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United States Department of Health and Human Services
Food and Drug Administration
10903 New Hampshire Avenue

Silver Spring, MD 20993

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Comments of Consumers Union to
The Food and Drug Administration on
“Food Labeling: Revision of the Nutrition
And Supplement Facts Labels”
Docket No. FDA-2012-N-1210
RIN 0910-AF22

**Introduction**

Consumers Union\(^1\) strongly supports the Food and Drug Administration’s (FDA) proposal to revise the Nutrition and Supplement Facts labels. Accurate and informative nutrition guidelines are an important part of our mission to work for a fair, just, and safe marketplace for consumers and to empower consumers to protect themselves. That includes helping consumers get the best nutrition information they can about the foods they purchase. We believe that these revisions will help consumers to make more informed choices about what they eat, and will aid consumers in making choices that support a healthy lifestyle.

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\(^1\) Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union works for telecommunications reform, health reform, food and product safety, financial reform, and other consumer issues. Consumer Reports is the world’s largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications.
Our comments address the topics below. Specifically, we make the following points:

I. We generally support the revision to the Nutrition Facts panel.

II. Addition of a line for added sugars will advance public health. The label should also reflect a Daily Value (DV) for added sugars, and sugars should be listed in terms of both teaspoons and grams.

III. The FDA’s reduction of the Daily Value for sodium to 2,300 milligrams is inconsistent with the most recent health guidelines. FDA should reduce the DV for sodium to 1,500 milligrams.

IV. We support the changes to the listing of dietary fiber, but recommend that FDA include a new line for added fibers.

V. We support the FDA’s proposed listing of essential vitamins and minerals of public health significance.

VI. We generally support the format changes, including for calories and serving sizes, and believe FDA should include a DV and percentage DV for calories.

VII. We recommend that FDA conduct a comprehensive consumer education campaign, including a significant focus on calories and serving size, when the new Nutrition Facts Panel appears on food labels.

VIII. We prefer the alternative format and call upon FDA to move forward with a rule to require a more legible ingredient list.

IX. FDA should take further important steps on labeling, including mandatory labeling of caffeine content, disclosure of whole-grain content on grain-based products, and federal front-of-package labels.

Overall, we support FDA’s proposal of this rule as well as the serving sizes revisions, and urge the agency to finalize both rules in a timely manner.

I. We generally support the revisions to the Nutrition Facts Panel.

We generally support the FDA’s proposal to revise the Nutrition Facts Panel (NFP). A revision is needed, as the FDA has not updated the Nutrition Facts label since the 2003 trans-fat rulemaking, and has not established new or updated Daily Values (DVs) for nutrients since 1995. Since that time, as the agency notes, the public health profile of the U.S. population has changed, new information has become available about nutrient definitions, reference intake values, and analytical methods, and new dietary recommendations have been published. We applaud FDA for proposing these long-needed updates to the NFP.

The Dietary Guidelines for Americans, 2010 (DGA) affirms the role of over-consumption of calories and physical inactivity as the primary risk factors contributing to the epidemic of overweight and obesity in this country, and urges a focus on improved nutrition and physical activity choices among Americans. Moreover, we know that consumers use and read these labels. As FDA notes in its rule, “[t]he percent of working age adults that reported using the Nutrition Facts Panel always or most of the time when shopping for food increased to 42 percent in 2009–2010 from 34 percent in 2007–2008. Among older adults the percentage increased to 57 percent in 2009–2010 from 51 percent in 2007–2008.” See 79 F.R 11880, 11887.
II. Addition of a line for added sugars will advance public health. The label should also reflect a Daily Value for added sugars and sugars should be listed in terms of both teaspoons and grams.

a. We support the addition of added sugars on the label and support public education regarding added sugars.

We support FDA’s proposal to list added sugars on the Nutrition Facts label (and distinguishing it from the notation for all sugars, which we would recommend be re-labeled “Total Sugars”). In 2003–2006, added sugars (sugar, high-fructose corn syrup, etc.) provided about 14 percent of total calories for the average American, and 25 percent or more of calories for over 36 million Americans. According to data from the National Health and Nutrition Examination Survey (NHANES) 2007-2008 and U.S. Department of Agriculture (USDA) average per-capita loss-adjusted food availability data from 2012, on average, Americans consumed between 18 and 23 teaspoons (about 300 to 390 calories worth) of added sugars per day, though consumption has declined modestly over the last several years.

The main sources of added sugars are nutrient-poor foods, including cakes, cookies, candies, dairy desserts, and sugar-sweetened beverages (SSB) such as soda pop, energy drinks, sports drinks, and fruit drinks. Excessive added sugars intake, particularly from SSB – the largest source of added sugars in Americans’ diets – increases the risk of obesity, diabetes, cardiovascular disease, and metabolic syndrome. An additional concern is that the higher that diets are in added sugars, the lower they are in a variety of vitamins and minerals, including calcium, vitamin A, iron, and zinc. Consuming foods high in added sugars makes it difficult to meet nutrient needs and stay within calorie limits. In contrast, foods high in natural sugars, such as fruits and dairy products, are often rich in other nutrients.

The current nutrition label does not provide information regarding added sugars, although consumers need such information to help them eat in accordance with one of the DGA’s key recommendations – namely, to reduce intake of calories from added sugars. Currently, some information regarding added sugars can be found in ingredient labels, but the exact amounts are not disclosed on food packages. In reading ingredient labels, consumers may not know all of the forms of added sugar that can be in a food, such as concentrated fruit juice, and they may not understand that ingredients are listed in order of predominance. Listing added sugars on the Nutrition Facts label would provide vital information on the amount of added sugars in a food and help consumers eat less added sugars.

For many programs across the country in schools and other institutions, the current label have also made it difficult for those deciding on program guidelines to follow the Dietary Guidelines and limit the amount of added sugars in provided foods. To date, limiting total sugars has been the only option – an option that results in complex standards with detailed exemptions for foods with fruit or dairy ingredients that are sources of naturally occurring sugars.

In addition to providing consumers with information on the amount of added sugars in food products, public education on the food sources and health consequences of excessive added sugars intake is needed. Today consumers are exposed to an abundance of nutrition information, including information on added sugars that may be hard to interpret. FDA should develop materials to explain that consuming foods high in added sugars makes it difficult to meet nutritional needs and stay within calorie
requirements. Such an education program should emphasize that sugars that occur naturally in fruits, vegetables, and dairy products do not pose any health problem, and, indeed, people should consume more fruits, vegetables, and low-fat dairy products.

However, merely replacing sugary-sweetened beverages with fruit juices loaded with total sugars, for example, would not do much to address the issues of obesity, overweight, diabetes, and other health problems related to excess sugar intake. Once the new labels are implemented, the FDA should educate people how to interpret the added sugars line. Consumers need to understand that beverages could contribute to obesity even though all their sugars are naturally occurring.

b. FDA should propose a DV for added sugars to provide much-needed context for consumers.

Daily Values (DV) are an essential tool for consumer comprehension and use of nutrition information. In its proposal, FDA notes:

Section 2(b)(1)(A) of the 1990 amendments mandated that FDA regulations implementing section 403(q) of the FD&C Act require that nutrition labeling must be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. In particular, the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of a total daily diet, compare the nutritional values of food products, and to plan general diets. We also noted that the percent DV information advises the consumer how much of a recommended intake of that nutrient is provided by the food. See 79 F.R. 11880, 11887 (Emphasis added; citations omitted).

To provide needed context for an acceptable intake of added sugars, FDA should specify a DV for added sugars and require that the percent DV be indicated on the added sugars line. Doing so would greatly assist effectuating FDA’s purpose in adding a line for added sugars. As the agency makes clear, the rationale for inclusion of added sugars on the label is grounded in FDA’s concern for overall dietary health:

Our review [of the information related to added sugars] is not based on the factors we have traditionally considered for mandatory declaration that are related to chronic disease, health-related condition, or health-related physiological endpoint linked to the particular nutrient. Instead, our review is based on the need for nutrient information for consumers to implement key dietary recommendations to assist consumers to maintain healthy dietary practices and the need for consumers to be able to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. See 79 F.R. at 11880, 11891 (Emphasis added).

We disagree with the narrowness of FDA’s rationale for labeling. In addition to generally helping people “maintain healthy dietary practices,” labeling of added sugars would help people reduce their risk of obesity, dental caries, type 2 diabetes, heart disease, certain cancers, and other health problems.
Recent clinical studies have found that high intakes of fructose-containing sugars raise levels of triglycerides, visceral fat, liver fat, blood glucose, insulin, and small, dense LDL cholesterol.\textsuperscript{10,11,12} When Swiss researchers randomly assigned 29 healthy, normal-weight men to avoid fructose-containing foods or to consume beverages containing either 40 or 80 grams of fructose, 40 or 80 grams of glucose, or 80 grams of sucrose per day, waist-to-hip ratio rose significantly and a smaller (more atherogenic) class of LDL was found in those consuming beverages containing 80 grams of fructose or 80 grams of sucrose after three weeks. Note that those changes occurred after only three weeks in men who consumed either 6.5 or 13 percent of their calories from added sugars.\textsuperscript{13}

In the longest and largest double-blind, randomized intervention trial done to date, Dutch researchers randomly assigned 641 normal-weight children aged 4 to 12 who typically drank sugar beverages to receive one 8 oz. can a day of a beverage sweetened with either sugar (104 calories, about the same as a cup of Coca-Cola) or artificial sweeteners (0 calories). After 1½ years, body weight, BMI, waist size, and fat mass increased more in the youngsters who got the sugary drinks.\textsuperscript{14}

A recent prospective study of more than 11,000 people in the National Health and Nutrition Examination Survey (NHANES) III – a nationally representative sample of Americans – followed for a median of 15 years found a higher risk of cardiovascular mortality with increasing added sugar consumption. Those who got at least 10 percent but less than 25 percent of their calories from added sugars had a 30 percent higher risk of dying of heart attack, stroke, or other cardiovascular event than those who got less than 10 percent of their calories from added sugars. The risk was nearly three times higher for those who consumed at least 25 percent of their calories from added sugars (10 percent of the study population).\textsuperscript{15}

The FDA has proposed including added sugars on the NFP because this information will provide consumers with a new tool for choosing healthier diets. FDA should follow through on its own stated purpose for including added sugars labeling by including a DV for added sugars. As FDA notes, the purpose of any DV is to equip consumers with actionable information. In the case of a new category for the label, as added sugars will be, information about appropriate levels of consumption for a healthy diet is even more critical.

Without a DV for added sugars, consumers could compare only the relative amounts of added sugars between products, but would generally not be able to consider the amount of added sugars in a product in the context of their overall daily diets. The average consumer would see a number, such as 20, next to added sugars and have no idea whether that is a lot or a little. Including a DV is essential to ensuring that consumers are successful in reducing their consumption of added sugars and the potential adverse health effects of excessive sugars intake.

In its proposal, the FDA states that there is no “quantitative sound scientific basis” to establish a Daily Reference Value for added sugars.\textsuperscript{16} We respectfully disagree. In 1999, the Center for Science in the Public Interest (CSPI), along with leading health experts and organizations, petitioned the FDA to adopt a DV of 10 teaspoons, or about 40 grams for added sugars (160 calories or 8 percent of total calories based on a 2,000-calorie per day diet).\textsuperscript{17} That was based on the U.S. Department of Agriculture’s (USDA) recommendation that people consuming a 2,000-calorie diet limit their consumption of added sugars to 10 teaspoons per day (8.4 percent of calories).\textsuperscript{18}
Proposing a DV for added sugars would align the FDA with many other health authorities that have recommended a safe limit (about 6 to 10 percent of calories) for daily added sugars consumption. For instance:

- In 2003, the World Health Organization (WHO) recommended that individuals consume less than 10 percent of their calories from “free” sugars. That includes added sugars, but also the “free” sugars in fruit juices, honey, and syrups. For example, an individual who consumes a 2,000-calorie diet could consume up to 200 calories’ worth (50 grams, 12 teaspoons) of added sugar.19 (WHO’s March 2014 draft again recommends less than 10 percent, while also suggesting that “a reduction below 5%” would confer additional health benefits.20)

- In 2009, the American Heart Association (AHA) recommended that women consume no more than 100 calories (25 grams), and men no more than 150 calories (37.5 grams) per day from added sugars. That is equivalent to roughly 6 percent of total calories (based on intakes of 1,800 calories for women and 2,200 for men.21

- In 2005, the DGA recommended quantitative limits for added sugars combined with solid fats based on the discretionary calorie allowance for each level of calorie intake.22 For example, after lower-calorie, nutrient-dense food in each food group are selected, someone consuming a 2,000-calorie diet would have no more than 267 discretionary calories to expend on solid fats and added sugars (assuming no alcohol, which is not the case for many U.S. adults). Dividing those calories equally between solid fats and added sugars, a reasonable and realistic recommendation, would mean that no more than 133 calories (33 grams or 8 teaspoons) per day should come from added sugars. That amounts to 6 percent of calories from added sugars in a 2,000-calorie diet.23

These reports and others provide an ample basis for FDA to set a DV for added sugars. Given the known adverse effects of added sugars on obesity, cardiovascular disease, and type 2 diabetes, as well as potential dilution of healthful nutrients, should FDA fail to establish a DV for added sugars in this rulemaking because of a perceived lack of authoritative advice (or other reason), we urge the agency to immediately commission the Institute of Medicine to review the existing evidence and identify an upper limit for added sugars upon which a DV could be established and then conduct a subsequent limited rulemaking to obtain public comment. We view the matter as urgent, because providing a percent-DV would greatly assist consumers in making sense of the new information on labels and in understanding its significance as part of an overall healthy diet, consistent with FDA’s objectives in the rule.

c. **FDA should require that the amount of added sugars shown on food labels be expressed in terms of teaspoons, as well as grams.**

Considering the FDA’s stated objective for requiring a new line for added sugars in the nutrition label, the FDA should require that added sugars be expressed in a way that is understandable for consumers – teaspoons.

Few Americans are familiar with the metric measures used for total sugars (and other nutrients), because they are unrelated to their common experiences, such as measuring sugar into coffee or tea. They do, however, instantly understand measurements such as teaspoons, tablespoons and cups, which are commonly used in cooking and baking. Therefore, for reasons that are similar to those provided by FDA in proposing the many revisions to serving sizes – including altering them to refer to more
common measures – we support the need for providing the amount of added sugar in teaspoons in addition to grams.

Using a well-understood measure is especially important for public health education campaigns, such as the California Department of Public Health’s ‘Rethink Your Drink’ initiative, which expresses the amount of added sugars in beverages in terms of teaspoons. In fact, a 2010 nationally representative telephone survey conducted by CSPI found that 72 percent of respondents thought that including teaspoons as a measurement for sugar on food labels would be of assistance: 38 percent preferred listing only teaspoons of added sugars on the label, while 34 percent of respondents preferred both teaspoons and grams. Just 20 percent of those polled preferred listing sugar only in grams.

According to a 2012 survey of 712 readers by Consumer World, an Internet-based publisher of a consumer resource guide, those surveyed online were exposed to Nutrition Facts information in which the amount of sugars in a product was expressed in grams rather than in common household measurements. Up to 80 percent of survey participants could not accurately say how much sugar was contained in a product, and many respondents significantly underestimated the actual amount of sugar in the product.

For example, when asked whether 25 grams of sugar in a serving of yogurt was a lot or a little, less than 25 percent of respondents deemed the product “extremely sugary.” However, when the same product was labeled as containing the same amount of sugar – six teaspoons – twice as many of the respondents – nearly half – considered it “extremely sugary.”

Because it would improve the clarity of the information provided about added sugars, listing the amount of added sugars in terms of both teaspoons and grams would be fully consistent with FDA’s purpose for including the line for added sugars, which was, as noted above, “based on the need for consumers to be able to readily observe and comprehend the information on sugars and to understand its relative significance in the context of a total daily diet.” Consumers are more apt to understand the sugar content of a food when that information is provided in a measurement familiar to them. For sugar, that measurement is teaspoons. And there would be ample space on a new line for added sugars for the term “x tsp.”

III. The FDA’s reduction of the Daily Value for sodium to 2,300 mg is inconsistent with the most recent health guidelines. FDA should reduce the DV for sodium to 1,500 milligrams (mg).

We are pleased that the FDA has proposed lowering the Daily Reference Value for sodium. However, the agency’s proposed reduction from 2,400 mg to 2,300 mg is inadequate to protect public health and risks, endorsing a level of sodium in products that may be life-threatening for the majority of Americans. Instead, the FDA should lower the DV for sodium to 1,500 mg.

According to the proposed rule, the FDA selected 2,300 mg because it represents the Upper Limit and is consistent with the 2005 and 2010 DGA recommendations for the general population. We respectfully disagree with that rationale. The Upper Limit represents the highest “tolerable” intake level that is likely to pose no risk of adverse health effects. According to the Institute of Medicine, it is not intended to be a recommended intake.
The DGA cautions that 2,300 mg is too high, or intolerable, for individuals who are 51 and older, children, African-American, or have hypertension, diabetes, or chronic kidney disease – in other words, approximately one-half of the American population.\(^{26,27}\) The Guidelines advise these individuals to consume no more than 1,500 mg per day. For that reason, 1,500 mg is an appropriate target level for the general population. As noted above, the DGA already recommends that amount for half of all Americans.

The 2010 Institute of Medicine report *Strategies to Reduce Sodium Intake in the United States* recommended that the FDA lower the DV for sodium to 1,500 mg based on the Adequate Intake. The level of 1,500 mg is also consistent with recommendations from the 2010 Dietary Guidelines Advisory Committee, the Centers for Disease Control and Prevention, the American Heart Association, and others in the public health community.

There is ample evidence to support setting the DV for sodium at 1,500 mg. Numerous studies show a direct relationship between sodium intake and blood pressure; as dietary salt intake rises, so does blood pressure. Excess sodium consumption is strongly associated with the development and worsening of high blood pressure and an increased risk for stroke, heart failure, kidney failure, gastric cancer and osteoporosis.\(^{28,29}\)

Studies have concluded that reducing sodium consumption would have significant health benefits and reduce medical costs. Reduced sodium intake could help prevent hypertension in non-hypertensive individuals and promote hypertension control. Reduced sodium intake is also associated with curtailing an age-related rise in systolic blood pressure, and reducing the risk of atherosclerotic cardiovascular events, congestive heart failure, and stroke.\(^{30}\)

One study, for example, found that reducing sodium intake by 1,200 mg daily could result in 60,000 to 120,000 fewer coronary heart disease events, 32,000 to 66,000 fewer strokes, 54,000 to 99,000 fewer myocardial infarctions, and 44,000 to 92,000 fewer deaths from any cause, as well as save $10 billion to $24 billion in health care costs each year.\(^{31}\) Another study projected that achieving a goal of 1,500 mg would reduce deaths from cardiovascular disease by between 500,000 and 1.2 million over the next 10 years.\(^{32}\)

While the health improvements mentioned above are based on theoretical calculations, actual benefits of sodium reduction appear to have been realized in the United Kingdom, which launched a sodium reduction program in 2003. Between 2003 and 2011, the average population sodium intake fell by 15 percent, according to 24-hour urinalyses, due to a gradual reduction in the sodium content of processed foods. During the same time period, the average population blood pressure also fell, and deaths from heart disease and stroke fell by a stunning 40 percent and 42 percent, respectively. The authors of that study believe that the decrease in blood pressure and the resulting decrease in mortality are likely the result, at least in significant part, of the decrease in sodium consumption.\(^{33}\)

The FDA expresses some concern that lowering the DV to 1,500 mg might be inconsistent with the 2013 IOM report *Sodium Intake in Populations: Assessment of Evidence*.\(^{34}\) We would caution the FDA against relying on that much-criticized IOM report as a basis for setting dietary policy. That IOM report should not change the Guidelines’ advice for three reasons:
• The IOM report found that there was too little evidence to conclude that reducing sodium intake below 2,300 mg would either increase or decrease the risk of cardiovascular disease. However, the IOM failed to consider hypertension itself as a health outcome, despite the indisputable relationship between blood pressure and cardiovascular disease. There is clear evidence from the DASH-sodium study that reducing sodium intake from 2,300 mg to 1,500 mg per day lowers blood pressure.35 Furthermore, it is infeasible to conduct large, long-term, controlled trials that compare heart attack and stroke rates in people who consume considerably less than 2,300 mg of sodium a day given the high sodium content of the American food supply.

• The IOM committee found possible harm of very low sodium intakes in people with heart failure. However, that conclusion was based largely on suspect evidence from one group of Italian researchers who randomly assigned patients with heart failure to normal or very-low-sodium diets. The researchers also restricted the patients’ water intake and gave them high doses of diuretics, an aggressive treatment that can deplete blood volume and is not used in the United States. (Moreover, last June, the journal Heart retracted a meta-analysis from the same research group because two of the studies had duplicate data,36 thus calling into question the researchers’ findings, irrelevant as they are to Americans.)

• Roughly 90 percent of Americans consume more than 2,300 mg of sodium per day (most also have inadequate potassium intake),28 and two out of three adults have hypertension or prehypertension.3 The Trials of Hypertension Prevention (TOHP) found that reducing sodium intake to less than 2,300 mg a day (10 percent of the participants) resulted in a 32 percent lower risk of cardiovascular disease among people with prehypertension, compared to people consuming 3,600–4,800 mg a day.37

The FDA also raised a concern that changing the DV for sodium to 1,500 mg might confuse consumers, because 1,500 mg represents a Reference Daily Intake (level to achieve) rather than a Daily Reference Value (level not to exceed). We do not believe this would be a serious issue. Because of the high sodium content of the food supply and the fact that the average American consumes more than 3,400 mg of sodium a day, it is unlikely that individuals will reduce their sodium intake too much and fall short of the 1,500 mg recommendation.

Finally, FDA notes that it would be difficult for consumers to reduce their sodium consumption to 1,500 mg because of the high-sodium content of the current food supply and taste preferences. We agree. However, lowering the DV for sodium would provide greater incentive for manufacturers to reduce the sodium content of their foods. Manufacturers would not want product labels to list an extremely high percentage of the DV for sodium, a scenario that would be more likely with a lower DV, thereby encouraging reformulation.

Most importantly, as the FDA acknowledges, “DVs are based on scientific data supporting healthy dietary practices, not on the levels of a nutrient present in the food supply.”39 Following that principle, the FDA’s decision should not be influenced by the current amount of sodium in the food supply or the difficulties a consumer may face in quickly beginning to consume a diet with no more than the recommended amount of sodium. FDA’s DV should be based on the science, which strongly supports a DV of 1,500 mg for sodium.
IV. We support the changes to the listing of dietary fiber, but recommend that FDA include a new line for added fibers.

We support continuing to require dietary fiber to be declared on the label, as well as FDA’s proposed new definition of dietary fiber, which would allow declaration of only those forms of dietary fiber that the agency has determined to have a physiological effect that is beneficial to human health. This definition would exclude soluble and insoluble non-digestible carbohydrates that do not have a demonstrated benefit for health. As we have seen fortification of foods with processed fiber that can make less healthful foods appear to be a healthier choice, such as ice cream bars fortified with inulin, the proposal’s inclusion of a test for added fiber that measures its benefits for health represents a considerable advance.

However, the Dietary Guidelines emphasize unprocessed forms of dietary fiber, which is often present as part of whole, healthy foods, such as vegetables and legumes, and notes that “[f]iber is sometimes added to foods and it is unclear if added fiber provides the same health benefits as naturally occurring sources.”40

We therefore recommend that FDA require manufacturers to disclose the amount of “added fiber” as a subcategory under “total fiber,” in a manner similar to the proposed requirements for disclosure of added sugars under the total sugars category. Consumers should be able to tell from reading the label how much of fiber has been added during processing versus the amount that is naturally in foods such as whole fruits, vegetables, whole grains, and beans.

V. We support the FDA’s proposed listing essential vitamins and minerals of public health significance.

We support FDA’s proposal to continue to require mandatory declaration of calcium and iron on the Nutrition Facts label and to begin to require mandatory declaration of vitamin D and potassium because the Dietary Guidelines for Americans, 2010 (DGA) considers these four vitamins and mineral to be nutrients of public health concern.41 Less than 2 percent of American adults get the recommended amount of potassium (4,700 milligrams a day), which can help lower blood pressure.42 Adequate calcium status, which is important for bone health, can be achieved through consumption of milk and milk products, but also some vegetables. A few foods (e.g., salmon and tuna) naturally contain vitamin D, which is important for bone and other health outcomes, while vitamin D is added to many others (e.g., milk and milk products, breakfast cereals, and yogurt). Lastly, 9 percent of women aged 12 to 49 are iron deficient, which is a concern for women who could become pregnant.43 Dietary sources of heme iron, which is more readily absorbed than the non-heme iron form, include lean meat, poultry, and seafood. Given the wide variety of foods in which these nutrients of public health concern are found, we support FDA’s decision to require mandatory labeling of these vitamins and minerals to help the general public and specific subpopulations meet nutrient requirements.

Additionally, we support FDA’s proposal to make declaration of vitamins A and C voluntary because they are not considered nutrients of public health concern in the current DGA.44 Data from NHANES 2003–2006 demonstrated that few children and pregnant women (i.e., vulnerable subpopulations at risk
for inadequate intake) have intakes (or serum levels indicative of deficiency) below the Estimated Average Requirement (EAR) for those nutrients.45

We support FDA’s criteria for mandatory and voluntary declaration of essential vitamins and minerals of public health significance on the Nutrition Facts label. As the FDA indicated, mandatory declaration of a nutrient was considered when there is 1) public health significance, and 2) a quantitative intake recommendation that can be used for setting a DV (or Daily Reference Value or Recommended Daily Intake), or 3) there is evidence highlighting the role of the nutrient in chronic disease risk. Voluntary declaration was considered appropriate for nutrients that are not essential vitamins and minerals that either 1) have a qualitative intake recommendation that does not have public health significance or 2) do not have a quantitative intake recommendation but have public health significance.46

Should the release of the Dietary Guidelines for Americans, 2015 precede the publication of FDA’s final rule on revision of the Nutrition Facts label, we recommend that decisions about mandatory and voluntary declaration of vitamins and minerals be based on the vitamins and minerals considered to be nutrients of public health significance in the most recent version of the DGA.

VI. We generally support the format changes, including for calories and serving sizes, and believe FDA should include a DV and percentage DV for calories.

We strongly support the FDA’s proposal to continue to require total calories to be declared on the label and to increase the prominence of the calorie declaration. One of two key concepts of the 2010 DGA, included because of the high prevalence of overweight and obesity, is to “maintain calorie balance over time to achieve and sustain a healthy weight.”47 To support consumers in selecting, preparing, and consuming foods and beverages with the appropriate number of calories to meet their needs for weight management, consumers must be able to easily see and use the number of calories in a serving of a particular food or beverage. Therefore, we strongly support the proposal to increase the type size for both the “Calories” heading and the numerical value and to require that the information be highlighted in bold or extra bold type.

We do think that FDA should include a DV for calories and a percentage DV for calories. Throughout the proposal, the FDA uses 2,000 calories per day as the reference point for calculating DVs for nutrients. Consumers should have the benefit of this yardstick for calories as well as information related to the percentage DV in caloric intake represented by a product.

Specifically, the DGA recommends that people “control total calorie intake to manage body weight.”48 For the two-thirds of adults and one-third of youth who are overweight or obese, this means consuming fewer calories. According to the Centers for Disease Control and Prevention,49 overweight and obesity increase the risk for many of the leading causes of death, including heart disease and stroke, several types of cancer, diabetes, and other conditions, including high blood pressure, high cholesterol, liver disease, sleep apnea, osteoarthritis, and gynecological problems.

Despite the fact that calorie information has been included on the Nutrition Facts label since its inception, it has not been displayed prominently. Instead, the information is shown in the same type size as the levels of cholesterol, sodium, and several other nutrients. While information about other nutrients
is important, information on calories is particularly important considering the prevalence of obesity and the resulting diseases, disabilities, and costs.

In addition to being able to easily identify the number of calories per serving, we believe it is essential for consumers to be able to easily identify and comprehend the serving size and number of servings per container. Therefore, we support the proposal to increase the prominence of the “Servings per container” declaration in a similar manner as the “Calories” declaration and recommend that FDA also consider increasing the size and prominence of the “Serving size” declaration.

Calorie information is only useful if consumers understand the amount of food or beverage that contains the specified number of calories (and other nutrients). If an individual’s portion size is much larger or smaller than the serving size specified on the label, the calories consumed will vary dramatically. Research has found that people tend to eat more when the portion size or serving container is larger, indicating a need for increased consumer education and awareness about what the labeled serving size means and appropriate portion sizes.\textsuperscript{50} Well-controlled clinical studies suggest that providing children and adults with larger food portions can lead to significant increases in energy intake.\textsuperscript{51}

One recent study found that many consumers are unable to make accurate comparisons among similar products that have different serving sizes and numbers of servings per container.\textsuperscript{52} In that study, consumers who made inaccurate comparisons consistently identified the product with the smaller number of calories per serving as the healthier one, regardless of the number of servings or total number of calories in the package. Another recent study found that a significant fraction of consumers who said they look at the Nutrition Facts label and ingredient list when shopping do not look at the serving size.\textsuperscript{53}

FDA should more closely review existing, and conduct additional, consumer research to determine the value of more prominently providing information about serving size in larger type size than proposed, in addition to the number of servings per container.

Overall, we strongly support and agree with the tentative conclusion that proposed changes to the calorie and serving size declarations would serve as an anchor to the Nutrition Facts label by focusing the reader’s attention on that information.

\textbf{VII. We recommend that FDA conduct a comprehensive consumer education campaign, including a significant focus on calories and serving size, when the new Nutrition Facts Panel appears on food labels.}

We strongly believe that a well-funded, coordinated, multi-component consumer education campaign to promote and explain the new Nutrition Facts label is necessary to help consumers understand the information provided by the label and how they could use it to make healthier food and beverage choices. As we have seen with FDA’s earlier public service campaigns, including its recent “The Real Cost” campaign targeting youth tobacco use, FDA has a unique ability to get the attention of the public and shape understanding about the risks of lifestyle habits and choices.

The consumer education campaign should be coordinated among federal government agencies, including FDA, CDC, other parts of the Department of Health and Human Services (HHS), USDA, and non-government entities, including food manufacturers, retailers, and non-profit organizations with an
interest in nutrition and health. The campaign should begin when the final or interim final Nutrition Facts label and serving size regulations are implemented. While it would be important for all consumers to know about, understand, and use the revised Nutrition Facts label, the consumer education campaign should primarily target consumers who are least likely to understand and use the label, including low-income and low-education consumers, who are more likely to suffer from many obesity- and nutrition-related chronic diseases.

The consumer education campaign should integrate with existing consumer education programs and initiatives, including SNAP-Ed, school-based nutrition education programs, and grocery store labeling and education initiatives. The education campaign should emphasize calories, since knowledge of calories is important for rolling back the obesity epidemic; sodium, because of its contribution to cardiovascular disease; and nutrients that will be on the Nutrition Facts label for the first time, such as added sugars.

More specifically, FDA notes in the proposal that it plans to conduct consumer research on several items prior to the publication of a final rule. In addition to the research agenda identified therein, we urge the agency to conduct additional research on several proposed changes and items on which comment has been requested. Needed research could be completed within the expected time, and should not delay publication of a final rule if the agency moves forward expeditiously in commissioning the research. Topics raised in the proposed rule on which we believe additional research is warranted include:

- Moving the DV to the left-hand column: Does this distract from or discourage consumers who are trying to obtain information from the label?
- Changing “% Daily Value” to “%DV:” Does this facilitate consumer understanding of the significance of daily values?
- Is consumer understanding assisted by measuring sugar in teaspoons in addition to grams?
- How does the relative size of information and the order of information on serving size, number of servings and calories impact consumer use and understanding?
- What is the impact of replacing the term “carbohydrates” with the term “carbs”?
- What is the impact of modifications to the footnote on consumer understanding of how the nutrition information on the label fits their daily nutrient needs?

In addition, we urge FDA to conduct research and publish its findings concerning the impact of nutrition labeling requirements on fortification of foods and beverages and the impact of that fortification on consumer intake of certain vitamins and minerals commonly added to foods and beverages through fortification.

VIII. We prefer the alternative format and call upon FDA to move forward with a rule to require a more legible ingredient list.

a. We strongly prefer the alternative format of the Nutrition Facts label.

We strongly prefer the alternative label format over the agency’s central proposal, because we think it will more effectively assist consumers in choosing more foods that are high in nutrients they should consume more of and fewer foods that are high in nutrients they should eat less of. Both the current
label and main proposed label are plain lists of information with lots of numbers and include nutrients that may be unfamiliar to many consumers. For certain nutrients, we suspect that some consumers don’t even know whether they should consume more or less of them. Providing context and advice within the label would, in effect, constitute part of FDA’s education campaign.

According to the proposed rule, about 40–55 percent of Americans regularly use the Nutrition Facts label when purchasing food. That percentage varies significantly by demographic group, with a Canadian study finding that individuals of higher income, higher education, and under age 65 are more likely to use nutrition labels to assess calorie and nutrient information about a product.

Research has found that people who use nutrition labels are more likely to have a lower body mass index (BMI), a measure of obesity, than people who do not, though such studies cannot establish cause and effect. The difference in label usage is particularly striking for women, with women who do read nutrition labels having a BMI that is 1.49 points lower than women who do not (for a woman who is 5’5” tall, that represents a difference of about 9 pounds). Again, while such studies cannot establish cause and effect, that finding suggests that increasing the use of nutrition labels could be an important tool for helping people manage their weight. Making the Nutrition Facts label more understandable could help to encourage more people to use nutrition labels, as well as help them to understand them and use them effectively in their food purchase and consumption decisions.

A label that takes a step towards providing interpretive data is consistent with the need to make information clearer for consumers with lower levels of health literacy and numeracy. Interpreting the data on the current and proposed label requires a high degree of background understanding about healthful and less-healthful nutrients. Grouping nutrients into categories that clearly indicate, in comprehensible language, which nutrients are more or less healthful would help to achieve the purposes underlying most of FDA’s proposed changes to the label, as it would make clear that consumers should consume less sodium and added sugars, among other items.

Following its detailed investigation and a prior report, the 2012 Institute of Medicine (IOM) report on front-of-pack labeling points out the overall need for interpretive information for consumers. The IOM also highlighted some of the barriers to current consumer understanding, noting studies that demonstrate that:

- “…a lack of nutrition knowledge is a major barrier to effective use of the NFP and may actually lower the motivation of some consumers to use the nutrition information on the label;”
- “…some racial groups…. are less likely… to use and understand nutrition labels, primarily because of lack of time to read labels and lack of understanding of the nutrition information;”
- “An estimated 90 million U.S. adults have literacy and numeracy skills that are inadequate to function in the current health care environment;”
- “Adults with low health literacy skills are less inclined to use nutrition labels and are at greater risk for diet-related health outcomes;”
- “…interpretational aids that make the nutrition label easier to use and enhance the ability to compare products may help consumers better understand how a product fits into their overall diet;” and
• consumers favor front-of-package interpretive labels, in part, because they “lack the cognitive
skills needed to use nutrition information to compare products and interpret the nutrients in the
context of their total diet.”

All of these factors equally would support the alternative label as a step in providing an interpretive
gloss on the NFP. Clearly labeling what consumers should do about particular nutrients would
effectuate a massive step forward in popular understanding of basic principles of nutrition, and would
embed this essential education on every package.

b. We call upon FDA to propose a rule to require a more legible ingredient list on
products and to group all sugars in the ingredient list.

We applaud FDA for several key proposed changes to the format of the Nutrition Facts label. However,
we encourage the FDA to propose further improving the food labels, by proposing regulations to require
a more legible and useful ingredient list.

In 1978, the FDA held a series of nationwide hearings and solicited written comments on food
labeling.59 Since then, FDA has made no effort to improve the ingredient label. Current guidelines
require manufactures to use a type size that is at least 1/16\text{th} inch in height, which is now smaller than
many print newspapers.60,61 Aside from using small print, many manufacturers use all capital letters, a
condensed and san serif font, minimal kerning, and full justification. That squeezes letters and words
together, making them even more difficult to read. The format of the ingredient list contrasts sharply
with the information presented in the Nutrition Facts panel, which must use upper and lower case letters,
ensure that letters never touch, and use at least 1 point of leading (i.e., the space between two lines of
text).62

A difficult-to-read ingredient list is particularly problematic for consumers suffering from food allergies,
an estimated 9.7 percent of American adults and 6.5 percent of children.63 The 2004 Food Allergen
Labeling and Consumer Protection Act requires that food products containing “major” food allergens
(milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) declare the allergen in the ingredient
list, or separately by placing the word “Contains” followed by the allergen.64,65 However, the Act
allows allergens to be printed in the same small type size as that used in the ingredient list.

Additionally, because the FDA does not require labeling to indicate the percentage of whole grains in a
product, consumers must deduce from the ingredient list the relative proportion of whole grains,
compared to refined grains. For example, if whole wheat is listed in small print in the middle of the
ingredient list, consumers are less likely to see it and recognize that the product likely contains only a
small amount of whole grains.

There is a critical need for a more legible ingredient list on products to better inform consumers. Last
fall, the Food Labeling Modernization Act was introduced in both the House and Senate. It would
require the FDA to modernize the ingredient list to include upper- and lower-case letters, bullet points
between adjacent ingredients, and other changes to improve the readability (see Figure).66 We urge the
FDA to act by supporting these changes that would make ingredient labels more useful for consumers
who want to make safer, more healthful food choices and to seek out or avoid specific food ingredients
for health, behavior, religious, or other reasons.
In addition, added sugars should be grouped together in the ingredient list. While adding a line in the Nutrition Facts label for added sugars would make it easier to understand the amount of those sugars in a product, many consumers would like to read the ingredient list to determine the relative amount of added sugars in a product. However, when various added sugars are scattered in the ingredient list, it is tough to estimate the total amount of those sugars and compare that to other ingredients. Furthermore, many consumers may not recognize the many guises of added sugars on food labels, such as corn syrup, dextrose, fructose, high-fructose corn syrup (HFCS), honey, lactose, maltose, molasses, raw sugar, and sucrose. Therefore, we recommend that the FDA require the grouping of sugar sources in the ingredient list and identifying them as such – with individual sugars in parentheses – so consumers could get a better idea of the sugars content in a product.

Figure. Label Makeover
IX. FDA should take further important steps on labeling, including mandatory labeling of caffeine content, disclosure of whole-grain content on grain-based products, and federal front-of-package labels.

a. To assist consumers, FDA should require labeling of the amount of caffeine per serving in foods and beverages.

We urge the FDA to require a disclosure of caffeine content below the Nutrition Facts panel or ingredient list. Many consumers are concerned about caffeine and need to know how much of that mildly addictive, stimulant drug is in foods and beverages. That’s particularly the case as more and more companies are adding to caffeine (or coffee or guarana) to new food categories, such as “water enhancers,” candies, and pancake syrup. Caffeine may cause anxiety and insomnia, and caffeine toxicity, which can occur in extreme cases, can “mimic amphetamine poisoning and lead to seizures, psychosis, cardiac arrhythmias and, potentially but rarely, death.”68

Consumers may not expect to find much caffeine in foods other than coffee, tea, and cola drinks. However, Consumer Reports has learned that many foods can be unexpected sources of caffeine, and consumers may be unaware of their daily intake of caffeine. In a 2011 story, Consumer Reports reported on caffeine amounts in coffee-flavored yogurts, (e.g., 30 mg in a six-ounce serving), frozen yogurts (e.g., 30 mg in a four-ounce serving), and ice creams (e.g., 42 mg in ½ cup). FDA has reported that caffeine has also appeared in jelly beans, popcorn, waffles, syrup, marshmallows, and sunflower seeds, among others, and sometimes the amount of caffeine is not disclosed.69

While there are no specific recommendations for caffeine in the United States, some population subgroups of consumers may be watching their caffeine intake for health reasons, and therefore would need to be able to ascertain the caffeine levels in everything they eat and drink. Children, in particular, can be quite sensitive to caffeine, and the American Academy of Pediatrics recommends that dietary intake should be discouraged for all children, due to the potentially harmful health effects of caffeine.70 Adults might want to limit caffeine intake in the evening to prevent it from interfering with their ability to sleep.

In addition, all consumers need to be mindful of recommended health limits on caffeine consumption; disclosing the caffeine content in the same place in all products (including coffee and tea) would aid consumers in making healthier decisions about their caffeine intake. Health Canada standards state that most healthy adults can safely consume up to 400 mg per day, 45 to 85 mg for children (4–12 years), and 2.5 mg/kg/day for children 13 years and older.71 In an August 2012 letter, the FDA stated that for healthy adults, caffeine intake up to 400 mg/day is not associated with adverse health effects. The American College of Obstetricians and Gynecologists recommends 200 mg for pregnant women. But without the labeling of caffeine content of foods and beverages, consumers – whether in a special population or not – will not be able to tell whether foods they want to consume would put them over those limits.

Although caffeine is listed in the ingredients section of a food label when added to a food product, that is insufficient.72 Consumers should be able to tell from the packaging of any food or beverage that contains added caffeine, coffee, tea, guarana, kola nuts, or other source exactly how many milligrams of caffeine a serving contains. That information is especially important for parents and caregivers who
want to control caffeine consumption by children, as well as individuals who are sensitive to caffeine. This labeling is also critical as some products, such as energy drinks, may have the same amount of caffeine in one commonly consumed serving as multiple cups of coffee. Therefore, we urge FDA to invite public comment on a possible requirement that foods, beverages, and dietary supplements disclose in a conspicuous, consistent location the specific amount of caffeine per serving. This would be appropriately responsive to the concerns that led FDA to announce in May 2013 that it would investigate the health and safety implications of the growing amounts of caffeine being added to food products, especially as to children and adolescents.73

b. FDA should require companies to provide the percentage of whole grains in grain-based foods.

For years, nutrition experts have urged consumers to eat more fiber and whole grains to improve their health. Notably, *The Dietary Guidelines for Americans, 2010* recommends that Americans consume at least half of all grains as whole grains.74 Some consumers have responded to that sound advice by seeking out products with names that tout their whole grain or multi-grain content. Yet many of these products are made with white flour as the first ingredient and contain little whole grains. As with added sugars, additional information is required as a fundamental first step in ensuring that consumers can act easily to follow consensus dietary recommendations.

FDA’s own regulations (21 CFR section 102.5 (b)) states that “[t]he common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.” Yet FDA’s enforcement record on these claims by a large number of companies is scant. Requiring all grain foods to indicate the percentage of whole grains in a conspicuous and consistent location on product labels would help effectuate that broader regulation in the grains category. If grain claims (“made with whole grains,” “multi-grain,” “contains whole grains,” and similar claims) are made on principal display panels, the disclosure should be made adjacent to those claims.

When consumers are thwarted by a lack of clarity in the marketplace, sound nutrition advice becomes far less meaningful and actionable. Informing consumers of the percentage of whole grains in grain-based products could address that problem by using space near the NFP label (and where appropriate on principal display panels when claims are made there). The percentage of whole grains (as a percentage of total amount of grains) should be listed on all grain-based products in a conspicuous, consistent location. If a product does not contain whole wheat or other whole grains, then the label should specify that it “contains no whole grain.”

c. FDA should immediately address the need for consistent and interpretive front-of-package labeling.

While we applaud FDA’s important proposed updates to the Nutrition Facts Panel, there remains a great need for easily understood, federally regulated, front-of-package nutrition labels. In an era in which diet-related health problems, such as obesity and heart disease, are far too frequent and consumers’ time
and ability to decipher the complicated Nutrition Facts label is frequently constrained, front-of-package (FOP) labels would greatly facilitate healthy consumer choices.

As described in the above section on consumer research on labeling, the population that is least likely to read and understand the information on the NFP is the same population that, for health reasons, needs clear, interpretive health information most. Lower health literacy and numeracy skills as well as restricted attention spans will, despite FDA’s best efforts, impact the number of consumers who can take full advantage of the proposed revisions to the NFP.

Most consumers, instead, are far more able to use information on the front of packages, which is what they see on store shelves while shopping. Yet front-of-package labeling in the U.S. is disjointed and inconsistent. A variety of different types of labels created by various stakeholder groups are used, creating confusion among consumers. Some of these systems are notably stronger than others, but many are flawed.

Most prominently, the Grocery Manufacturers’ and Food Marketing Institute’s “Facts Up Front” labeling system pulls some information from the nutrition label to the principal display panel, but does not interpret that information for consumers. That approach is not sufficiently conducive to aiding consumers’ quick judgments about which foods are healthiest to purchase, because it simply reiterates a few of the nutrients on the Nutrition Facts Panel, without providing more context. In addition, because it is a voluntary approach, the least healthy foods are also less likely to be labeled.

An ideal front-of-package nutrition label would create a single measure that takes into account the overall healthfulness of a food, including calories, added sugars, fats, and sodium. We welcome the addition of added sugars to the Nutrition Facts Panel, as this will allow its use in a future front-of-package label.

Some systems use traffic light-type indicators to identify how healthful different nutrient levels are, while others use numerical or other ranking systems. Each means of rating healthfulness has advantages and challenges. We suggest actively developing the body of research to evaluate which system is most effective at encouraging healthful food choices by consumers.

When considering appearance we ask that FDA keep in mind that simple, familiar front-of-package labels were the most successful in encouraging healthy eating choices. For comparison purposes, it would also be ideal to also have front-of-package labels as signage or shelf tags on produce and other foods that are not packaged with individual wrapping or boxes. Finally, when such labeling goes into effect, the FDA would need to mount a comprehensive education program that teaches consumers how to use those labels.
Conclusion

Consumers Union strongly supports the update to the Nutrition Facts Panel. We appreciate FDA’s consideration of our views on this issue of great importance to the health and wellbeing of American consumers.

Respectfully submitted,

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Endnotes


23 The 2010 Dietary Guidelines are consistent with this, stating that no more than 5 to 15 percent of calories should come from a combination of solid fats and added sugars. http://www.cnpp.usda.gov/dgas2010-policydocument.htm.


38 The average sodium intake found by NHANES of 3,400 mg per day significantly understates actual intake, because participants in NHANES surveys typically understate their food intake and because NHANES does not ask about salt added in cooking or at the table. Actual intake is likely to be closer to 4,000 mg per day.

39 79 FR at 11917.


41 Id.


45 79 FR at 11939.

46 79 FR at 11890–11891.


48 Id.


54 79 FR at 11887.


59 43 FR 25296.

60 21 CFR 101.2. Information panel of package form food.


64 After the law was passed, FDA required a ninth allergen, carmine/cochineal extract, to be disclosed on labels. See 74 Fed Reg 207 (Jan. 5, 2009).


73 Id.
