highlight in color those that might be considered added sugars. Upon logging in, the customer receives a notice that the following recipes may need to be updated.

When asked how the company will offer the revised software to existing customers, she said that it would already be there when customers log in. There will be a welcome screen highlighting what changes have occurred and what's different. They won't have to reinstall or repurchase the software.

• **Owl Software.** Ann M. Roland, vice president of Owl Software, Crownsville, Md. (www.owlsoft.com), said that the company's *TechWizard*[™] nutrition

Advice from Symposium Speakers

Speakers at the June 2014 IFT Annual Meeting symposium "Anticipating FDA Proposed Changes to Nutrition Facts Labels: Implications for Foods Marketed in the U.S." reviewed the proposals and offered advice to food manufacturers.

Robert C. Post, senior director, nutrition and regulatory affairs, Chobani, said that food manufacturers will need to be ready to explain to consumers the differences in their current and future food labels and will need to translate the science that supports the changes into strategies that ensure continued marketability of their products. He said that the proposals provide a historic opportunity for companies to recalibrate what they say about their products. He described what he called the CLEAR approach to marketing communication: C for creativity (showcase product superiorities), L for language (use positive words), E for emotion (translate science into a consumer-motivating emotion to drive demand), A for advantage (emphasize added value), and R for rationale (develop and maintain a sound-science basis for marketing communications).

Victor L. Fulgoni, senior vice president, Nutrition Impact LLC, described the National Health and Nutrition Examination Survey

(NHANES) and discussed how current dietary information obtained from it can be used in addressing issues with the proposed nutrition labeling changes. These include redefining RACCs, modeling formulation changes that may be needed to maintain current claims with possible changes to Daily Values, and modeling the potential impact of the proposed labeling changes on intake of nutrients such as sodium. NHANES is a continuous survey with data released on about 10,000 individuals in the United States every two years. The FDA used 2003–2008 data for assessment of current intake of foods in reassessing the RACCs, he said, but more current data (2009–2010) are available, and newer data (2011–2012) will probably also be available before a final rule is issued.

Elizabeth Campbell, senior advisor, EAS Consulting Group LLC, said that the proposed changes in nutrition labeling will trigger changes in most food labels, affecting current claims on packages. She described how the proposed Nutrition Facts panel differs from the current panel and said that it is important for food manufacturers to determine, among other things, how changes in Daily Values, RACCs, and serving sizes may affect their products' nutrient content and health claims.

labeling software will require a certain degree of revision to accommodate the new rules since the proposed labeling changes are far-reaching, but she doesn't see any insurmountable issues in updating the software. The software allows users to create properties and assign values to associate with ingredients and formulas, she said, so it already offers the capability to track the new proposed components such as added sugars. The greater issue is that food companies will have an added burden implementing the new rules. Roland said that the finalized label formats will be included in the software as soon as possible and clients will receive revised software.

• **SweetWARE.** David Dunetz, president of SweetWARE, Oakland, Calif. (www.sweetware.com), said that the company's *nutraCoster*[™] Professional nutrition analysis and recipe/formula

costing software will include the new formats shortly after the rules are finalized and will be available in an upcoming upgrade. He said that the changes to the software would be just a matter of presentation since the calculations are virtually the same. So on a grand scale, he said, the changes are relatively minor. Dunetz said that the main problem the proposed regulations pose with regard to nutrition labeling software is the controversial issue of including added sugars on the label. It's not something that companies can get from lab analyses, he said. It will require formulation information, and obtaining the data for inclusion in the databases will take time. **FT**



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