



July 25, 2014

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane; Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-1210; Food Labeling: Revision of the Nutrition and Supplement Facts Labels

Dear Sir or Madam:

The American Society for Nutrition (ASN) appreciates the opportunity to comment on the proposed rule “Food Labeling: Revision of the Nutrition and Supplement Facts Label.” ASN is dedicated to bringing together the world's top researchers to advance our knowledge and application of nutrition. ASN has more than 5,000 members, many who have been closely involved with the development of the food label - from conducting the research and data collection that form the scientific foundation supporting label information to developing the nutrition policies that govern how the label is developed and used. ASN member scientists served on the 2010 Dietary Guidelines Advisory Committee (DGAC) and the Institute of Medicine (IOM) Dietary Reference Intake (DRI) panels, including the Committee that wrote *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* and other reports referenced in the proposed rule.

ASN applauds FDA for undertaking a major revision to the Nutrition Facts label, and for the commitment to the prevention of chronic diseases through nutrition. ASN also commends the attention FDA has given to increasing the Nutrition Facts label's relevance to addressing the obesity epidemic - in particular, by highlighting calorie content.

Mandatory or Voluntary Declaration of Non-Statutory Nutrients

We invite comment on our use of the most recent consensus reports and whether the information and data on which FDA relies from such reports for proposed changes is consistent with current scientific information, the factors for considering mandatory and voluntary declaration of non-statutory nutrients, and whether there is an appropriate alternative analysis to application of these factors.

ASN strongly supports the use of quantitative intake recommendations, such as the IOM reports used to establish the DRIs, to guide declaration of non-statutory nutrients. ASN supports the appropriate use of the *Dietary Guidelines for Americans, 2010 (DGA)*,¹ or the *2015 DGA*, if available, to guide declaration of non-statutory nutrients, such as when

¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 7th Edition, Washington, DC, 2010.

quantitative intake recommendations are not in IOM reports and can be supported by a Nutrition Evidence Library systematic review.

Calories

We invite comment on the tentative conclusion to no longer permit the declaration of “Calories from fat” on the Nutrition Facts label.

ASN strongly supports the decision to no longer permit “Calories from fat” on the Nutrition Facts label. There is little biological reason for consumers to focus on calories from fat, except in cases when extremes in dietary fat intake are consumed. “Calories from fat” does not provide useful information to the American public leading to a reduction in chronic disease risk, but rather, will divert attention from more important issues such as type of fat consumed and total calories.

We invite comment on the tentative conclusion not to establish a DRV for calories and include a percent DV for the declaration of calories.

ASN supports the decision to not establish a DRV for calories nor to require or permit a percent DV for calories on the Nutrition Facts label since there is no appropriate quantitative intake recommendation for calories that can be applied to the general US population.

Fat

We invite comment on the proposed definition of fatty acids [aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group], as well as on our tentative conclusion that acetic, propionic, and butyric acids should not be excluded from the definition of total fat.

ASN supports FDA’s current definitions of fatty acids, saturated fat, and total fat and agrees that, according to a food chemistry definition, acetic, propionic, and butyric acids are short-chain fatty acids. However, ASN believes that consumer education around this subject is warranted so that consumers understand that the physiological effects of acetic, propionic, and butyric acids are different from the health effects that have been linked to longer-chain fatty acids.

We request comment on whether mandatory labeling of trans fat would still be necessary if the tentative determination that partially hydrogenated oils, the source of industrially produced trans fat, may not be generally recognized as safe is finalized.

ASN believes that the declaration of *trans* fat remains relevant on the food label, regardless of whether FDA determines that partially hydrogenated oils (PHOs) are not considered GRAS. Therefore, ASN supports that *trans* fat be declared on the food label. ASN believes that before *trans* fat should be considered for removal from the Nutrition Facts label, important research questions related to how this determination may affect public health overall must be answered. ASN strongly believes FDA must address

research questions, such as those listed below, prior to considering the removal of mandatory *trans* fat labeling. For example:

- What are the health implications related to natural *trans* fat consumption?
- If ruminants become the primary source of *trans* fat, what would the average intake of *trans* fat/ day be for the average consumer? Does this level cause health concerns?
- What are the health implications of product reformulations on the general public?

We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the individual declaration of n-3 or n-6 polyunsaturated fatty acids, as well as EPA or DHA.

ASN is not aware of an appropriate alternative analysis for n-3 or n-6 polyunsaturated fatty acids, as well as EPA or DHA.

Carbohydrate

With respect to added sugars, we request comments on our tentative conclusions and proposed provisions for mandatory declaration of added sugars, the placement of this information as double indented line below total sugars, and means to verify compliance.

ASN has concerns with FDA’s rationale for the inclusion of added sugars on the food label. While IOM reports^{2,3} and the 2010 DGA¹ recommend reducing intake of calories from added sugars and consumption of foods and beverages containing added sugars, additional conclusions regarding added sugars remain elusive based on insufficient evidence regarding the effects of added sugars (beyond contribution of excess calories) on health outcomes. The 2011 IOM Front-of-Package labeling report³ also notes this is likely due to “the inability to distinguish analytically between added and naturally occurring sugars in foods without obtaining proprietary product information and including that information on the Nutrition Facts panel; and the relatively small number of food and beverage categories with high amounts of added sugars.” Consumption of excess calories from any source, including sugars or starches, whether added or naturally occurring, may lead to a diet that exceeds daily energy requirements and could contribute to weight gain. This topic is controversial and a lack of consensus remains in the scientific evidence on the health effects of added sugars alone versus sugars as a whole. There is also a lack of evidence on the usefulness of a declaration of added sugars on the label to improve food choices and the health of consumers. Therefore, ASN recommends

² Institute of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. Washington, DC: The National Academies Press, 2002.

³ Institute of Medicine. *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices*. Washington, DC: The National Academies Press, 2011.

careful consideration of the totality of the scientific evidence, as well as consideration of compliance and other technical issues.

Both IOM reports^{2,3} note that added sugars are not chemically different from naturally occurring sugars, thus raising issues about compliance. Since there are no analytical methods to distinguish between naturally occurring sugars and those added to foods or beverages, manufacturers may encounter difficulties in accurately declaring the amount of added sugar in a final product. False reporting may also be a possibility leading to an inaccurate portrayal of added sugars in a final product, since the use of maintenance and review of records appears to leave room for loopholes.

ASN also has concerns that the inclusion of added sugars on the label may divert attention away from total calories and other important contributors to weight gain. The inclusion of added sugars on the label may confuse consumers and create the perception that naturally occurring sugars are somehow more beneficial because they are “natural” and do not have health effects similar to added sugars⁴. The 2011 IOM Front-of-Package labeling report³ reviewed numerous studies which suggest that consumers have difficulty understanding the role of various nutrients and may not interpret label information from the perspective of how nutrients in foods may impact their daily diet. ASN points out the concern that it is not obvious which nutrients to consume more of versus less when reading the Nutrition Facts label so the inclusion of something on the label may not translate into the desired health benefits. There is no supporting evidence that indicates that the inclusion of added sugars on the food label will translate into the American public reducing caloric intake from added or total sugars or total energy intake, therefore leading to a reduction in chronic disease risk and weight management. For these reasons, ASN also does not support added sugar labeling on a voluntary basis or solely for products that exceed a certain percentage of calories from sugars.

While ASN agrees with the statement in the proposed rule that notes mandatory declaration of added sugars may prompt product reformulation, it is important to consider potential unintended consequences of reformulation as well. When sugar is removed from a solid food product, it generally must be replaced with something so as not to affect the bulk of the product. The replacement is often fat and/or starch which could lead to a product with higher calories per serving. ASN encourages FDA to carefully consider potential adverse consequences of this proposed determination, including gaining input from food scientists.

ASN appreciates FDA’s recognition that consumer education on the role of added sugars in the diet is necessary, as ASN believes this topic is currently not well understood by the

⁴ Bertino M, Liska D, Spence K, Sanders L, Egan V. Added sugar labeling: implications for consumers. *FASEB J.* April 2014;28(1):630.11.

general population. An investment in consumer education relative to added sugars could be made by focusing efforts on the total sugars content of products and the sources of added sugars revealed in the ingredient list, which can both already be found on the food label. Such an investment is likely to be most productive for consumer understanding relative to added sugars, and would assure that consumers do not experience increased confusion, which they may encounter if added sugars are declared on the Nutrition Facts label. Furthermore, ASN believes that adequate consumer testing to determine consumer understanding of terms including total sugars, added sugars, and sugars, and how this information is translated by consumers should be conducted prior to any determination to change the food label, not after. Consumer studies to determine how and if declaration of added sugars impacts healthful eating are highly important and should be conducted as well. ASN supports FDA's plans to conduct consumer studies to inform future actions, and expects that these studies will be made publicly available.

We also invite comment, including the submission of available research, on whether calories from added sugars should be declared on the Nutrition Facts label in lieu of a gram declaration of added sugars to aid consumers in maintaining healthy dietary practices.

ASN is not aware of available research on whether calories from added sugars should be declared on the Nutrition Facts label in lieu of a gram declaration of added sugars to aid consumers in maintaining healthy dietary practices, and regards this type of research as highly important before a determination can be made. All concerns ASN has raised regarding declaration of added sugars on the Nutrition Facts label in gram amount also apply to declaration of calories from added sugars in lieu of a gram declaration on the label.

We also invite comment, including available data and information, on products that are subjected to non-enzymatic browning reactions and fermentation, and data on the amount of variability that occurs among various types of products where added sugars are transformed into other compounds as a result of chemical reactions during food processing.

ASN is not aware of data or information on the topic of products that are subject to non-enzymatic browning reactions, leavening, and fermentation, and the transformation of added sugars during these processes, and regards this type of data as highly important before a determination can be made. ASN encourages FDA to gain food scientist input to be aware of all unintended consequences of this proposed determination. It is important for added sugars in the final product to be accurately portrayed on the Nutrition Facts label if this is determined to become a mandatory declaration. Since both intrinsic and added sugars are transformed during non-enzymatic browning reactions, leavening, and fermentation, food manufacturers will likely be unable to discern the amount of added sugars that remain in a finished product as a result of chemical reactions during food processing. Most of the sugar will be converted into other compounds. Although some

sugar may reside, there are no analytical methods to accurately measure the amount of added sugar remaining in the finished product.

With respect to dietary fiber, we invite comment on the proposed definition of dietary fiber and retaining the term “dietary fiber.” [(1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; (2) isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that FDA has granted to be included in the definition of dietary fiber, in response to a petition submitted to FDA under 10.30 (21 CFR 10.30) demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or (3) isolated or synthetic non-digestible carbohydrates (with 3 or more) monomeric units) that are the subject of an authorized health claim. We invite comment, including the submission of information on consumer understanding of the term “dietary fiber” relative to other relevant terms.

ASN strongly recommends that any guidance on submissions to demonstrate physiological effects of synthetic/isolate/novel fibers that are beneficial to human health should be made publicly available for comment before FDA publishes a final rule on “Food Labeling: Revision of the Nutrition and Supplement Facts Label.” ASN recommends that FDA follow a process that is aligned with Health Canada’s approach for dietary fiber approvals. ASN has concerns that the current proposed approach to approve dietary fiber using the citizen petition process is not appropriate given that this process has no timing constraint to ensure that FDA responds promptly. ASN recommends that FDA include in their guidance a core list of “physiological effect(s)” that are beneficial to human health and for which FDA will consider submissions. For example, in Health Canada’s 2012 “Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products,” they list the below physiological effects as acceptable functions of dietary fiber and novel fiber sources.

- Improves laxation or regularity by increasing stool bulk;
- Reduces blood total and/or LDL cholesterol levels;
- Reduces post-prandial blood glucose and/or insulin levels; or,
- Provides energy-yielding metabolites through colonic fermentation.

However, they recognize that the list is not exclusive and other effects attributable to dietary fiber may be recognized as the science evolves. FDA may also consider preparation of a “grandfather” list of dietary fiber sources for which there is existing substantial scientific agreement indicating their beneficial effects, similar to Health Canada’s 2013 “List of Dietary Fibres Permitted for Use in Foods Available for Sale in Canada,” which will be updated regularly.

Additional information to allow for better understanding of what evidence is necessary to demonstrate that isolated and synthetic non-digestible carbohydrates have a physiological effect that is beneficial to human health should be provided for public comment prior to a determination relative to dietary fiber.

We are not proposing to change the current requirement to declare dietary fiber using the term “dietary fiber.” However, we request comment on this issue, including consumer understanding of the term “dietary fiber” relative to other relevant terms.

ASN is not aware of consumer research in the public domain on consumer understanding, interpretation, and use of the term dietary fiber relative to other relevant terms on food labels, and regards this type of research as highly important before a determination can be made.

We are proposing to eliminate the provision for voluntary declaration of “Other carbohydrate” on the Nutrition Facts label, and tentatively conclude that the proposed amendment is unlikely to have a significant impact on industry or consumers. We invite comment on this issue, including the submission of any other data or factual information that we should consider in making a final determination.

ASN supports the determination to eliminate the provision for voluntary declaration of “Other carbohydrate” on the Nutrition Facts label. Since there is no quantitative intake recommendation, the scientific evidence does not demonstrate public health significance, and since most consumers are not likely to understand what the term “Other carbohydrate” entails (i.e., starch, oligosaccharides), this determination makes sense. ASN is not aware of any data or other factual information in the public domain around consumer understanding of the term “Other carbohydrate,” and regards this type of data as highly important before a determination can be made.

Sodium

We invite comment on our consideration of various options and tentative conclusions related to sodium discussed in section II.G., including the proposed DRV. In particular, we invite comment on:

(a) The rationale for the proposed DRV of 2,300 for sodium;

ASN supports the rationale for the proposed DRV of 2,300 mg of sodium per day. This number reflects the best available scientific evidence on the relationship between sodium and health outcomes at this time,⁵ as well as the desirability to have dietary recommendations that are achievable for most Americans given the current food supply. As indicated in the proposed rule, the average sodium consumption for Americans ages four years and older is approximately 3,650 mg sodium/day. Most consumers recognize that sodium is a nutrient to limit and, thus, it is most appropriate to use the upper limit (UL) of 2,300 mg, which represents the level of dietary intake of a nutrient that is recommended to not be exceeded during any given day. Although intake below 2,300 mg sodium/day is desirable for some individuals, particularly those at risk of

⁵ Institute of Medicine. *Sodium Intake in Populations: Assessment of Evidence*. Washington, DC: The National Academies Press, 2013.

hypertension, the 2,300 mg recommendation seems most achievable given the current food supply and intake levels in the general US population.

(b) Whether a RDI of 1,500 mg would be more appropriate and why;

ASN does not support that an RDI of 1,500 mg would be more appropriate. Setting a recommendation too low makes it likely unattainable for most of the US population, which would not have the desired effects of lowering sodium intake and improving public health. Indeed, the 2013 IOM report on sodium⁴ notes that the evidence on direct health outcomes is not consistent and insufficient to conclude that lowering sodium intakes below 2,300 mg per day either increases or decreases risk of CVD outcomes or all-cause mortality for the general population. The level of 1,500 mg sodium/day was set forth in the IOM report *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*⁶ as an Adequate Intake (AI) level, which represents the level of dietary intake of a healthy population. AI is typically used as a goal to achieve when there is not sufficient evidence to set an EAR and RDA, and is directed at adequacy (concern about not consuming enough of a nutrient, rather than consuming elevated levels).

(c) Alternative approaches for selecting a DV for sodium and their public health basis for these approaches. We are also interested in comment, including data and factual information on consumer understanding, interpretation, and use of the percent DV of sodium declared on food labels, and the understanding and potential influences of a DV that reflects an RDI based on an AI (an intake level to not consume less of), instead of a DRV based on a UL (an intake level not to exceed).

ASN is not aware of consumer research in the public domain on consumer understanding, interpretation, and use of the percent DV of sodium declared on food labels, and the understanding and potential influences of a DV that reflects an RDI based on an AI, instead of a DRV based on a UL, and regards this type of research as highly important before a determination on sodium can be made.

Essential Vitamins and Minerals of Public Health Significance

In section II.H., we are proposing to:

(a) Retain mandatory declaration of calcium and iron;

ASN supports mandatory declaration of calcium and iron, given the scientific data that show the public health need for these nutrients within the general US population.

(b) Provide for voluntary declaration of vitamins A and C. We request comment about whether there is an appropriate alternative analysis to application of the factors in section I.C. regarding the mandatory declaration of vitamin A and vitamin C;

⁶ Institute of Medicine. *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*. Washington, DC: The National Academies Press, 2005.

ASN supports voluntary declaration of vitamins A and C, given the scientific data that show the public health need for these nutrients has decreased within the general US population. ASN is not aware of appropriate alternative analyses regarding the mandatory declaration of vitamins A and C.

(c) Require the declaration of potassium and vitamin D. We request comment about whether there is an appropriate alternative analysis to the application of the factors in section I.C. regarding the mandatory declaration of vitamin D;

ASN supports the mandatory declaration of potassium and vitamin D, given the scientific data that show the public health need for these nutrients within the general US population. ASN is not aware of an appropriate alternative analysis regarding the mandatory declaration of vitamin D.

(d) Retain voluntary declaration of several other vitamins and minerals. We are also proposing to require that all vitamins and minerals declared on the Nutrition Facts label must include their quantitative amounts (in addition to the requirements for corresponding percent DV declaration). We invite comment on these tentative conclusions, including the appropriate placement of the quantitative amounts of nutrients on the Nutrition Facts label, including data and other available information on the impact of mandatory labeling of vitamins and minerals on food fortification.

ASN has concerns with including the quantitative amounts of mandatory and voluntary vitamins and minerals on the Nutrition Facts label. ASN recognizes that for patients told to consume a specific amount of a nutrient by a health professional, such as 500 mg of calcium per day, the quantitative listing could be highly useful. However, ASN has concerns that including gram declarations for vitamins and minerals may further complicate the label, making it more confusing for the average consumer. Indeed, though the IOM report *DRI: Guiding Principles for Nutrition Labeling and Fortification*⁷ recommended that absolute amounts of micronutrients be added to the food label, the report's list of potential drawbacks resulting from this change was much longer than the list of potential benefits. The 2003 IOM report on using the DRIs to guide nutrition labeling noted that studies conducted by FDA to originally design the Nutrition Facts label found consumers preferred to have both percent DVs and absolute amounts included on the label, but consumers did a better job of using the label to guide and improve their food choices when it only showed percent DV. New consumer research should be conducted prior to a determination to indicate whether gram declarations of vitamins and minerals remain confusing to the average consumer or provide added value that translates to increased health benefits for the majority of consumers. There are other potential unintended consequences that should also be considered, including fortification to increase the absolute amounts of mandatory and voluntary nutrients declared.

⁷ Institute of Medicine. *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*. Washington, DC: The National Academies Press, 2003.

We invite comment on the proposed mandatory declaration of vitamin D, potassium, calcium and iron on the label, including how we consider the public health significance of each. We also invite comment on whether the presence of these nutrients presents concerns related to label space or the need for consumer education.

Various methods of determination and/or calculation currently appear to be used by the FDA, the DGAC, and the IOM to determine if the current population or subgroups have inadequate nutrient intakes. ASN recommends that a transparent and consistent process be determined and utilized by relevant bodies to establish inadequate nutrient intakes, using measures beyond just dietary intake levels whenever possible, including the most recent scientifically-based consensus reports. Dietary intake of certain nutrients may appear to be inadequate; however, in some cases serum levels may indicate otherwise. ASN applauds FDA's use in this proposed rule of biomarkers of nutrient status, where possible, along with other appropriate evidence, to determine which nutrients are consumed in inadequate amounts.

ASN also notes the concern that it is not obvious on the Nutrition Facts label which nutrients should have decreased consumption versus those that should be increased. Consumer education continues to be needed to help consumers understand and interpret the Nutrition Facts label, and use it to make more informed food choices.

Reference Daily Intakes for Vitamins and Minerals

In section II.I., we are proposing to use population-coverage RDAs, when available, or AIs as the basis for establishing RDIs. We invite comment on our analysis and rationale, including available data and information related to our analysis, and any available data on what role, if any, the basis of the DV (EAR or RDA) has on consumption of nutrients above the UL and in discretionary fortification of foods; we request comment and data on lowering the RDI of B12 to 2.4 mg.

ASN supports the rationale for using population-coverage RDAs when available, or the highest AI, as the basis for establishing RDIs to ensure that the entire population, including at-risk or vulnerable subgroups, are covered by the RDI. ASN also stresses the importance of using revised reference values to form the basis for the RDAs, whenever possible.

ASN does not support using a population-weighted EAR as the basis for establishing RDIs. Using a population-weighted approach may result in a higher risk of nutrient inadequacy for some population groups given that the EAR is the median value of estimated nutrient requirements for various life stages and gender groups.

Units of Measure, Analytical Methods, and Terms for Vitamins and Minerals

We invite comment on issues related to units of measure, nomenclature, and analytical methods, which are discussed in section II.J. We invite comment on available

scientifically valid methods that are capable of measuring folic acid and folate separately.

ASN has serious concerns with the proposed change of unit of measure for folate and folic acid to mcg Dietary Folate Equivalent (DFE). While there is scientific support to alter the unit of measure to DFE, a significant portion of the US population, specifically women of childbearing age, require folic acid to prevent neural tube defects (NTD). In June 2000, 61 million women of childbearing age lived in the U.S.⁸ Every year, 3,000 pregnancies are affected by neural tube defects in the U.S.⁹ While label endpoints include prevention of both deficiency and NTD, NTD presents the more pressing public health concern for our nation and therefore should be the consideration for folic acid/folate labeling.

There has been a concerted effort by healthcare professionals and the public health community for consistent messaging directed towards women of childbearing age to consume 400 mcg of folic acid each day. Requiring DFE on the food label would result in the inability to determine the amount of folic acid in a food product, increasing consumer confusion and decreasing the usefulness of the food label to women of childbearing age. A breakfast cereal labeled as containing 400 mcg DFE may lead women of childbearing age to believe this product provides the desired 400 mcg of folic acid, when in fact it only provides 235 mcg of added folic acid. While the option to allow the declaration of the amount of folic acid in parenthesis is notable, this may only aid in consumer understanding if the amount of folic acid in parenthesis is allowed to be declared as mcg, rather than mcg DFE. ASN also has serious concerns that conventional foods would not be allowed to use the term folic acid on the Nutrition Facts label. Consumers should be able to accurately compare Supplement Facts labels (which may use the term folic acid) with Nutrition Facts labels and understand the amounts of folic acid each provide.

While ASN strongly supports the proposed consumer education efforts surrounding the proposed new unit of measure, DFE, consumer research prior to a determination to change the unit of measurement for folate/folic acid is warranted to better understand if the proposed units of measurement will help consumers make more informed food choices or will lead to misunderstanding of food label components. ASN urges FDA to carefully consider unintended consequences of this proposed determination, including input from public health nutritionists and food scientists.

⁸ U.S. Census Bureau. Population Profile of the United States: 2000. Accessed July 14, 2014 from <http://www.census.gov/population/pop-profile/2000/chap04.pdf>

⁹ Centers for Disease Control and Prevention. Spina Bifida and Anencephaly Before and After Folic Acid Mandate - United States, 1995-1996 and 1999-2000. MMWR 2004;53(17):362-365.

We invite comment on available validated methods that are capable of individually measuring all rac- α -tocopherol acetate and RRR- α -tocopherol;

ASN is not aware of data on available scientifically validated methods capable of individually measuring all rac- α -tocopherol acetate and RRR- α -tocopherol, and regards this type of data as highly important before a determination can be made. For example, there is no AOAC International official method of analysis or other analytical procedure to distinguish between the different forms of vitamin E that may be found in foods and dietary supplements. ASN does not encourage changes to the Nutrition Facts label that cannot be assessed with the use of scientifically validated measurements of analysis. As noted previously, ASN has concerns that without the use of reliable analytical methods, recordkeeping alone may present compliance issues.

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

We invite comment on issues related to nutrition labeling for foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women, which are addressed in section II.K., including

(a) Any available relevant empirical research as to whether the proposed declaration of saturated fat and cholesterol for infants and children 1 through 3 years of age is likely to be confusing to consumers or otherwise result in restriction of fat intakes among these subpopulations;

ASN is not aware of available relevant empirical research as to whether declaring saturated fat and cholesterol on products for infants and children 1 through 3 years of age will result in restricted fat intakes for these subpopulations, regards this type of research as highly important, and cautions FDA to not make a determination before appropriate research has been conducted to better understand the impacts of labeling of products represented or purported to be specifically for infants and children 1 through 3 years of age on the health of these subpopulations.

(b) How consumers would understand and use the information on amounts of saturated fat and cholesterol in the nutrition labeling of foods for infants and young children and whether there is a need for an explanatory footnote to accompany such proposed mandatory declaration;

Again, ASN cautions FDA to not make a determination before appropriate research, including consumer testing, has been conducted to better understand the impacts of declaring saturated fat and cholesterol on the labels of products represented or purported to be specifically for infants and children 1 through 3 years of age and if an explanatory footnote would assist in improving consumer understanding when accompanying any relative declaration.

(c) Our tentative conclusion that declaration of added sugars should be mandatory on foods represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women;

As with the Nutrition Facts label for the general population, ASN has significant concerns with FDA's rationale for the inclusion of added sugars on the food label, and would not support the declaration of added sugars on labels of products represented or purported to be specifically for infants 7 through 12 months of age, children 1 through 3 years of age, and pregnant and lactating women. This topic is controversial and a lack of consensus remains in the scientific evidence on the health effects of added sugars alone versus sugars as a whole. Therefore, ASN recommends careful consideration of the totality of the scientific evidence, as well as consideration of compliance and other technical issues. Consumer testing is also highly important prior to any determination relative to added sugars being made.

(d) Adequacy of the proposed RDIs for vitamins and minerals for older infants and children 1 through 3 years of age.

While FDA reviewed current quantitative intake recommendations (which included functional indicators of nutritional status when available), and considered previous comments on the topic, ASN encourages FDA to also consider dietary intake data and public health need, in addition to quantitative intake recommendations, to determine appropriate RDIs for vitamins and minerals to be established for older infants 7 months through 12 months of age and children 1 through 3 years of age.

Dietary Supplements

We invite comment on whether we should consider changes to the footnote statement "Percent Daily Values are based on a 2,000 calorie diet" used on dietary supplement labels to be consistent with any changes to the footnote statement in the Nutrition Facts label.

ASN believes that the Supplement Facts label should be the same as the Nutrition Facts label that is found on conventional foods. As mentioned throughout ASN's response, consumer understanding and translation of the Nutrition Facts label is limited. Different versions of Nutrition Facts and Supplement Facts labels for conventional foods and dietary supplements will not lend themselves to increased consumer use and understanding of the tools.

Format

We invite comment on

(a) Including the use of an alternative format design or requiring the use of a specific font;

ASN encourages the FDA to conduct adequate consumer studies to determine the understanding of the proposed and alternate Nutrition Facts label formats and if either of these formats assist consumers in making more informed diet choices. Research is

necessary to understand if the proposed and alternate formats for the Nutrition Facts label will be effective in aiding in improved health for the general population. If FDA has conducted such studies, ASN expects that they will be made publicly available prior to any determination on format and font.

(b) Our tentative conclusion that emphasizing both the number of calories per serving and the number of servings per container will serve as an anchor to highlight this information and grab the reader’s attention, and therefore will assist consumers to effectively use this information in the Nutrition Facts label;

While ASN finds the emphasis of both the number of calories per serving and the number of servings per container acceptable, we recommend that serving size also must be emphasized in order to help consumers to easily identify and better understand the important connection between number of servings and calories per serving. Therefore, ASN supports the proposal to increase the prominence of the “Servings per container” declaration in a similar manner as the “Calories” declaration, and recommends that FDA also increase 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 as well. Research has shown that when the portion size or serving container is larger, consumers will eat more.¹⁰ This indicates a need for increased consumer education and awareness about what the labeled serving size means, as well as appropriate portion sizes.

(c) Whether any of the changes that are being proposed to the Nutrition Facts label should also be required for certain products with Supplement Facts labels that list calories and/or other macronutrients, and if so, under what conditions and for which dietary supplement products should such labeling be required;

As noted in previous responses, ASN believes that the Supplement Facts label should be the same as the Nutrition Facts label that is found on conventional foods. Consumer understanding and translation of the Supplement/Nutrition Facts labels is limited. Different versions of Supplement and Nutrition Facts labels for conventional foods and dietary supplements will not lend themselves to increased consumer use and understanding of the tools.

(d) Our tentative view that there is no need to propose changing the order of how serving size and servings per container are listed on the Supplement Facts label, or to

¹⁰ Rolls BJ, Morris EL, Roe LS. Portion size of food affects energy intake in normal-weight and overweight men and women. *Am J Clin Nutr* 2002 76;6:1207-1213.

make amendments in the type size or capitalization corresponding to our proposed changes for this information on the Nutrition Facts labels;

As noted in previous responses, ASN believes that the Supplement Facts label should be the same as the Nutrition Facts label that is found on conventional foods. Consumer understanding and translation of the Supplement/Nutrition Facts labels is limited. Different versions of Supplement and Nutrition Facts labels for conventional foods and dietary supplements will not lend themselves to increased consumer use and understanding of the tools.

(g) The double indented placement of added sugars below total sugars and invite available research data and other factual information relevant to the proposed double indented placement of added sugars below total sugars;

ASN has concerns with the rationale FDA uses to support the declaration of added sugars on the Nutrition Facts label, whether for the general population or for infants and children, and pregnant and lactating women. This topic is controversial and a lack of consensus remains in the scientific evidence on the health effects of added sugars alone versus sugars as a whole. Therefore, ASN recommends careful consideration of the totality of the scientific evidence, as well as consideration of compliance and other technical issues. Consumer testing is also highly important prior to any determination relative to added sugars being made.

(j) Using data provided consumer research we plan to conduct during this rulemaking that will test consumer reactions to a definition of percent DV, a succinct statement on calories, and several statements related to the “5/20 rule”;

ASN believes that a more consumer-friendly footnote would allow for increased consumer understanding of the Nutrition Facts label, and agrees that the definition of percent DV, a succinct statement on calories, and statements related to the “5/20 rule” could be useful. ASN suggests that it would be most beneficial to FDA to allow the stakeholder community an opportunity to review various options for a revised footnote prior to unveiling the updated Nutrition Facts label. ASN encourages FDA to conduct consumer education to better understand how consumers may use a revised, more consumer-friendly footnote to assist with making more informed food choices.

(q) Listing the total carbohydrate content in a serving as “Total Carbs” instead of “Total Carbohydrate” or “Total Carb” and its listing used on all label formats;

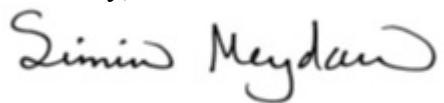
ASN does not support changing the determination of total carbohydrate to total carb on the food label. The term “Total Carbohydrate” (or Carbohydrate Total) is set forth in the Nutrition Labeling and Education Act (NLEA) and this term is scientifically accurate.

(r) An alternative concept for the Nutrition Facts label format that indicates “quick facts” about a product’s nutrient content and explicitly points out nutrients to “avoid too much” of as well as nutrients to “get enough” of;

ASN encourages FDA to conduct thorough consumer testing prior to any determination to use an alternate concept for the Nutrition Facts label, including a “quick facts” version, to better understand if an alternate concept would increase consumer understanding and use of the Nutrition Facts label, and lead to consumers making more informed food choices.

Thank you for your consideration of ASN’s comments on the proposed rule. ASN notes that the food environment and consumer education both play a significant role in translation and understanding of the food label to make healthier choices. ASN strongly recommends that FDA conduct a comprehensive consumer education campaign, including a significant focus on calories, serving size, and new elements of the revised Nutrition Facts label, prior to when it first appears on food products. Consumer education is necessary to lead to increased consumer understanding and therefore behavior change that benefits health. ASN urges FDA to fully involve all stakeholders, including ASN, in the implementation of the revised label and any related consumer education campaigns. Please contact Sarah Ohlhorst, Director of Government Relations, [sohlhorst@nutrition.org; 301.634.7281] if ASN may provide additional information.

Sincerely,

A handwritten signature in black ink that reads "Simin Meydani". The signature is written in a cursive style and is positioned to the left of a vertical line.

Simin N. Meydani, D.V.M., Ph.D.
ASN President, 2014-2015