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Revision of the Nutrition Facts Label: Proposed Rules

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Summary

High rates of obesity and chronic diseases have prompted federal, state, and local initiatives such as exercise promotion, nutrition education, and food labeling. Nearly two-thirds of U.S. adults are overweight or obese, suggesting that consumers need to be more aware of their calorie intake. Labeling of the nutritional content of foods has been recommended by researchers and policymakers as a tool to address the obesity epidemic.

National survey data indicate that the frequency of food label use among consumers has increased in the past decade; however, despite widespread use, certain elements of the Nutrition Facts label are outdated and confusing to consumers. Consumer research highlights the importance of salient and easy-to-understand nutrition information. The purpose of the Nutrition Facts label as a public health tool is to provide consumers with nutrition information that may help them make more informed food choices. Mandating declaration of certain nutrition information on the label may also prompt food manufacturers to reformulate products to make them healthier and more attractive to consumers. Increasing awareness about the nutritional content of various foods may promote healthier eating behaviors among consumers, resulting in lower calorie intake and, over time, decreasing rates of overweight and obesity.

The Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938 authorizes the Food and Drug Administration (FDA) to regulate labeling of most food products other than meat and poultry. The Nutrition Labeling and Education Act (NLEA) of 1990 amended the FFDCA to require that most foods, with the exception of meat and poultry, bear nutrition content labels. Since its introduction in 1993, the Nutrition Facts label has undergone few changes, while nutrition science and public health research have changed significantly.

To ensure that the Nutrition Facts label remains scientifically valid and helpful to consumers, the FDA is proposing to update the label. In March 2014, FDA published two proposed rules that would amend previous labeling regulations. The first rule addresses which nutrients must be included on the label, the recommended intake of these nutrients, and the format in which the information is to be displayed. More specifically, the proposed changes include but are not limited to

- required information about “added sugars,”
- removal of “Calories from Fat,”
- required declaration of potassium and vitamin D,
- updated Daily Values for certain nutrients, and
- changed label design.

The second rule proposes to change serving sizes to more accurately reflect actual food consumption behavior in the United States. The comment period on the proposed rules ended on August 2, 2014, and the FDA is currently finalizing the rules. In July 2015, FDA issued a proposed supplemental rule that would, among other things (1) require declaration of the percent daily value (%DV) for added sugars; and (2) change the current footnote on the Nutrition Facts label, reopening a comment period for 60 days.

The estimated annual health care costs of obesity-related illness are $190.2 billion, or almost 21% of annual medical spending in the United States. Congress and the Obama Administration have shown a strong interest in developing policies to reverse the trend of rising obesity rates. The Healthy, Hunger-Free Kids Act (P.L. 111-296) addresses several nutrition-related concerns, and Section 4205 of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended)

required FDA to promulgate regulations for labeling of foods sold in some chain restaurants and vending machines (see CRS Report R42825, *Nutrition Labeling of Restaurant Menus*). Congress, consumers, food industry representatives, and federal regulators all have a stake in nutrition labeling. This report provides a brief overview of the proposed changes to the Nutrition Facts label, as well as the public health significance of these changes.

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Introduction

Nutrition labeling of foods first became a topic of discussion at the 1969 White House Conference on Food, Nutrition and Health.[1] Various recommendations intended to combat hunger in America were proposed, including providing nutrition information on food labels to inform consumers about the nutrient content of the food they were eating. In the 1970s, a voluntary nutrition labeling program was established by the Food and Drug Administration (FDA)[2] and the United States Department of Agriculture (USDA)[3] under their respective statutes; however, the nutrition label formats slightly differed between the two agencies, making comparisons among food products difficult. Despite some interagency consideration of whether the nutrition labels needed to be updated, actions on any food labeling reform stalled. In 1988, the Surgeon General's report on *Nutrition and Health*[4] was published, citing mounting evidence that dietary changes could reduce the incidence of certain chronic diseases such as heart disease, cancer, and diabetes. In 1989, the launch of an Institute of Medicine (IOM)[5] study provided an assessment of the implications of nutrition and health knowledge for food labeling, and laid out a roadmap for modifying ingredient and nutrition labeling policy.[6] That same year, the Nutrition Labeling and Education Act (NLEA) was introduced, and then signed into law on November 8, 1990 (P.L. 105-535). The Act granted FDA explicit authority to require nutrition labeling on most food packages and included provisions addressing nutrition labeling regulations, nutrient content and health claims, and uniform nutrition labeling. In 1992, FDA proposed a format for nutrition labeling, which is still being used today (see **Figure 1**).

[1] White House Conference on Food, *Nutrition and Health, Final Report*, U.S. Government Publishing Office, 1970, p. 341.

[2] U.S. Department of Health, Education, and Welfare, Food and Drug Administration, Regulation for the Enforcement of the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act, *Federal Register*, vol. 38, no. 13, Jan. 19, 1973, pp. 2124-2137 and no. 49, Mar. 14, 1973, pp. 6950-6964.

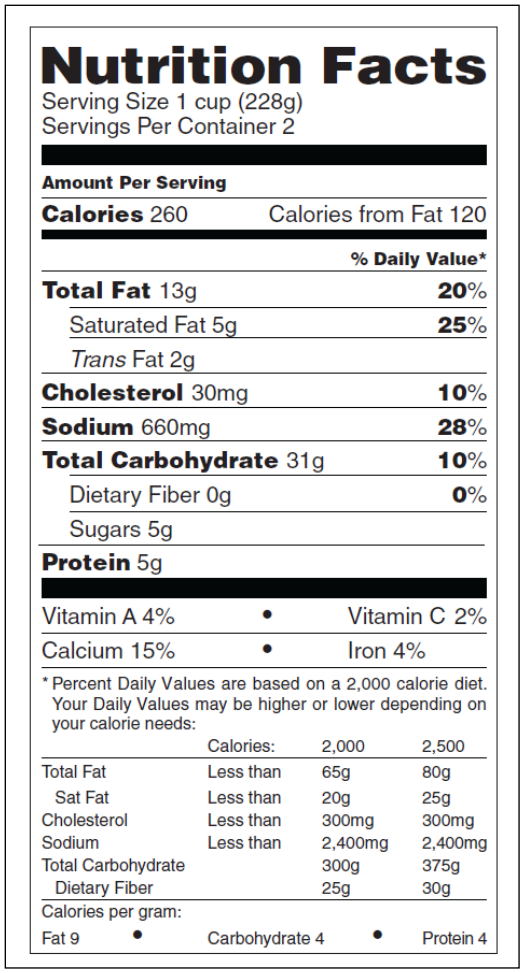
[3] USDA, FSIS Standards and Labeling Policy Book, 1986, p.172.

[4] HHS, Public Health Service, *The Surgeon General's Report on Nutrition and Health*, DHHS (PHS) Pub. No 88-50210, 1988, p. 727.

[5] The membership of the National Academy of Sciences voted to change the name of the Institutes of Medicine to the National Academy of Medicine, effective July 1, 2015.

[6] IOM, *Nutrition Labeling: Issues and Directions for 1990s*, Donna V. Porter and Robert O. Earl, eds. National Academy Press: Washington, DC, 1990, p. 355.

Figure 1. Basic Format of the Nutrition Label



Nutrition Facts
Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20**%
Saturated Fat 5g	**25**%
Trans Fat 2g	
Cholesterol 30mg	**10**%
Sodium 660mg	**28**%
Total Carbohydrate 31g	**10**%
Dietary Fiber 0g	**0**%
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values 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

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Source: 21 C.F.R. 101.9(d)(12).

Since the implementation of the NLEA, consumers have become increasingly more aware of the Nutrition Facts label. National survey data indicates that the frequency of food label use among consumers has increased in the past decade. The FDA's Health and Diet Surveys found that the percentage of consumers reporting that they "often" read a food label the first time they purchase a food product rose from 44% in 2002 to 54% in 2008.[7, 8, 9] The National Health and Nutrition Examination Survey (NHANES)[10] reported a similar increase, with the percentage of working age adults that reported using the Nutrition Facts label "always" or "most of the time" when shopping

[7] FDA, *2002 Health and Diet Survey: Topline Frequency Report*. November 2007. http:www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm202786.htm.

[8] FDA, *Health and Diet Survey: Dietary Guidelines Supplement-Report Findings (2004&2005)*, January 2008, http://www.fda.gov/downloads/Food/ScienceResearch/ResearchAreas/ConsumerResearch/UCM080413.pdf.

[9] FDA, *2008 Health and Diet Survey: Topline Frequencies*, January 1, 2010. http://www.fda.gov/food/foodscienceresearch/consumerbehaviorresearch/ucm193895.htm.

[10] The National Health and Nutrition Examination Survey (NHANES) is a program conducted as a series of surveys focusing on various population groups or health topics. NHANES is administered by the Centers for Disease Control and Prevention (CDC), and its findings are used to determine the prevalence of major diseases and risk factors for diseases. NHANES data are also used to assess nutritional status and its association with health and disease.

for food increased to 42% in 2009-2010 from 34% in 2007-2008. Among older adults the percentage increased to 57% from 51%.[11]

However, consumer research data also suggests that despite reported widespread use of food labels, certain elements of the Nutrition Facts label may need improvement. Among these elements causing confusion is the percent daily value (%DV) declaration, with the majority of consumers being unable to identify what that number means.[12]

The FDA is proposing to revise the Nutrition Facts label to both provide updated nutrition information and improve how that nutrition information is presented to consumers. The proposed changes reflect current public health concerns in the United States (i.e., growing rates of obesity and chronic disease) and correspond to new information on consumer behavior and consumption patterns.

This report describes the FDA's two proposed rules to update the Nutrition Facts label in order to provide consumers with more up-to-date nutrition information. The first rule reflects the changes in nutrition science and public health research, specifically addressing modifications to which nutrients must be listed on the label, as well as an updated design to display the new information. The second rule addresses updates to serving size and labeling requirements for specific package sizes. In July 2015, FDA issued a proposed supplemental rule that would, among other things (1) require declaration of the percent daily value (%DV) for added sugars, and (2) change the current footnote on the Nutrition Facts label. This report also discusses some of the concerns raised by industry, policymakers, and the public.

Background on Nutrient Intake and Dietary Guidance

The prevalence of obesity in the United States remains high and although there have been no significant changes in obesity between 2003-2004 and 2011-2012, one-third of adults and 17% of children are still obese.[13] Chronic diseases such as heart disease, cancer, and stroke, which are associated with obesity, are the leading causes of death and disability in the United States.[14] The 2010 Dietary Guidelines for Americans (DGA) cite the role of physical inactivity and calorie overconsumption as the primary factors contributing to the increased prevalence of overweight and obesity.[15] The DGA are evidence-based recommendations issued jointly by the USDA and Department of Health and Human Services (HHS) every five years. These recommendations are created by a committee of nationally recognized experts in the field of human nutrition and chronic disease prevention, and they provide the basis for federal food and nutrition policy, as well as nutrition education initiatives.[16] In February 2015, the 2015 Dietary Guidelines Advisory

[11] J Todd, "Changes in Eating Patterns and Diet Quality Among Working-Age Adults, 2005-10, EER-161", Washington, DC: U.S. Department of Agriculture, Economic Research Service; January 2014.

[12] L Levy, R Patterson, A Kristal, et al., "How Well Do Consumers Understand Percentage Daily Value on Food Labels?" *American Journal of Health Promotion: AJHP*, vol. 14, no. 3, (Jan-Feb 2000), pp. 157-160.

[13] C Ogden, M Carroll, and B Kit, et al., "Prevalence of Childhood and Adult Obesity in the United States, 2011-2012," *JAMA*, vol. 311, no. 8 (2014), pp. 806-814.

[14] Centers for Disease Control and Prevention, *Chronic Diseases and Health Promotion*, http://www.cdc.gov/chronicdisease/overview/index.htm.

[15] USDA and HHS, *Dietary Guidelines for Americans, 2010*, 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[16] HHS, *Questions and Answers on the 2015 Dietary Guidelines for Americans*, http://www.health.gov/

Committee (DGAC) submitted its recommendations for the 8th edition of the DGA to the Secretaries of HHS and USDA.[17] The Secretaries are to consider the DGAC's scientific recommendations, as well as comments from federal agencies and the public in the development of the final policy document.

The nature and number of recommendations issued in the final DGA policy documents have changed since the first edition of the guidelines was published in 1980. The 2010 report, for example, was different from previous reports because for the first time, it addressed an American public of which the majority was overweight or obese, yet deficient in several key nutrients. According to NHANES data, the number of calories consumed by individuals in the United States increased from an average of 1,875 calories per day in 1977-1978 to 2,067 per day in 2005-2008, an increase of 10.2%.[18] But despite growing obesity rates and caloric overconsumption, nutrient deficiencies are still prevalent in many subpopulations. According to the 2010 DGA, dietary intakes of nutrients such as potassium, dietary fiber, calcium, and vitamin D are low enough to be of public health concern for children and adults. Less than 2% of American adults get the recommended amount of potassium,[19] and the rate of nutrient deficiencies in the general U.S. population ranges from less than 1% for folate, vitamin A, and vitamin E to about 10% for vitamin B_6, iron, and vitamin D. The highest rates of vitamin D deficiency (31%) occur in non-Hispanic blacks. The CDC also reports higher rates of iron deficiency in Mexican-American children aged one to five years (11%) and in non-Hispanic black (16%) and Mexican-American women (13%) of childbearing age when compared to other race/ethnic groups.[20]

The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* reflects a slightly different public health environment. For example, more recent NHANES data show that obesity rates seem to have stabilized since 2003-2004, and daily caloric intake has declined by 118 calories (about 5%), on average, between 2005-2006 and 2009-2010.[21] It has been suggested that these changes may be, in part, attributed to various local, state, and federal policy initiatives. With the passage of the Affordable Care Act in 2010, chain restaurants and fast food establishments have started to post calorie counts on menus.[22] The federal government has changed school lunch requirements, limiting calories, sodium, and saturated fat content in school meals. And individual cities have taken their own actions (e.g., soda taxes in Berkley, CA). In the 2015 scientific report, the DGAC determined that Americans are overconsuming two nutrients—sodium and saturated

dietaryguidelines/q-and-a.asp#RP1.

[17] HHS Office of Disease Prevention and Health Promotion, *Scientific Report of the 2015 Dietary Guidelines Advisory Committee*, February 19, 2015, see http://www.health.gov/dietaryguidelines/.

[18] B Lin and R Morrison, "Food and Nutrition Intake Data: Taking a look at the Nutritional Quality of Foods Eaten at Home and Away from Home," *Amber Waves*, Economic Research Service, vol. 10, no. 2 (June 2012).

[19] M Cogswell, A Carriquiry, and J Gunn, et al., "Sodium and Potassium Intakes among US Adults: NHANES 2003-2008," *American Journal of Clinical Nutrition*, vol. 96, no. 3 (September 2012), pp. 647-657.

[20] CDC, "Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population 2012." Atlanta (GA): National Center for Environmental Health; April 2012.

[21] J Todd, *Changes in Eating Patterns and Diet Quality Among Working-Age Adults, 2005-2010*, USDA Economic Research Service, ERR-161, January 2014, http://www.ers.usda.gov/media/1259670/err161.pdf.

[22] Section 4205 of the ACA required FDA to promulgate regulations to enforce mandatory calorie labeling in restaurants and similar retail food establishments. Due to pressures from various stakeholders, FDA has extended the date for complying with the menu labeling rule until December 1, 2016. However, in anticipation of the menu labeling requirements, some chain restaurants began posting calorie counts pre-regulation.

fat—and two food components—refined grains[23] and added sugars.[24] The DGAC concluded that independent of where food is obtained or prepared, the diet quality of the U.S. population does not meet recommendations for fruit, vegetables, dairy, or whole grains, and exceeds recommendations for sodium and saturated fat, as well as refined grains, solid fats, and added sugars.[25]

Although most of the proposed changes to the Nutrition Facts label are based on the 2010 DGA policy document, FDA published a supplemental notice of proposed rulemaking with additional proposed revisions,[26] based on the scientific rationale included in the 2015 DGAC report.

FDA Authority to Regulate Nutrition Labeling

The 1938 Federal Food, Drug, and Cosmetic Act (FFDCA)[27] authorized the Food and Drug Administration to regulate food products and their ingredients. In 1990, Congress passed the Nutrition Labeling and Education Act, which amended the FFDCA to require that all foods, with certain exceptions, bear nutritional content labels.[28] The NLEA gave FDA explicit authority to require nutrition labeling and control health claims on food labels.

In 1991, FDA issued more than 20 proposals to implement the NLEA and in 1992, FDA issued several final regulations which became effective in 1993.[29] The published regulations addressed (1) the declaration of nutrients on food labeling, mandatory and voluntary, as well as the format for declaration; (2) label reference values for declaring the nutrient content of a food; (3) two types of reference values, Reference Daily Intakes (RDIs) and Daily Reference Values (DRVs), which are used to declare nutrient contents as percent Daily Values (DVs) on the Nutrition Facts label; (4) exemptions for specified products; and (5) circumstances for a simplified form of nutrition labeling.[30]

The NLEA also authorized the FDA to "establish regulations defining serving size or other unit of measure."[31] To establish serving sizes, FDA consulted the Nationwide Food Consumption Surveys (1977-1978 and 1987-1988) and considered three statistical estimates (i.e., mean, median, and mode) for each food product category. Using this methodology, the FDA established

[23] A refined grain refers to any grain product that is not a whole grain. Refined grains are missing the bran, germ, and/or endosperm of the grain and tend to be low in fiber.

[24] The phrase "added sugars" refers to sugars that are added during the processing of foods. Names for added sugars include brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado sugar, trehalose, and sucrose.

[25] HHS Office of Disease Prevention and Health Promotion, *Scientific Report of the 2015 Dietary Guidelines Advisory Committee*, February 19, 2015, see http://www.health.gov/dietaryguidelines/.

[26] 80 *Federal Register*, 44303.

[27] P.L. 75-717, as amended.

[28] P.L. 101-535, 104 Stat. 2353.

[29] F Scarbrough, "Food Labeling," in *Modern Nutrition in Health and Disease*, ed. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), pp. 1490-1492.

[30] 79 *Federal Register*, 11883.

[31] P.L. 101-535, §2(b)(1)(B); 21 U.S.C. §343 note.

reference amounts customarily consumed (RACCs)[32] and provided a process for manufacturers to derive serving sizes from the RACCs.[33, 34]

Since FDA's issuance of the 1992 regulations, the Nutrition Facts label has undergone few changes. The recommended daily values (DVs) were last updated in 1995 (60 FR 67164; December 28, 1995) and the label itself was modified in 2003 when the FDA amended the labeling regulations to require the declaration of *trans*-fatty acids. (68 FR 41434; July 11, 2003).

Proposed Rules

In response to new scientific information and a public health profile characterized by high rates of obesity and chronic disease, the FDA is proposing two rules to revise the 1993 labeling regulations. The Nutrition Facts label as a public health tool serves to provide consumers with nutrition information that may help them make more informed food choices. Mandating declaration of certain nutrition information on the label may also prompt food manufacturers to reformulate products to make them healthier and more attractive to consumers.

For the purpose of this report, the rule "Food Labeling: Revision of the Nutrition and Supplement Facts Label"[35] will be referred to as the first rule or rule 1. The rule "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"[36] will be referred to as the second rule or rule 2.

Selected Aspects of Proposed Rule 1[37]

The following sections present the changes proposed as part of the first rule. These updates specifically address changes to the label's required nutrients and the label's design. While some changes seem relatively non-controversial, others have generated debate. This section discusses major changes and flags stakeholder concerns.

Require Information About "Added Sugars"

The first proposed rule includes a provision mandating an "added sugars" line on the Nutrition Facts label. "Sugars" are defined as the number of grams of sugar in a serving of a food item. This includes the sum of all monosaccharides (i.e., glucose, fructose, galactose) and disaccharides

[32] Reference amounts customarily consumed (RACCs) reflect the amount of food or drink that would typically be consumed per eating occasion. RACCs are calculated for persons four years of age or older.

[33] 21 C.F.R. §101.9(b)(1).) defines "serving size" to refer to the amount of food customarily consumed per eating occasion by persons four years of age or older, which is expressed in a common household measure that is appropriate to the food.

[34] F Scarbrough, "Chapter 107: Food Labeling," in *Modern Nutrition in Health and Disease*, ed. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), pp. 1490-1492.

[35] 79 *Federal Register* 11883.

[36] 79 *Federal Register* 11990.

[37] Please note that the recordkeeping requirements for compliance are not discussed in this report. In brief, certain circumstances require manufacturers to make and keep records sufficient to verify the label declaration for the amount of added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid in products. The manufacturer would then have to provide these records upon request by FDA.

(i.e., sucrose, lactose, and maltose).[38] This designation includes both those sugars naturally occurring in foods such as fruit (fructose) or milk products (lactose), as well as those added during the production process to items such as soda or other sweetened beverages, cereals, and candy. Under current regulations, manufacturers are required to declare on the label the amount of sugar in a food item. However, manufacturers do not have to differentiate between naturally occurring sugar and added sugar. Artificial sweeteners and sugar alcohols that are added to a food are not included in the "Sugars" designation; they are required to be labeled in the ingredients statement but not on the Nutrition Facts label itself.

A key recommendation of the 2010 DGA is to reduce the intake of calories from added sugars, as studies show that diets high in added sugars can decrease the intake of nutrient-rich foods and increase overall calorie intake.[39] The American Heart Association estimates that Americans consumed an average of more than 22 teaspoons of added sugar per day from 2001 to 2004.[40] The average American consumes 16% of their total daily calories from added sugars,[41] and added sugars contribute extra calories to a diet, which may lead to weight gain and obesity.[42] A declaration of added sugars on the Nutrition Facts label would let consumers know how much sugar has been added to the product beyond the naturally occurring sweetener, and requiring manufacturers to disclose the amount of added sugar in a food item may also change how much sweetener they add to their products.

The inclusion of the added sugars label on the Nutrition Facts panel has received support from several public health and nutrition stakeholders.[43] However, some groups have also asked that FDA establish a recommended daily value for sugar (see "Update Reference Values for Certain Nutrients"), which would give consumers a daily target or upper limit. Groups have also suggested that it may be appropriate to use a more common metric of sugar such as the number of teaspoons as opposed to grams.[44]

In July 2015, FDA issued a proposed supplemental rule that would require a mandatory percent daily value (%DV) declaration for added sugars.[45] In the initial iteration of the proposed rule, FDA proposed mandatory declaration of the amount of added sugars in a food item but not a percent DV, citing lack of scientific evidence to substantiate such a recommendation. However, the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (2015 DGAC) published in February 2015 provided new scientific evidence to support establishing a reference amount for added sugar intake. Specifically, the DGAC's report concluded that there is a moderate relationship between added sugar intake and cardiovascular disease, and a strong association between added sugar consumption and type 2 diabetes in adults. Cohort studies

[38] 21 C.F.R. §101.9 (c)(6)(ii).

[39] USDA and HHS, *Dietary Guidelines for Americans, 2010,* 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[40] R Johnson, L Appel, and M Brands, et al., "Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement from the American Heart Association." *Circulation,* vol. 120, no. 11 (September 2009), pp. 1011-1020.

[41] R Ervin, B Kit, and M Carroll, et al., "Consumption of added sugar among U.S. children and adolescents, 2005–2008," NCHS data brief, no 87. Hyattsville, MD: National Center for Health Statistics. 2012.

[42] IOM, "Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report", Washington, DC: National Academies Press; 2010.

[43] Letter from Elliott M. Antman, President, American Heart Association, to FDA, July 22, 2014. Letter from Shereen Arent, Executive Vice President Government Affairs & Advocacy, American Diabetes Association, to FDA, June 4, 2014. Letter from Environmental Working Group, to FDA, June 30, 2014.

[44] Letter from Elliot M. Antman, President, American Heart Association, to FDA, July 22, 2014.

[45] 80 *Federal Register* 44303.

comparing groups with varying levels of added sugar consumption support the recommendation to keep added sugars intake below 10% of total calories, which is consistent with the World Health Organization's recommendation to keep added sugar intake to less than 10% of total energy intake.[46] In light of this new evidence, FDA determined that it has the scientific basis to establish a percent DV for added sugars, proposing that the percent DV be based on the recommendation that the daily intake of calories from added sugars not exceed 10% of total calories. The DV, which is used to calculate the percent DV that consumers see on the Nutrition Facts label, would be 50 grams of added sugars for adults and children four years of age and older and 25 grams for children one through three years of age.[47]

There has been some controversy surrounding the mandatory labeling of added sugars. Some food industry groups are questioning the FDA's statutory authority under the FFDCA, stating that the agency may only require the labeling of sugar if it will help consumers maintain healthy dietary practices.[48] Members of certain food industry groups have also argued that there is a lack of evidence to justify a label that distinguishes between naturally occurring and added sugars because sugar is sugar.[49] Others have said that FDA's added sugars proposal may be preemptive, as the Secretaries of HHS and USDA have not yet released the final policy document that is the 8th edition of the DGA.[50]

Remove "Calories from Fat"

The second provision of the first rule proposes to remove "Calories from Fat" from the Nutrition Facts label. Currently, manufacturers are required to declare the amounts of "Total Fat," "Calories from Fat, "Saturated Fat," and "*Trans* fat." However, evidence suggests that the type of fat is more important than total fat intake in regard to chronic disease risk.[51]

Dietary fats are categorized as saturated, *trans*,[52] monounsaturated, and polyunsaturated fatty acids, with most American consuming too much saturated and *trans* fat and not enough unsaturated fat.[53] In general, animal sources tend to provide a greater proportion of saturated fat, and plant sources tend to provide more of the mono- and polyunsaturated fats. Over the years, evidence has suggested that a higher intake of saturated fat is associated with greater risk of cardiovascular disease, and recommendations have been to reduce intake of saturated fats and replace them with monounsaturated and polyunsaturated fatty acids. Specifically, the DGA recommend that Americans consume less than 10% of calories from saturated fat, and lowering that number to 7% of calories may further reduce the risk of cardiovascular disease.[54] However, it is worth noting that some recent studies have found evidence against the association between

[46] World Health Organization, *Sugars intake for adults and children*, 2015, http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/.

[47] In the context of a 2000 calorie diet, 10% equates to 200 calories from added sugar or about 50 grams of added sugar (there are 4 calories in a gram of sugar) or 12.5 teaspoons of added sugar.

[48] See http://insidehealthpolicy.com/wlf-gma-added-sugar-req-nutrition-labels-violates-first-amendment.

[49] See http://insidehealthpolicy.com/wlf-gma-added-sugar-req-nutrition-labels-violates-first-amendment.

[50] M O'Flaherty, OFW Law, July 24th, 2015, http://www.ofwlaw.com/2015/07/24/surprise-fda-proposes-a-daily-value-for-added-sugars/.

[51] 79 *Federal Register* 11891.

[52] *Trans* fatty acids are a type of unsaturated fat but they are structurally different from mono and polyunsaturated fats.

[53] USDA and HHS, *Dietary Guidelines for Americans, 2010*, 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[54] *Ibid*.

saturated fat intake and cardiovascular disease risk.[55] Meanwhile, the evidence against *trans* fat intake remains strong, with studies reporting an strong association between *trans* fatty acid intake and cardiovascular disease risk. Furthermore, an IOM review suggests there is insufficient evidence to set a level of intake that would pose no adverse health effects and at this time,[56] the recommendation is for Americans to keep their intake of *trans* fatty acids as low as possible.[57]

FDA consumer research also indicates that removal of the declaration of "Calories from Fat" has no effect on consumers' ability to judge the healthfulness of a product. Thus, FDA would continue to require "Total Fat," "Saturated Fat," and "*Trans* Fat" on the label, but not "Calories from Fat." No substantive comments for or against this proposal have been identified.

Require Declaration of Potassium and Vitamin D, Permit Vitamins A and C

As part of the first rule, FDA is also proposing to update the nutrients that are required to be listed on the Nutrition Facts label. The current Nutrition Facts label regulations mandate the declaration of vitamins A and C, as well as calcium and iron. FDA states that these four nutrients were considered to be "of public health significance" based on their inadequate intakes among specific segments of the U.S. population at the time the regulations were established.[58]

However, more recent data has informed the FDA proposal to update the list of vitamins and minerals that must be included on the Nutrition Facts label.[59, 60] To determine whether a non-statutory[61] nutrient should be a mandatory or voluntary declaration, two factors are considered: existence of quantitative intake recommendations and public health significance.[62] Based on consideration of these factors, the FDA is proposing to require the declaration of potassium and vitamin D, and to permit, rather than require, the declaration of vitamins A and C. Calcium and iron continue to be considered nutrients of public health significance so there will be no change to their mandatory labeling.

FDA analysis demonstrates that while American consumers get adequate amounts of vitamins A and C, potassium and vitamin D have been identified as nutrients of concern for certain subpopulations. Vitamin D plays an important role in bone health and NHANES biomarker

[55] R Chowdhury, S Warnakula, and S Kunustor, et al., "Association of Dietary, Circulating, and Supplement Fatty Acids with Coronary Risk: A Systematic Review and Meta-analysis," *Annals of Internal Medicine*, vol. 160, no. 6 (2014), pp. 398-406.

[56] IOM, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 8: Dietary Fats: Total Fat and Fatty Acids", Washington, DC: National Academies Press, 2002.

[57] USDA and HHS, *Dietary Guidelines for Americans, 2010,* 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[58] 79 *Federal Register* 11918.

[59] HHS and USDA, *Dietary Guidelines for Americans, 2005,* 6th Edition, Washington, DC.

[60] USDA and HHS, *Dietary Guidelines for Americans, 2010,* 7th Ed., Washington DC, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[61] For purposes of the proposed rule, FDA considers the nutrients that are not statutorily required but subject to FDA discretion under §403(q)(2)(A) of the FFDCA as "non-statutory nutrients" to distinguish from those nutrients that are explicitly required by the statute.

[62] Public heath significance refers to two elements: (1) whether there is evidence of a relationship between the nutrient and a chronic disease, health-related condition, or health-related physiological endpoint and (2) whether there is evidence of a problem with the intake of a nutrient and evidence of the prevalence of the chronic disease related to it.

data,[63] as well as the high prevalence of osteoporosis and osteopenia among the U.S. population,[64] suggest inadequate dietary intake. Potassium is also considered a nutrient of public health significance as it plays an important role in blood pressure regulation, and data indicates both a low likelihood of potassium adequacy and a high prevalence of hypertension in the U.S. population.[65]

The FDA proposal to include vitamin D on the list of mandatory nutrients has generated some debate. Vitamin D is a hormone synthesized by the body in response to sunlight exposure, and some experts question the efficacy of orally consumed vitamin D.[66] There is also concern that mandating vitamin D disclosure will encourage mass fortification, as vitamin D is naturally found in few foods. This also raises questions about the potential for overconsumption and toxicity, as vitamin D is a fat-soluble hormone that can be stored in fat tissue long-term.[67]

In addition, there is also concern about the proposal to permit rather than require declaration of vitamins A and C. Although overt deficiency of these two nutrients is not common among the U.S. population, inadequate intake of these nutrients remains a concern.[68]

Update Reference Values for Certain Nutrients

The FDA is also proposing to update the recommended Daily Values (DVs) for certain nutrients to help consumers understand how these nutrients fit into the context of a daily diet.[69] The DV or %DV indicates to consumers how much of the recommended intake of a nutrient is provided by a certain food. The **text box** below explains how DVs are determined.

Reference Values

There are two sets of reference values for reporting nutrients on the Nutrition Facts label: Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs). To limit consumer confusion, a single term, Daily Value (DV), is used to designate both the DRVs and the RDIs.

Daily Reference Values (DRVs) were developed to inform consumers about the maximum intake of a nutrient and are provided for total fat, saturated fat, cholesterol, total carbohydrates, dietary fiber, sodium, and protein; DRVs are established for adults and children four years and older.

Reference Daily Intakes (RDIs) were developed to help consumers meet a nutrient requirement or daily minimum. RDIs are provided for vitamins and minerals, as well as for protein for children under the age of four and pregnant and lactating women.

The DRVs and RDIs are determined using **Dietary Reference Intakes (DRIs)**:

The **Recommended Daily Allowance (RDA)** is the basis for the RDI. The RDAs are intake goals referring to the average daily nutrient intake level sufficient to meet the nutrient requirement of nearly all (97%-98%) individuals in a particular life stage and gender group. The RDA is set using the Estimated Average Requirement (EAR).

[63] IOM, "Dietary Reference Intakes for Calcium and Vitamin D", Washington, DC: National Academies Press, 2011.

[64] HHS, "Bone Health and Osteoporosis: A Report of the Surgeon General", October 14, 2004.

[65] IOM, "Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate, Chapter 5: Potassium", Washington, DC: National Academies Press; 2005. pp. 186-268. USDA and HHS, *Dietary Guidelines for Americans, 2010*, 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[66] Letter from Marion Nestle, Professor, New York University, to FDA, July 17, 2014.

[67] G Jones, "Chapter 18: Vitamin D," in *Modern Nutrition in Health and Disease*, ed. A. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), pp. 279-291.

[68] Letter from Simin N. Meydani, D.V.M., Ph.D., American Society for Nutrition President, to FDA, July 25, 2014.

[69] 79 *Federal Register* 11879.

The **Estimated Average Requirement (EAR)** is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group.

An **Adequate Intake (AI)** is established when there is insufficient evidence to develop an RDA and is set at a level assumed to ensure nutritional adequacy. It is used to establish the RDI in the absence of an RDA.

The **Tolerable Upper Intake Level (UL)** is the maximum daily intake that is unlikely to cause adverse health effects. The UL is not intended to be a recommended level of intake.

Sources: C Lewis and L Meyers, "Chapter 106: Dietary Reference Intakes," in *Modern Nutrition in Health and Disease*, ed. A. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), pp. 1480-1489. Food and Drug Administration, "Guidance for Industry: A Food Labeling Guide (14. Appendix F: Calculate the Percent Daily Value for the Appropriate Nutrients), January 2013.

Since the implementation of the NLEA, new reports from the IOM and the 2010 DGA have updated the quantitative intake recommendations of certain nutrients. The FDA is proposing to update the reference values used in the declaration of %DV on the Nutrition Facts label so that it is consistent with the new data. These updated reference values have been proposed for several nutrients including sodium, dietary fiber, and potassium, which are required to be declared on the label, as well as vitamin K, chloride, choline, and vitamin B_{12}, which are permitted[70] but not required to be on the label.

Reduce Sodium Limits

The FDA is proposing to reduce the Daily Value (DV) for sodium. Regulations under the NLEA established the DRV for sodium as 2,400 mg; however, more recent scientific literature and recommendations from the 2005 and 2010 DGA highlight the need to reconsider this value.[71, 72] In accord with the 2005 and 2010 DGA recommendations, FDA is proposing to reduce the DRV to 2,300 mg. This value is consistent with a 2013 IOM report on sodium intake, which established the Tolerable Upper Intake Level (UL) of sodium to be 2,300 mg.[73] The IOM report determined that there is insufficient evidence to conclude that lowering sodium intakes below 2,300 mg will increase or decrease the risk of cardiovascular disease outcomes or all-cause mortality in the general U.S. population. Meanwhile, some public health groups propose that 2,300 mg is still too high and that 1,500 mg would be a more appropriate target level for the general population.[74, 75]

Increase Dietary Fiber Recommendations

The FDA is also proposing to increase the DRV for dietary fiber intake. Currently, the DRV for dietary fiber is 25 grams. In 2002, an IOM report set an Adequate Intake (AI) for total fiber of 14 grams per 1,000 calories for total fiber.[76] Based on this report, FDA is proposing to increase the

[70] Several essential vitamins and minerals are permitted but do not have to be declared on the Nutrition Facts label: vitamin E, vitamin K, vitamin B_6, vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride.

[71] HHS and USDA, *Dietary Guidelines for Americans, 2005,* 6th Ed., Washington, DC.

[72] USDA and HHS, *Dietary Guidelines for Americans, 2010,* 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[73] IOM, *Sodium Intake in Populations: Assessment of Evidence*, Washington, DC, 2013, pp. 235-284.

[74] Letter from Elliot M. Antman, President, American Heart Association, to FDA, July 22, 2014.

[75] Letter from Trust for America's Health, to FDA, May 23, 2014.

[76] IOM, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 7: Dietary, Functional, and Total Fiber", Washington, DC: National Academies Press,

DRV for dietary fiber to 28 grams per day, using a reference calorie intake of 2,000 calories per day. The declaration of dietary fiber will continue to be mandatory, but a new definition of dietary fiber would allow only those forms of dietary fiber that the FDA has determined to be of "physiological benefit" to human health to be included in the amount declared. In the past, food manufacturers have been permitted to fortify food products with processed fiber.[77] However, it remains unclear whether processed added fiber confers the same health benefits as naturally occurring sources from fruits, vegetables, and whole grains.[78]

There is some industry concern regarding FDA's proposal to change the definition of dietary fiber, as manufacturers may be unclear as to what qualifies as a "physiological benefit."[79] Furthermore, some argue that this requirement imposes a pre-authorization[80] approach similar to that required for health claims.[81]

Increase Potassium

Under current regulations, the DRV for potassium is 3,500 mg. In 2005, IOM established age- and gender-specific Adequate Intakes (AI s) for potassium based on its beneficial health and physiologic effects. Because potassium is an essential mineral with available age- and gender-specific AIs, FDA is proposing to establish an RDI of 4,700 mg based on the AI and in place of the DRV. Comments have arisen regarding the use of an AI to determine the RDI, particularly if there is a lack of scientific evidence to establish a Recommended Daily Allowance (RDA), as is the case with potassium. Some are proposing that if there is insufficient evidence to establish an RDA, then the current DRV of 3,500 mg should be maintained.[82]

Establish New Definition for Vitamin K

As for the permitted but not required nutrients, FDA is proposing to set an RDI of 120 mcg for vitamin K. Currently, there is no specific definition for vitamin K, and the AIs are based on intake data from NHANES, which specifically represent the intake of vitamin K_1 or phylloquinone—the major form of vitamin K in the diet.[83] Foods with the highest phylloquinone content include leafy, green vegetables such as spinach, kale, and collard greens, as well as fats and oils.[84] Because the

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2002.

[77] Letter from Elliot M. Antman, President, American Heart Association, to FDA, July 22, 2014.

[78] USDA and HHS, *Dietary Guidelines for Americans, 2010*, 7th Ed., Washington DC: U.S. GPO, http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm.

[79] Letter from Douglas MacKay, Senior Vice President, and Andrea Wong, Vice President, Scientific & Regulatory Affairs, Council for Responsible Nutrition, to FDA, August 1, 2014.

[80] For the FDA to authorize the use of a health claim, certain criteria must be met. Generally, these health claims must meet a significant scientific agreement (SSA) standard as determined by the FDA. For more information on the SSA review process, *see* FDA, *Guidance for Industry: Evidence-based Review System for the Scientific Evaluation of Health Claims*, Silver Spring, MD, January 2009, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm.

[81] Letter from Kathryn L. Wiemer, MS, RD, Senior Fellow, General Mills Bell Institute of Health and Nutrition, to FDA, August 1, 2014.

[82] *Ibid*.

[83] There are three general forms of vitamin K: Phylloquinone, menaquinone, and menadione. The AIs have been established for phylloquinone, which is the major dietary form.

[84] J Suttie, "Chapter 20: Vitamin K," in *Modern Nutrition in Health and Disease*, ed. A. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), pp. 305-306.

established AI for vitamin K is specific to phylloquinone, FDA is proposing to set an RDI of 120 mcg for vitamin K that would pertain only to Vitamin K_1. Some comments have been raised regarding the exclusion of vitamin K_2 from nutrition labeling. Other regulatory bodies such as the European Food Safety Authority (EFSA) and Health Canada recognize vitamin K_2 as contributing toward vitamin K adequacy, so some are asking FDA to consider including vitamin K_2 in the declaration of vitamin K.[85]

Increase Chloride

FDA is also proposing to revise the RDI for chloride to 4,700 mg from the current RDI of 3,400 mg. The RDI for chloride is proportional to the DRV for sodium, as the IOM set AIs and ULs for chloride on an equimolar basis[86] with those of sodium. This is because dietary chloride comes from sodium, and chloride losses in the body tend to follow sodium. No substantive comments in opposition of this proposal have been identified.

Establish RDI for Choline

FDA is proposing to set an RDI of 550 mg for choline. Currently, FDA regulations do not establish a reference value for this nutrient, which is most abundant in foods such as eggs and liver.[87] Based on IOM established age- and gender- specific AIs for choline, FDA is proposing to establish an RDI. This proposal does not appear to have any substantive concern or opposition.

Reduce Vitamin B_{12}

FDA is proposing to lower the RDI for vitamin B_{12} from 6 to 2.4 mcg. This value of 2.4 mcg reflects the RDA established by IOM in 2000. Some concern has been expressed regarding this proposal. Vitamin B_{12} is most abundant in animal products including meat, fish, eggs, and milk, but fortified breakfast cereals are a source as well.[88] Concern has been raised that reducing the RDI may result in lower vitamin B_{12} fortification which would in turn, lower the amount of crystalline vitamin B_{12} in the food and dietary supplement supply.[89] This may make it more difficult for those at risk to achieve adequate intake of this nutrient, particularly vegetarians or individuals age 50 years and older who already have a reduced capacity to absorb dietary B_{12}.

Update Units of Measure

Vitamins A, D, and E

FDA is proposing to change the units used to declare vitamins A, D and E from International Units (IUs) to a metric measure. The declaration of vitamin D which will now be mandatory must appear in micrograms (µg or mcg). Vitamins A and E may be declared voluntarily, but if declared,

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[85] Letter from Douglas MacKay, Senior Vice President, and Andrea Wong, Vice President, Scientific & Regulatory Affairs, Council for Responsible Nutrition, to FDA, August 1, 2014.

[86] Equimolar refers to substances having an equal number of moles. In chemistry, moles are a unit of measurement used to express the amount of a substance.

[87] S Zeisel, "Chapter 30: Choline," in *Modern Nutrition in Health and Disease*, ed. A. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), p. 416.

[88] R Carmel, "Chapter 27: Cobalamin (Vitamin B_{12})," in *Modern Nutrition in Health and Disease*, ed. A. Catharine Ross, Benjamin Caballero, Robert Cousins, Katherine Tucker, Thomas Ziegler, 11th ed. (Lippincott Williams & Wilkins, 2014), pp. 369-386.

[89] Letter from Simin N. Meydani, D.V.M., Ph.D., American Society for Nutrition President, to FDA, July 25, 2014.

their designated units would be µg Retinol Activity Equivalents (RAE) and milligrams (mg) α-tocopherol, respectively. No substantive comments opposing this proposal have been identified, but it has been suggested that education efforts may be necessary to make consumers aware of these changes.

Folate and Folic Acid

FDA is also proposing to change the units used to declare the amount of total folate on the Nutrition Facts label. Currently, the RDI for folate is listed in micrograms, and this value represents both the naturally-occurring food folate, as well as the synthetic folate that has been added to the food product. In 1992, the United States Public Health Service (USPHS) recommended that all women capable of becoming pregnant should consume 400 mcg of synthetic folic acid per day to prevent neural tube defects.[90] In 1998, IOM established an RDA of 400 mcg Dietary Folate Equivalents (DFE).[91] Although these two values appear to be identical, they are functionally different. The Dietary Folate Equivalents, as defined by IOM, adjust for the lower bioavailability of food folate compared with that of synthetic folate.[92] Bioavailability refers to the amount of a substance that is available for use by the target tissue after absorption. The bioavailability of food folate is almost 50% lower than that of synthetic folate, meaning less of it is available for use by the body.

Public health stakeholders and manufacturers are concerned that this label change will be confusing to consumers. Because of the difference in measuring folate in DFEs versus micrograms, a food product or dietary supplement that stated it contained 100% of the DV of folate (400 mcg DFE) would not actually contain 100% of the USPHS-recommended level of folic acid to prevent neural tube defects (400 mcg) because it takes 235 mcg of folic acid to equal 400 mcg DFE.[93] FDA adds that consumer education efforts to explain the "equivalents" would be necessary, but some are still concerned that this change may result in sub-optimal folate intake, which may impact previous public health efforts to prevent neural tube defects.[94]

FDA is also proposing to change the terminology used to declare folate on the Nutrition Facts label. Currently, "folic acid" and "folacin" are synonyms of folate and can be used in declaration. The proposed rule would eliminate using "folacin" and would require that the term "folate" be used in labeling of conventional foods, and that the term "folic acid" be used in the labeling of dietary supplements only. Manufacturers and public health stakeholders are concerned that removing "folic acid" from the Nutrition Facts label may make it more difficult for women to recognize which foods contain the recommended 400 mcg of folic acid.[95]

[90] CDC, Recommendations for the use of folic acid to reduce the number of cases of spina bifida and other neural tube defects, MMWR 1992;41(No. RR-14), http://www.cdc.gov/mmwr/preview/mmwrhtml/00019479.htm.

[91] IOM, "Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline", Washington, DC: National Academies Press, 1998.

[92] As defined by IOM, mcg DFE= mcg food folate + (1.7x synthetic folic acid).

[93] Letter from Annette Dickinson, PhD, Adjunct Professor, University of Minnesota, to FDA, May 16, 2014.

[94] Letter from Emil Wigode, Director of Federal Affairs, March of Dimes, to FDA, August 1, 2014.

[95] Letter from Annette Dickinson, PhD, Adjunct Professor, University of Minnesota, to FDA, May 16, 2014.

Update Labeling of Foods for Infants, Young Children, and Pregnant or Lactating Women

FDA is reconsidering the labeling requirements of foods, other than infant formula, represented or purported to be specifically for infants, children under four years of age, and pregnant and lactating women.

Modifying the Categorization of Children Younger than Four Years of Age

FDA is proposing to modify the current age category of "children less than 4 years" to "infants 7 to 12 months" and "young children 1 through 3 years." FDA is proposing to change the age categories so that they are the same as those used by IOM to determine the DRIs.

Mandatory Declaration of Calories and Required Nutrients

FDA is also proposing to require the declaration of calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein on foods represented to be specifically for infants 7 to 12 months, children one through three years of age, and pregnant and lactating women. Currently, the labeling requirements for the general population apply to foods for infants, young children, and pregnant and lactating women, with certain exceptions.

Foods represented as being specifically for infants and children less than four years of age are not permitted to declare a %DV for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber. Under the proposed rule, FDA would require declarations of %DV for some of those nutrients, specifically those with established reference values (DRVs or RDIs). For infants 7 to 12 months, reference values haven been established for total fat, total carbohydrate, and protein. For children one through three years of age, reference values have been established for calories, total fat, total carbohydrate, dietary fiber, protein, and sodium. For pregnant and lactating women, reference values have been established for calories, total fat, saturated fat, cholesterol, total carbohydrate, sodium, dietary fiber, and protein.

In addition, under current regulations, foods purported to be specifically for infants and children less than two years of age are not permitted to declare calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol. However, consensus reports provide no recommendations for nutrient guidelines for fatty acids to children younger than two years of age. There is also no evidence to suggest that infants 7 to 12 months would be different than children one through three years of age. Thus, under the proposed rule, FDA is proposing to permit the declaration of calories from saturated fat, and the amount of polyunsaturated and monounsaturated fat. If finalized, this would be the same as the proposed voluntary declarations for the general population.

In accord with the nutrients required to be declared on the Nutrition Facts label for the general population, FDA is also proposing mandatory declaration of added sugar, vitamin D, and potassium, and permitting rather than requiring declaration of vitamins A and C. In addition, several essential vitamins and minerals are permitted but do not have to be declared on the Nutrition facts label: vitamin E, vitamin K, vitamin B_6, Vitamin B_{12}, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride.

Comments on the proposed rule have suggested that FDA also establish RDIs for children 4 through 13 years of age, as their nutrition needs may be different than that of adults.[96] Others caution that there is a lack of available empirical research on declaration of saturated fat and cholesterol for infants and children one through three years of age, recommending FDA not make any labeling determinations until such research is conducted.[97] Public health groups also suggest FDA work with IOM to establish a DRV for sugar, as sugar consumption among children is high,[98] replacing intake of nutrient-dense foods such as fruits, vegetables, and whole grains.

Changes to Label Design

In addition to updating the nutrient information on the label, FDA is also proposing the following changes to the Nutrition Facts label format: (1) Increasing the prominence of calories and serving size; (2) reversing the order of the "Serving Size" and "Servings Per Container" declarations and increasing the prominence of "Servings Per Container"; (3) right-justifying the quantitative amounts declared in "Serving Size Statement"; (4) changing "Amount Per Serving" to "Amount Per ___" (e.g., Amount Per 1 cup); (5) removing the declaration "Calories from Fat"; (6) modifying presentation of "%DV"; (7) declaring "Added Sugars"; (8) declaring the absolute amounts of vitamins and minerals; (9) requiring dual column labeling under specific conditions; (10) modifying the footnote; (11) requiring that all nutrients be highlighted with some type of bold or extra bold font; (12) adding a horizontal line below the heading "Nutrition Facts"; and (13) replacing "Total Carbohydrate" with "Total Carbs." The changes are displayed in **Figure 2**.

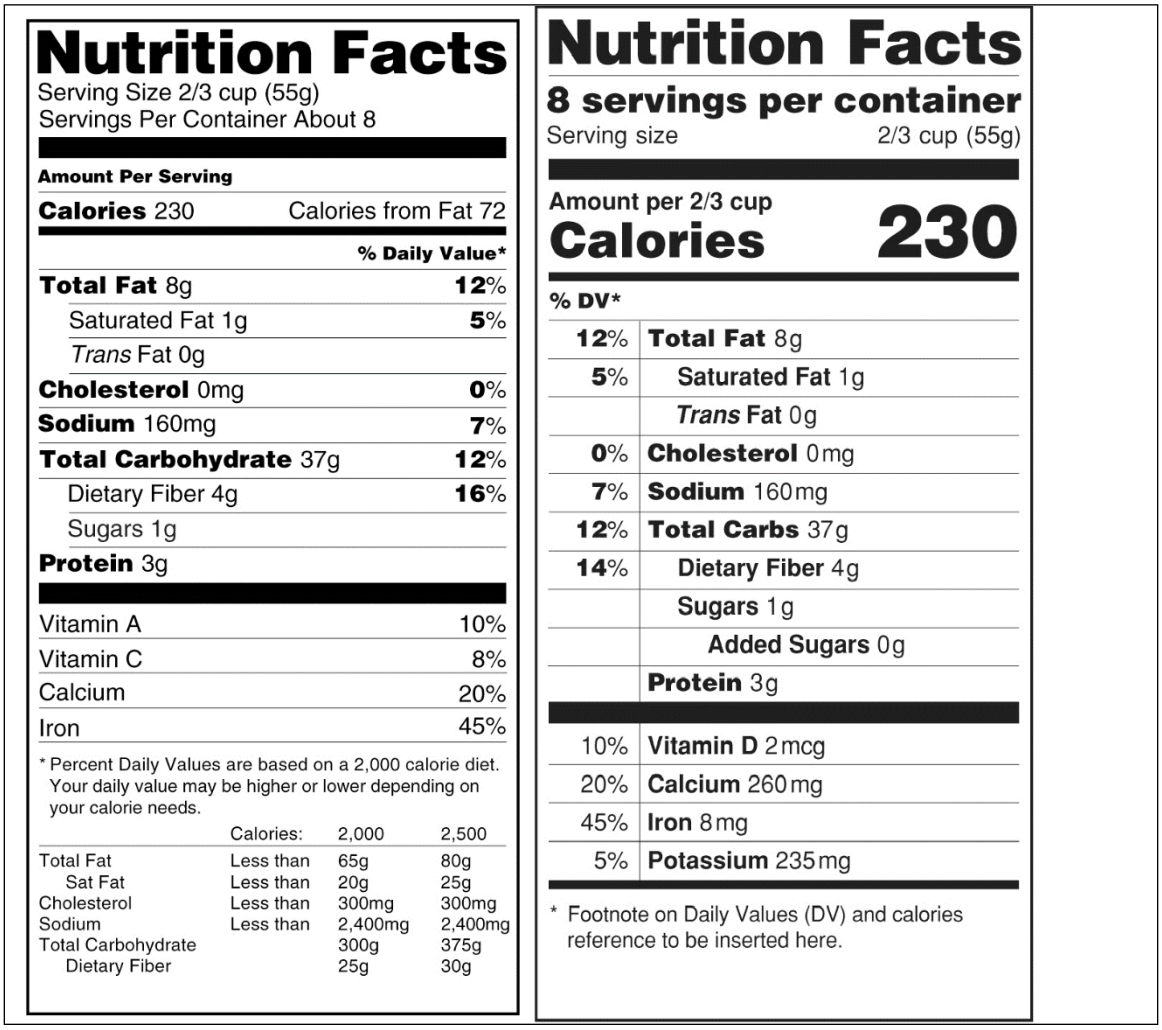
[96] Letter from Douglas MacKay, Senior Vice President, and Andrea Wong, Vice President, Scientific & Regulatory Affairs, Council for Responsible Nutrition, to FDA, August 1, 2014.

[97] Letter from Simin N. Meydani, D.V.M., Ph.D., American Society for Nutrition President, to FDA, July 25, 2014.

[98] Letter from Elliott M. Antman, President, American Heart Association, to FDA, July 22, 2014.

Figure 2. Label Format

Current vs. Proposed



Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

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

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** 160mg
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.

Source: FDA, "Food Labeling: Revision of the Nutrition and Supplement Facts Label; Proposed Rule," 79 *Federal Register*, 11974, March 3, 2014.

Notes: For dietary fiber, the "% Daily Value" for the current label (left) is 16%, which is based off the current DRV of 25g. The "%DV" for the proposed label (right) is based off the proposed DRV of 28g.

Comments have arisen regarding whether 2,000 calories should continue to be used as the reference intake level. The reference value of 2,000 calories is based on estimated energy requirements (EERs) set by IOM. An EER is defined as the energy (or calorie) "intake that is predicted to maintain energy balance in a healthy adult of defined age, gender, weight, height, and level of physical activity consistent with good health" (79 FR 11892). Thus, the EER varies by characteristics such as gender, weight, height, and level of physical activity, and calorie needs differ among individuals. The value 2,000 is a reference value rather than a recommendation. The EERs were also established based on individuals of normal weight, but they may not be relevant to today's American population characterized by a high prevalence of obesity and overweight. However, the IOM Labeling Committee concluded that the 2,000 calorie reference intake level is the best approach, as it would provide continuity while not encouraging higher calorie consumption.

In the proposed rule published in March 2014, FDA proposed to remove the footnote listing reference values for certain nutrients for 2,000 and 2,500 calorie diets. In the supplemental notice of proposed rulemaking issued by FDA in July 2015, based on consumer research, FDA is proposing to include a footnote explaining the percent Daily Value. The proposed statement

would be shorter than the current footnote to allow for more space on the label, stating: "*The percent daily value (%DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice." Certain foods would be exempt from the proposed footnote requirement, for example, those that use the terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the label or in the labeling of foods as defined in 21 C.F.R. 101.60(b).

Selected Aspects of Proposed Rule 2

The following section presents the changes proposed as part of the rule "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." This rule specifically addresses modifications to the serving size requirements to reflect how people eat and drink today. This rule would also require that certain packaged foods, specifically those that may be consumed in one sitting or multiple sittings, contain calorie and nutrition information for a single serving, as well as for the whole package. The comments and concerns regarding the proposed rule are also discussed in this section.

Changes to the RACCs

As part of the second proposed rule, FDA is proposing to amend the reference amounts customarily consumed (RACCs). RACCs reflect the amount of food or drink that would typically be consumed per eating occasion, and they are used to determine serving sizes listed on the Nutrition Facts label.[99] Current serving sizes are based on RACCs that were established in 1993 using 1977-1978 and 1987-1988 food consumption data. However, analysis of more recent data indicates that the serving sizes people eat and drink today have changed since serving size requirements were established 20 years ago.[100]

FDA proposed to revise the previously established RACCs for several food categories including, but not limited to, beverages, bakery products, desserts, and sugars and sweets. Under the proposed rule, the RACC for beverages (i.e., "carbonated and noncarbonated beverages, wine coolers and water" and "coffee or tea, flavored and sweetened") would be increased from 8 fl. oz. (240 mL) to 12 fl. oz. (360 mL), and the RACC for bakery products (i.e., "Bagels, toaster pastries, muffins (excluding English muffins)") would be increased from 55 g to 100 g to reflect current consumption patterns.

To determine whether the RACC for a food product should be updated, FDA is proposing to use food consumption data from NHANES (2003-2008). If the NHANES median consumption data shows an increase or decrease of at least 25% compared to the RACCs established in 1993, FDA would update the RACC amount for that food product. In some cases, other factors such as consistency among products with similar consumption data and similar dietary use or product characteristics may also be considered.[101]

[99] 21 C.F.R. §101.9(b) established procedures for converting RACCs into serving sizes to be displayed on the Nutrition Facts label.

[100] L Young and M Nestle, "Expanding Portion Sizes in the US Marketplace: Implications for Nutrition Counseling," *Journal of the American Dietetic Association,* vol. 103, no. 2 (February 2003), pp. 231-234.

[101] 79 *Federal Register* 11991-11992.

Changes to Single-Serving Sizes

In accord with more recent consumption data, FDA is proposing that a product sold and packaged individually, containing up to 200% of the RACC, would be considered a single serving. Current regulations require products packaged and sold individually that contain less than 200% of the RACC to be labeled as a single-serving container. However, products that have "large" RACCs of 100 g (or 100 mL) or greater, containing between 150% and 200% of the RACC have been exempt from this requirement and can be labeled as having either one or two servings. These products have been exempt from the provision because when the RACCs were established, it was considered unlikely that a person would consume twice the reference amount. However, consumption patterns have changed and under the proposed rule, this exemption would no longer be warranted. Thus, to address containers that may be consumed in one sitting, FDA is proposing to amend the definition of a single-serving container.

Research shows that consumers have trouble accurately determining the calorie and nutrient content for an entire package when multiple servings are listed. This is particularly true for packages that may be, and often are, consumed in one sitting. Proponents of the rule suggest that updating the serving size on the Nutrition Facts label will allow consumers to more easily calculate the number of calories they are eating. Adjusting the serving size to reflect the amount consumers typically eat may also make individuals more aware of the nutritional content of what they are eating without requiring them to measure or calculate totals themselves. However, there is also concern that increasing the serving size would lead consumers to believe that the larger portion is the recommended serving size which would in turn result in consumption of bigger portions and more calories.[102] Consumers may not recognize that the serving size is a standard reference size, as opposed to a recommendation on how much to eat.

Use of Dual Column Labeling

As part of the second rule, FDA is also proposing to require certain products to include an additional column on the Nutrition Facts label (see **Figure 3**). For packages that are larger and could be consumed in one sitting or multiple sittings, manufacturers would be required to provide "dual column" labels to indicate both "per serving" and "per package" calorie and nutrient information. Specifically, FDA is proposing mandatory dual-column labeling for food containers that contain 200% and up to 400% of the RACC. Products that contain more than 400% of the RACC would not be required to include a second column, as data shows that products containing more than four times the RACC are less likely to be consumed in one sitting.[103] For example, under the proposed rule, the new RACC for ice cream would be 1 cup, and a pint of ice cream contains 2 cups. Two cups is 200% of the 1 cup RACC, so manufacturers would be required to include a second column displaying the nutrition information for the entire pint of ice cream. However, a family sized bag of chips would not be required to include a second column, as the whole bag contains more than 400% of the RACC, and consumption data indicates that people are unlikely to eat such a portion in one sitting.

Consumer research indicates that when dual column labeling is used, more people are able to correctly identify the number of calories and nutrients per container and per serving of food

[102] Letter from Shereen Arent, Executive Vice President Government Affairs & Advocacy, American Diabetes Association, to FDA, June 4, 2014.

[103] W Juan, Memorandum to file: "Comparison between the foods consumed in the United States from NHANES 2003-2008 at the 90th percentile and Reference Amounts Customarily Consumed (RACCs) per eating occasion by general category and product category," February 11, 2014.

compared to the current single-column label.[104] Portion sizes of foods purchased at supermarkets, stores, and restaurants have increased in recent years, and studies show that increases in package and portion size are related to higher calorie intake among consumers.[105] FDA is proposing that dual-column labeling may help certain consumers recognize the amount of calories and nutrients in the amount they are consuming or may consume, particularly if they eat the whole package instead of one serving.

Figure 3. Dual Column Format

Nutrition Facts

2 servings per container

Serving size 1 cup (255g)

	Per 1 cup		Per container	
Calories	**220**		**440**	
	% DV*		**% DV***	
Total Fat	**8%**	5g	**15%**	10g
Saturated Fat	**10%**	2g	**20%**	4g
Trans Fat		0g		0g
Cholesterol	**5%**	15mg	**10%**	30mg
Sodium	**10%**	240mg	**21%**	480mg
Total Carbs	**12%**	35g	**23%**	70g
Dietary Fiber	**21%**	6g	**43%**	12g
Sugars		7g		14g
Added Sugars		4g		8g
Protein		9g		18g
Vitamin D	25%	5mcg	50%	10mcg
Calcium	15%	200mg	30%	400mg
Iron	6%	1mg	10%	2mg
Potassium	10%	470mg	20%	940mg

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

Source: Food and Drug Administration, "Food Labeling: Revision of the Nutrition and Supplement Facts Label; Proposed Rule," 79 *Federal Register*, 11976, March 3, 2014.

Some have expressed concern that dual-column labeling may clutter the label and lead to customer confusion. It has also been suggested that the required changes would take up package

[104] B Antonuk and L Block, "The Effect of Single Serving Versus Entire Package Nutritional Information on Consumption Norms and Actual Consumption of a Snack Food," *Journal of Nutrition Education and Behavior*, vol. 38, no. 6 (Nov/Dec 2006), pp. 365-370.

[105] B Wansink and J Kim, "Bad Popcorn in Big Buckets: Portion Size Can Influence Intake as Much as Taste," *Journal of Nutrition Education and Behavior*, vol. 37, no. 5 (Sept/Oct 2005), pp. 242-245.

space that could be used for nutrition education messages. Others are concerned that these changes could cost food companies significant amounts of money.[106]

For those food products that require additional preparation (e.g., macaroni and cheese, pancake mixes, and pasta), current regulations permit nutrition information for the product to be presented in two forms, "as purchased" and "as prepared." Under the proposed rule, for products that contain at least 200% and up to 400% of the RACC, FDA is proposing that products requiring further preparation and voluntarily containing the "as purchased" and "as prepared" columns be exempt from dual column labeling. This exemption would also apply to food products that are commonly eaten in combination such as cereal and milk.

Compliance, Costs, and Considerations

Compliance Timeframes

A final rule is to be published, but the exact timing is unknown. In the proposed rules, FDA provides a compliance date two years after the effective rule date. However, industry representatives expect that a longer timeline of three to five years may be needed for full compliance.[107]

Costs and Benefits

The FDA's Preliminary Regulatory Impact Analysis (PRIA) points to several elements of cost to industry for the proposed rules: (1) labeling redesign costs; (2) recordkeeping costs; and (3) food reformulating costs. Cost estimates for implementation of the label redesign vary widely but assuming both a two-year compliance timeline and that both rules have the same compliance dates, the costs of labeling redesign are estimated to be in the range of $1,073 million to $3,083 million, with a mid-range estimate of $1,876 million. Related recordkeeping costs are estimated to be $28 million at a 3% discount rate and $27 million at a 7% discount rate. FDA estimates the total costs of reformulating food products to be in the range of $103 million to $905 million, with a mid-range estimate of $440 million. Although given the increase in cost factors since the implementation of the NLEA in 1990, as well as the increase in the number of SKUs[108] of food and beverages now on the market and the use of specialized packaging, industry representatives suggest that the cost will likely be higher than that projected by FDA.[109] Industry costs may also affect market prices, which would then impose costs on consumers as well.

According to FDA, the goal of the proposed rules is multipronged. The proposed rules would (1) better align the nutrition information provided on the Nutrition Facts label with more recent data on consumption patterns and dietary recommendations; (2) improve the content and design of the Nutrition Facts label to make important information more prominent and easier to understand; and (3) potentially prompt food manufacturers to reformulate products to maintain health and nutrient claims. In turn, these changes may positively affect the growing rates of obesity and

[106] Letter from Kathryn L. Wiemer, MS, RD, Senior Fellow, General Mills Bell Institute of Health and Nutrition, to FDA, August 1, 2014.

[107] Letter from Brian Sharoff, President, Private Label Manufacturers Association, to FDA, April 30, 2014.

[108] Stock keeping unit (SKU) refers to a distinct item offered for sale, with attributes that distinguish it from other items. These attributes include manufacturer, product description, material, size, color, packaging, and warranty terms.

[109] Letter from Brian Sharoff, President, Private Label Manufacturers Association, to FDA, April 30, 2014.

chronic diseases and impact the economic burden of obesity and chronic diseases. FDA estimates that the present value (PV) of the benefits (i.e., decreasing rates of obesity and chronic disease) associated with the proposed rules for the U.S. population over the next 20 years ranges from $1.9 billion to $47.1 billion, with a mean estimate of $21.1 billion. Annualized over 20 years, FDA estimates that the benefits of the proposed rules would equal approximately $2 billion per year.[110]

However, the true cost and benefits from the proposed rules are challenging to determine, as researchers cannot isolate the effect of one intervention on obesity and chronic disease prevalence rates. It is important to note that the proposal to revise the Nutrition Facts label is just one approach that has been proposed to address the public health concerns surrounding growing rates of obesity and chronic disease. But it is not the only approach.

Considerations

Prior to the publication of a final rule, FDA plans to conduct consumer research on several items, including the proposed revisions to the label format. FDA intends "to evaluate how variations in the label format may affect consumer understanding and use of the Nutrition Facts label"[111] and then use this research to inform consumer education efforts. Comprehensive consumer education that teaches individuals how to use the proposed label has been supported by various public health groups. The current nutrition label requires consumers to have some background knowledge on healthful and unhealthful nutrients.[112] Additional steps toward providing interpretative information may help consumers make more informed nutrition decisions. Public health and nutrition stakeholders point to the importance of considering consumer literacy, as lower health literacy and numeracy skills moderate consumers' ability to read and understand the Nutrition Facts label.

In addition, proposed changes to the Nutrition Facts label, in particular those based on the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (e.g., the supplemental proposed added sugars rule issued in July 2015), have been met with opposition. Media reports have flagged several recommendations in the DGAC's most recent report, with some maintaining that the committee went too far in making policy recommendations without sufficient evidence. Controversial recommendations included support for establishment of a DRV for added sugar, and to limit red and processed meat consumption, raising concerns that the DGAC made dietary recommendations that are not solely based on the nutritional value of foods (e.g., factors such as sustainability).[113]

Congress has tried to limit the scope of the Dietary Guidelines via the appropriations process. It is, however, important to note that the DGAC report is strictly advisory in nature, and it is

[110] FDA, "Preliminary Regulatory Impact Analysis (PRIA) for the Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Docket No. FDA-2012-N-1210) and 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 (Docket No. FDA-2004-N-0258)", 2014. http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM385669.pdf.

[111] 79 *Federal Register*, 11882.

[112] Letter from Jeanne Blankenship, MS RDN, Vice President, Policy Initiatives and Advocacy, Academy of Nutrition and Dietetics, and Pepin Andrew Tuma, Esq., Director, Regulatory Affairs, to FDA, August 2, 2014.

[113] A O'Connor, "Nutrition Panel Calls for Less Sugar and Eases Cholesterol and Fat Restriction," http://well.blogs.nytimes.com/2015/02/19/nutrition-panel-calls-for-less-sugar-and-eases-cholesterol-and-fat-restrictions/?_r=0.

ultimately up to the Secretaries of HHS and USDA to write the final policy document. It remains to be seen which of the proposed changes to the Nutrition Facts label may ultimately become part of the *Code of Federal Regulations*.

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