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RE: **Comments on for consideration by the U.S. Department of Agriculture and U.S. Department of Health and Human Services**

Dear Dr. Olson and Ms. Tagtow:

The Grocery Manufacturers Association (GMA)[†] respectfully submits comments to the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Agriculture (USDA) for consideration on the 2015 Dietary Guidelines Advisory Committee (DGAC) Report.

Since the inception of the Dietary Guidelines for Americans in 1980 and based on consumer research, U.S. food and beverage manufacturers have added new better-for-you products to the food supply for consumers of all ages. The 2014 GMA Health and Wellness Survey, administered and analyzed by Georgetown Economic Services, found that more than 30,000 better-for-you products were developed and introduced to the marketplace between 2002 and 2013. These reformulated or newly introduced products have reductions in industrial *trans* fat, saturated fat, sodium, sugar or total calories. GMA members continue to work to provide consumers with affordable product choices that meet their nutrient and calorie needs.

Executive Summary

GMA has consistently supported both the DGAC process toward development of the Dietary Guidelines for Americans (DGA) and the resulting Guidelines policy document. GMA recognizes the importance of

dietary guidelines that encourage Americans to eat a healthful diet containing foods and beverages that help them achieve and maintain a healthy weight, promote health, and prevent disease. A set of evidence-based Dietary Guidelines on which to base federal food and nutrition policy is indispensable in an environment where the evidence defining the relationship between health and food, nutrition, and physical activity is constantly evolving. GMA appreciates the complexity of the DGAC responsibility to translate and distill current science into a set of recommendations from which the DGA can be developed. Many of the 2010 DGA recommendations were carried forward into the 2015 DGAC report, including the conclusions and resulting recommendations around whole grains, fruits, vegetables, and low fat/fat free dairy. Although many of the new recommendations of the 2015 DGAC are firmly based on the scientific literature the final report contains areas of concern. GMA encourages the Departments to base the final policy document on a total diet approach which emphasizes the importance of a varied and balanced diet within calorie needs and supported by a solid scientific foundation.

The GMA comments will address the following four key points.

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GMA is concerned that the DGAC completed work beyond their congressionally mandated scope and outside of their collective areas of expertise.

One of GMA's significant areas of concern is that the DGAC and its Scientific Report went beyond the scope and charter of their assignment. As the Dietary Guidelines charter and Federal Register notice¹ clearly states:

“The law instructs that this publication [*The Dietary Guidelines for Americans*] shall contain nutritional and dietary information and guidelines for the general public, shall be based on the preponderance of scientific and medical knowledge current at the time of publication, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program.”

The purpose of the DGA is to provide advice to Americans (ages 2 and over) for making food and activity choices that promote health. This DGAC went beyond the above cited congressionally-assigned mandates and area of expertise in a number of areas. Of particular concern are recommendations on public policy, taxation, labeling and ingredient safety. There is little evidence that the DGAC completed the necessary scientific research to ensure that all recommendations in these areas are based on sound evidence. Thus, it is appropriate to call into question the DGAC recommendations in these areas.

While the DGAC identifies various forms of restrictions on food marketing as potential policy recommendations to improve the health of Americans, the Committee acknowledges it did not conduct scientific research on this topic. The DGAC report states, “Because of time demands, the Committee could not address other important settings, such as after-school settings, recreational settings, and faith-based institutions, as well as more macro-environmental influences such as food marketing and economic impacts.”² As no work was completed by the DGAC to assess the impact of food marketing on children's dietary intake, GMA questions the validity of DGAC's recommendations in this area. This issue is covered in greater detail in comments submitted by the Children's Food and Beverage Advertising Initiative (CFBAI). GMA supports CFBAI's comments.

GMA was also disappointed to see the Committee recommend “the use of economic and taxing policies to encourage the production and consumption of healthy foods and to reduce unhealthy food. For example, earmark tax revenues from sugar-sweetened beverages, snacks foods and desserts high in calories, added sugar, or sodium and other less healthy foods for nutrition education initiatives and obesity prevention programs.”³ The Committee's failure to conduct a review of the scientific literature in the area of taxation and its effect on health outcomes calls into question the appropriateness and legitimacy of this DGAC recommendation.

¹ 78 Fed. Reg. 8147

² Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Part D, Chapter 4, Pg 2, Lines 69-71.

³ Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Part B, Chapter 2, Pg 9, Lines 309-313.

Aside from being confusing and administratively complex, such taxes are regressive, because they disproportionately impact low-income citizens. This type of taxation is also arbitrary and paternalistic because it attempts to define a food as “good” or “bad” for consumers. According to the Academy of Nutrition and Dietetics (AND), “the classification of specific foods as good or bad is overly simplistic and can foster unhealthy eating behaviors.”⁴ Educating consumers about how to meet their individual needs, tastes and preferences through the proper balance of activity and dietary patterns empowers consumers to maintain healthy choices.

The DGAC report recommends that “policy changes within the federal Supplemental Nutrition Assistance Program (SNAP), similar to policies in place for the WIC program, should be considered to encourage purchase of healthier options, including foods and beverages low in added sugars. Pilot studies using incentives and restrictions should be tested and evaluated.”⁵ The use of pilot studies to test restrictions is arbitrary. Suggested pilots that limit consumer food choice in programs like SNAP would require the Federal Government to construct and maintain a list of “good” and “bad” food for the 300,000 food and beverage products currently available in the marketplace. However, no clear standards exist for defining food as “good” or “bad.”

Moreover, there is very limited evidence that punitive restrictions on SNAP benefits will have the intended impact on recipient’s health and wellbeing. About 70 percent of all SNAP participants are expected to purchase a portion of their food with their own money. There is no guarantee that restricting the use of benefits will affect food purchases other than substituting one form of payment (SNAP benefits) for another (cash).

Conversely, incentives have proven to be beneficial and improve the dietary patterns of SNAP recipients. The *Food, Conservation, and Energy Act of 2008* authorized and funded the Healthy Incentives Pilot (HIP) to determine if financial incentives provided at the point of sale to SNAP participants would increase their consumption of fruits, vegetables, and other healthful foods. According to USDA, “HIP participants (respondents aged 16 and older) reported higher consumption of dark green vegetables, red/orange vegetables, and other vegetables (e.g., celery, cucumbers, mushrooms, green beans, etc.), and fruits other than citrus, melons and berries (e.g., apples, pears, bananas, grapes, etc.) than non-HIP participants.”⁶ GMA supports SNAP incentives – not punitive restrictions – as the way to encourage healthy eating.

⁴ Academy of Nutrition and Dietetics. 2013. AND Position. Total diet approach to communicating food and nutrition information. *J Acad Nutr Diet*. 2013;113:307-317.

⁵ Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Part D. Chapter 6, Pg 28, Line 1015-1018.

⁶ Bartlett S, Klerman J, Wilde P, Olsho L, Logan C et al. Evaluation of the Healthy Incentives Pilot (HIP) Final Report. Prepared by Abt Associates for the U.S. Department of Agriculture, Food and Nutrition Service, September 2014. Available online at <http://www.fns.usda.gov/ops/research-andanalysis>.

In the area of nutrition front-of-pack (FOP) labeling, the DGAC conducted no analysis of existing FOP systems such as *Guiding Stars* and *Facts Up Front*, nor did they examine any existing consumer research on FOP labeling systems. GMA has concerns with the recommendation of the DGAC which adopted a 2011 Institute of Medicine (IOM) Committee (Phase 2)⁷ recommendation as sufficient rationale for the DGAC to make a policy recommendation. This is particularly problematic because in Phase 1 of their analysis of the scientific basis for FOP labeling, the IOM Committee noted several methods to address public health concerns including nutrient-specific schemes.

In 2011, GMA and the Food Marketing Institute (FMI -- representing food retailers) launched *Facts Up Front* – a front-of-pack fact based labeling program that brings important information from the Nutrition Facts Panel and displays it in a simple and easy-to-use standard format on the front of food and beverage products. *Facts Up Front* is grounded in nutrition science and research regarding consumer messaging about nutrition, including the 2010 DGAs. The program was developed following an extensive review of the available scientific evidence regarding dietary patterns and associated health outcomes.

Facts Up Front can help consumers make informed choices, whether they are nutrition novices or experts. By making key nutrition information more prominent and more accessible with a uniform label across brands, categories and stores, consumers can use it to quickly compare products and identify the foods that meet their personal nutrition needs.^{8,9}

Regarding the Committee's review of the safety of caffeine and aspartame, it is beyond the scope and expertise of the DGAC, or the mandate given by Congress to USDA and HHS to develop the Dietary Guidelines for Americans, to deal with these matters. Additionally, the DGAC's recommendations regarding the GRAS status of sodium are also outside of their scope. The FDA's Office of Food Additive Safety is best positioned to evaluate all ingredients, and is the appropriate authority to develop policies relating to the safety of food ingredients.

By and large, substantial areas of the Report are based on accepted scientific methods and/or evidence. The aforementioned topics stray from strict adherence to science and evidence which detracts from the overall report. GMA urges the Departments to only consider those recommendations that were scientifically evaluated with high scientific standards and rigor.

⁷ IOM (Institute of Medicine). 2012. *Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices*. Washington, DC: The National Academies Press.

⁸ Kees J, Royne MB, Cho Y. Regulating front-of-package nutrition information disclosures: a test of industry self-regulation vs. other popular options. *J Consumer Affairs* 2014;48(1):147-174.

⁹ Smith Edge M, Toner C, Kapsak WR, Geiger CJ. The impact of variations in a fact-based front-of-package nutrition labeling system on consumer comprehension. *JAND* 2014;114(6):843-854.

GMA has questions and concerns with the methodologies used to develop the conclusion and implication statements.

Given the critical role that dietary guidance recommendations play in informing national policy and public health interventions, it is essential that DGAC recommendations are based on the complete body of available scientific evidence and strong scientific agreement. The strength of this evidence must also be evaluated by rigorous and consistent standards to provide reliable guidance for policy makers. As noted by the DGAC, three different methods were used to answer research questions: a Nutrition Evidence Library (NEL) systematic review, existing sources of evidence, and food pattern modeling and data analysis.

GMA is fully supportive of the systematic evidence-based analysis approach of the NEL. The six step process was developed to provide a standardized and systematic way to evaluate new research that has emerged since the previous guidelines. The NEL process is designed to minimize bias, and ensure transparency and reproducibility, resulting in evidence-based conclusions. As reported by the DGAC, however, this process was only used to answer 27% of the research questions. Given that the NEL process was not consistently applied across all questions throughout the DGAC process, this brings into question whether the full body of scientific literature was evaluated.

Per the DGAC report, 45% of research questions were answered using existing sources of evidence. The practice of limiting the evidence reviewed to a select few reviews or meta-analyses, excluding other relevant studies or additional meta-analyses from the review process, brings into question possible selection bias and interpretation bias. Reliance on pre-existing reviews does not ensure that the literature being used to answer the research question has undergone the rigorous and unbiased evidence review process as is done with the NEL. GMA also questions if the inclusion criteria for the pre-selected systematic reviews used to answer the research questions were analyzed and supplemented appropriately to meet research needs.

The remaining approximately 30% of questions were answered using data analyses and food pattern modeling. The food pattern modeling work of the DGAC was developed for the 2005 DGAC to determine the hypothetical effects on nutrient levels resulting from specific dietary changes such as modifying the amounts or types of foods in a pattern. This analysis was used to test the influence of various dietary recommendations on diet quality. While the conclusions drawn using food pattern modeling are not graded as with an NEL systematic review, the conclusions were still used to develop evidence-based recommendations. This is of concern to GMA as the conclusions resulting from modeling may not be supported by realistic consumption levels nor current evidence and were not tested to assess efficacy.

Additionally, discrepancies exist in the methodology used in dietary pattern analysis. GMA questions the development of some of the dietary pattern groupings that were not reflective of work completed

by the 2010 DGAC. GMA also has concerns and note inconsistencies when inclusion criteria for dietary pattern analysis were reviewed. For example, research studies with less than 30 subjects per arm were excluded from this analysis without explanation. This exclusion criterion appears to be arbitrary and not based upon a more appropriate measure such as power analyses. We ask that the Departments be mindful of these methodological deficiencies and inconsistencies when considering any conclusion or implication statements developed on the basis of dietary pattern analysis.

GMA questions the application of the grading system for some of the conclusion statements developed by the DGAC. As noted in the USDA NEL Conclusion Statement Evaluation Criteria, a grading of strong is assigned to studies of strong design free from design flaws, bias and execution problems. Additionally a strong rating by the NEL is applied to a conclusion that is substantiated by a strong body of evidence and is unlikely to change if new evidence emerges and typically is based on both randomized controlled trials (RCT) and prospective cohort studies. Studies of weaker design for a question are considered to be of moderate strength. A moderate grade applies to a conclusion statement that is based on evidence that has some methodological concerns and new data might arise which would modify the conclusion statement. GMA questions the assignment of a strong rating to the conclusion statements that were developed based solely upon observational and epidemiological studies as these types of research can only identify associations, not cause and effect. Additionally, GMA has concerns that the grading scale was not applied consistently across the report.

GMA is also concerned with some of the implication statements put forth by the DGAC. As noted in Part D, Chapter 1, lines 129-130, implication statements were developed to provide context for conclusions and varied in length depending upon the question or topic. GMA is concerned that some of the implication statements were not developed in direct relation to the strength of the conclusion statement. This is particularly concerning in cases where the strength of evidence to support a conclusion statement was rated limited. Additionally some of the implication statements were not developed based upon the scope of the research question.

GMA is concerned that several of the conclusion statements presented in the DGAC Final Report do not appear to be based on the preponderance of scientific evidence.

GMA has consistently supported both the DGAC scientific review process and the development of the DGA policy document. A set of evidence-based Dietary Guidelines on which to base federal food and nutrition policy is indispensable in an environment where the evidence defining the relationship between health and food, nutrition, and physical activity is constantly evolving and at times misrepresented by the media. GMA appreciates the complexity of the DGAC responsibility to translate and distill current science into a set of dietary recommendations from which the DGA can be developed. Nevertheless, the DGAC recommendations must be based on the totality of evidence and the evidence must be graded by rigorous yet consistent standards to provide appropriate guidance for policy makers. The following topics highlight conclusions of concern to GMA.

Dietary Patterns

GMA applauds the DGAC for recognizing that multiple dietary patterns can achieve health-related benefits and that they may be tailored to an individual's needs and preferences. GMA, however, has concerns with the emphasis that the DGAC placed on the dietary patterns of Healthy US, Healthy Mediterranean and Healthy Vegetarian. The typical consumers' dietary pattern has many differences from the above dietary patterns in both food components and overall nutrient content. As noted by Krebs-Smith, et al., "nearly everyone fails to meet the Dietary Guidelines."¹⁰ Consumer research in 2011 found that 82% of adults in the U.S. cited "not wanting to give up foods they like as a reason for not eating healthier."¹¹ This thinking supports the need for moderation and proportionality when developing achievable and practical dietary guidance. These concepts prevent consumers from relying on radical changes such as the elimination of certain foods or food groups from their diet. Research shows that when this sort of extreme attitude is adopted, individuals set themselves up for failure.¹² The inclusion of achievable, empowering, and practical messages promoting positive dietary and lifestyle changes in the Dietary Guidelines can result in successful behavior changes by consumers.

GMA encourages the Departments to frame the policy document around a total diet approach to healthy eating which promotes calorie balance rather than focus on individual nutrients to limit or encourage. A total diet approach emphasizes the importance of a varied and balanced diet within calorie needs, and was endorsed by the AND in 2013 as the most important focus of a healthful eating style. A total diet approach asserts that there are no inherent "good foods" or "bad foods." As such there is "no single food or type of food ensures good health, just as no single food or type of food is necessarily detrimental to health."⁴ The Departments should be balanced in their recommendations, equally emphasizing food groups to encourage and food groups to decrease.

Breakfast

We encourage the Departments to provide practical guidance to consumers on making healthy meal and snacking choices that help meet nutrient needs and fit within total daily calorie requirements. Research has consistently shown that regular breakfast cereal consumption is directly associated with

¹⁰ Krebs-Smith S, Guenther P, Subar A, Kirkpatrick S, Dodd K. Americans do not meet federal dietary recommendations. *J Nutr.* 2010;140:1832-1838.

¹¹ Academy of Nutrition and Dietetics. Nutrition and you: Trends 2011. <http://www.eatright.org/nutritiontrends>. Accessed August 21, 2014.

¹² Zywiak WH, Connors GJ, Maisto SA et al. Relapse research and the reasons for drinking questionnaire: a factor analysis of Marlatt's relapse taxonomy. *Addiction.* 1996 Dec;91 Suppl:S121-130.

better diet quality and inversely associated with body weight, and other health outcomes including cardiovascular disease.¹³

Nevertheless, breakfast skipping remains prevalent among all age groups in the U.S. with over 10% of children skipping breakfast (National Health and Nutrition Examination Survey, NHANES 2009-10).¹⁴ Breakfast skipping is of particular concern for children, as breakfast provides children with more than 30% of daily calcium, iron, and B vitamin requirements, while constituting less than 20% of daily caloric intake.¹⁴ U.S. studies show that key nutrients not consumed when breakfast is skipped, including calcium, and other minerals and essential vitamins, are not recouped during the day's remaining meals.¹⁵ Additionally, breakfast eaters tend to consume less fat, and more fiber and whole grains than non-breakfast eaters.¹⁶ Nine out of 10 Americans are not meeting 2010 DGA recommendations to "make half their grains whole;" in fact most people are barely eating one ounce equivalent/serving per day.¹⁷ More than half of whole grains are eaten at breakfast, and cereals are a leading source of whole grain for Americans, making breakfast a vehicle for this important food component to encourage.¹⁸ The 2015 DGAs should continue to encourage Americans to eat breakfast and reinforce the connection between breakfast consumption, healthy weight maintenance, and improved nutrient and whole grain intakes.

Snacking

The DGAC report indicates that the majority of the U.S. population was found to consume three meals plus at least one snack per day. This trend of eating was found to be consistent between 2005-2006 and 2009-2010. Data from NHANES 2009-10 (ages 2+), which this DGAC acknowledged, indicates that snacking contributed 24% of daily calorie intake, 20% of fat, 13% of sodium, and 38% of total sugar intake. Snacking also contributed at least 10% of 9 essential nutrients, including vitamin C, vitamin D, calcium, and iron, and 20% of fiber to the total diet.¹⁴

¹³ Williams PG. The benefits of breakfast cereal consumption: A systematic review of the evidence base. *Adv Nutr.* 2014;5:636S-673S.

¹⁴ Centers for Disease Control and Prevention (CDC). National Center for Health Statistics (NCHS). National Health and Nutrition Examination Survey (NHANES) Data. Hyattsville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2009-10. <http://www.cdc.gov/nchs/nhanes>

¹⁵ O'Neil CE, Nicklas TA, Fulgoni VL 3rd. Nutrient intake, diet quality, and weight/adiposity parameters in breakfast patterns compared with no breakfast in adults: National Health and Nutrition Examination Survey 2001-2008. *J Acad Nutr Diet.* 2014 Dec;114(12 Suppl):S27-43.

¹⁶ Deshmukh-Taskar PR, Nicklas TA, O'Neil CE, Keast DR, Radcliffe JD, Cho S. The relationship of breakfast skipping and type of breakfast consumption with nutrient intake and weight status in children and adolescents: the National Health and Nutrition Examination Survey 1999-2006. *J Am Diet Assoc* 2010;110(6):869-878.

¹⁷ Albertson AM and Joshi N. Whole grain consumption and associations with body weight measures in the United States: results from NHANES 2009-10 and the new USDA Food Patterns Equivalents Database (810.23) *FASEB J* April 2014;28:810-823.

¹⁸ NPD Group, Whole Grains by Eating Occasion, 2006-2011; May 2011.

Snacking and snack foods are a theme throughout the DGAC report, yet few specific recommendations are provided. Given the prominent role that snacking plays in the American diet¹⁹ and the number of products available in the market today, GMA encourages the Departments to develop recommendations that include snacking as a component of healthy dietary patterns. Snacking recommendations that support nutrient-dense food choices that contribute to improve intakes of key nutrients and food groups of need would be aligned with the USDA food patterns which also recognize snacking as part of a healthy dietary pattern.

Protein - Meats and Poultry

GMA noted differences in the dietary pattern work of the DGAC as compared to previous DGACs. These differences were most apparent when considering the food groups and categories used to make up the patterns. The Dietary Pattern conclusion of Subcommittee 2 of the DGAC included a list of common characteristics of dietary patterns associated with positive health outcomes which did not include lean meats and poultry. This conclusion and resulting recommendation are inconsistent with the 2010 Dietary Guidelines for Americans which recommended consuming nutrient-dense foods and beverages, including lean meats and poultry. In addition, the exclusion of lean meats and poultry is not mirrored in composition work completed by the DGAC on the dietary patterns of interest. In Appendix E-3.7 the composition of the Healthy US and Healthy Mediterranean patterns developed at 2000 calorie level include 23 oz of meat and poultry a week, suggesting that lean meats do in fact play a role in promoting positive health outcomes. While the 2015 DGAC recommended a reduction in the consumption of red meats and did not include lean meats in their dietary pattern recommendations, GMA notes that they continue to support the consumption of lean and red meats as important sources of heme iron as well as complete proteins as was done by the 2010 DGAC.

GMA questions the recommendation for reduction of red meat as part of the overall dietary pattern conclusions when high quality evidence from at least 12 randomized controlled clinical trials support lean red meat as a beneficial component in a healthy dietary pattern.^{20,21,22,23,24,25,26,27,28,29,30,31} In

¹⁹ Sebastian RS, Wilkinson Enns C, Goldman JD. Snacking patterns of US adults: What We Eat In America, NHANES 2007-2008. Food Surveys Research Group Dietary Data Brief No. 4. June 2011. Available at: <http://ars.usda.gov/Services/docs.htm?docid=19476>

²⁰ Flynn MA, et al. Serum lipids in humans fed diets containing beef or fish and poultry. *Am J Clin Nutr* 1981;34:2734–2741.

²¹ Flynn MA, et al. Dietary “meats” and serum lipids. *Am J Clin Nutr* 1982;35:935–942.

²² Scott L, et al. Effects of a lean beef diet and of a chicken and fish diet on lipoprotein profiles. *Nutr Metab Cardiovasc Dis* 1991; 1:25–30.

²³ Scott L, et al. Effects of beef and chicken consumption on plasma lipid levels in hypercholesterolemic men. *Arch Intern Med* 1994; 154:1261–1267.

²⁴ Davidson MH, et al. Comparison of the effects of lean red meat vs lean white meat on serum lipid levels among free-living persons with hypercholesterolemia: a long-term, randomized clinical trial. *Arch Intern Med* 1999; 159: 1331–1338.

addition, the DGAC did not seem to appreciate that some red meat could also be lean until a late stage in their deliberations. A regulatory definition for lean meat exists but this was not utilized in its entirety by the DGAC as evidenced by the definition included in Appendix E-5: Glossary of Terms. According to USDA's Food Safety and Inspection Service "lean" is defined as 100 grams of individual food with less than 10 grams of fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol.³² This "lean" definition would include all meat and poultry products, including red and processed meats. As noted by the DGAC during their public meetings, conclusions could only be drawn on the food groupings present in the evidence reviewed, thus the DGAC was not able to address red and processed meats that could be considered lean. GMA urges the Departments to reconsider the exclusion of meat and poultry from a healthy dietary pattern.

Protein - Beans and Peas

GMA supports the DGAC conclusion that identified the important role of plant-based foods such as fruits, vegetables, whole grains, legumes, nuts and seeds in healthy dietary patterns for Americans. The food manufacturing industry is increasingly recognizing the role that beans, peas and other legumes can play as nutritionally-dense ingredients in prepared foods. GMA is concerned, however, with the omission of beans from the definition of foods providing protein. In Part D, Chapter 1, lines 1221-2 in, the definition of protein foods omits beans: "a broad group of foods including meat, poultry, fish/seafood, eggs, soy, nuts and seeds."

Further, beans as a source of protein receives only a footnote describing beans as a quantity equivalent for a serving of protein. This is in stark contrast to the 2010 DGA, which has a special sidebar on page 35 and states that "Beans and peas are excellent sources of protein. They also provide other nutrients, such

²⁵ Hunninghake DB, et al. Incorporation of lean red meat into a National Cholesterol Education Program step I diet: a long-term, randomized clinical trial in free-living persons with hypercholesterolemia. *J Am Coll Nutr* 2000; 19: 351–360.

²⁶ Beauchesne-Rondeau E, et al. Plasma lipids and lipoproteins in hypercholesterolemic men fed a lipid lowering diet containing lean beef, lean fish, or poultry. *Am J Clin Nutr* 2003; 77:587–593.

²⁷ Melanson K, et al. Weight loss and total lipid profile changes in overweight women consuming beef or chicken as the primary protein source. *Nutrition* 2003; 19:409–414.

²⁸ Hodgson JM, et al. Partial substitution of carbohydrate intake with protein intake from lean red meat lowers blood pressure in hypertensive persons. *Am J Clin Nutr* 2006; 83:780-7.

²⁹ Mahon AK, et al. Protein intake during energy restriction: effects on body composition and markers of metabolic and cardiovascular health in postmenopausal women. *J Am Coll Nutr* 2007; 26:182–189.

³⁰ Roussell MA, et al. Beef in an Optimal Lean Diet study: effects on lipids, lipoproteins, and apolipoproteins. *Am J Clin Nutr* 2012; 95:9-16.

³¹ Roussell MA, et al. Effects of a DASH-like diet containing lean beef on vascular health. *J Hum Hypertens* 2014 Jun 19.

³² USDA-FSIS-OPPED-LCPS. 2007. A guide to federal food labeling requirements for meat, poultry, and egg products. http://www.fsis.usda.gov/shared/PDF/Labeling_Requirements_Guide.pdf.

as iron and zinc, similar to seafood, meat and poultry.”³³ Recognition of beans as a source of protein is important in light of their status as one of the few plant-based sources of protein, and also because of the broad usage of beans as an inexpensive source of protein in school lunch programs, and as a source of protein and iron in the Women, Infants, and Children program. We ask that the Departments correct the omission that was made by the 2015 DGAC and include beans in the definition of protein foods.

GMA would like to stress the importance of consistency as a consumer learning strategy when assigning beans to food groups. Through the years, in resources such as the Dietary Guidelines, Food Pyramid, MyPlate, Exchange Lists for Meal Planning and DASH diet, beans have been classified in eight different food groups. When the 2015 DGAC examined dietary patterns of interest, beans are listed only under the Vegetable category in Table E3.1.A1 Healthy US Style Food Patterns, Table E-3.7.A2 Healthy Mediterranean Style Food Patterns, as well as in Table E3.1.A2 USDA Food Patterns - Item Clusters, Representative Foods and Percent of Consumption. In contrast, the 2005 and 2010 Dietary Guidelines for Americans recognized beans and peas for their unique nutritional profile and included them in both the Vegetable and Protein food groups. To further understanding about how to use this nutrient-dense food, GMA urges that the Departments be consistent the 2005 and 2010 DGA and include beans in both the Vegetable and Protein food groups.

GMA requests increased recognition of beans as an excellent-to-good source of multiple shortfall nutrients. Beans are an excellent source of fiber and folate, and a good source of potassium, iron, and magnesium; yet, recommendations for increased intake of these shortfall nutrients rarely highlight beans. GMA hopes that increased recognition of the nutrient contributions of beans, especially in the case of the under-consumed nutrients of fiber and potassium, might aid in increased consumption of these nutrients.

GMA notes the DGAC report uses multiple, and inconsistent terms to describe this food category (dry beans, cooked dry beans, beans, beans and peas, and legumes) and consumer interpretation of the terms varies widely. The term “dry beans” is shown by consumer research to mean “beans that require soaking for preparation and are typically packaged in bags.” More than 9 out of 10 consumers exclude canned beans when asked to classify food products that are “dry” or “dried” beans. Consumer research on the term “legumes” has shown that less than 2 out of 3 consumers believe beans, whether packaged in cans or bags, are classified as legumes, while one out of 3 consumers would include peanuts as a legume. Recently, the term “pulses” has been introduced to describe the “family” of beans, peas and lentils. Research shows that only 33% of consumers have ever heard of the term, with only 29% believing that they know what the term means. Of the 29% who believe they know what the term means, over half think the term is related to the circulatory system. Consumer research has further shown that the term “Beans,” followed by a descriptive phrase of the best-selling bean types (i.e.,

³³ U.S. Department of Agriculture and U.S. Department of Health and Human Services. The Dietary Guidelines for Americans, 2010. Page 35. Retrieved from: http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/PolicyDoc.pdf

“Beans, such as black beans, pinto beans, and kidney beans”) has the highest level of consumer understanding and is inclusive of all packaging forms (unpublished data available upon request).³⁴ GMA requests that the term used in the 2015 DGAs to describe this food category be guided by consumer research, used consistently, and be inclusive of all packaging forms.

Dairy

We acknowledge the importance of continuing the 2010 DGA recommendation to increase intake of fat free or low fat milk and milk products such as milk, yogurt, cheese or fortified soy beverages. As the diet patterns show, and this DGAC has noted, calcium and vitamin D are still shortfall nutrients in U.S. diets, and over 80% of the entire U.S. population does not meet the daily dairy intake recommendation. Recent research suggests that healthy diet patterns can also include some full fat dairy foods. Dairy fat is a highly palatable source of nutrients, including vitamin A, vitamin K, and vitamin D.^{35,36} Recent reviews indicate that the majority of observational studies have failed to find an association between the intake of dairy products and increased risk of CVD, coronary heart disease and stroke regardless of milk fat levels.^{37,38} A meta-analysis with data from over 600,000 subjects in 49 observational studies and 27 randomized controlled clinical trials looking at fatty acids associated with risk of heart disease concluded that “current evidence does not clearly support cardiovascular guidelines that encourage high consumption of polyunsaturated fatty acids and low consumption of total saturated fats.”³⁹ These results concur with another meta-analysis of prospective epidemiologic studies showing no significant evidence for concluding that dietary saturated fat is associated with an increased risk of Coronary Heart Disease (CHD) or Cardiovascular Disease (CVD).⁴⁰ In addition, the cholesterol-lowering benefits of soy protein have been demonstrated in over 150 clinical trials (meta-analysis), which is recognized as an approved health claim in 13 countries.^{41,42,43,44,45,46,47,48} GMA asks that the Departments continue to

³⁴ MMR Research Associates. (2015) Bean Terminology Research. Unpublished raw data.

³⁵ Haug, A, Hostmark AT, Harstad OM. Bovine milk in human nutrition – a review. *Lipids in Health and Disease* 2007;6:25.

³⁶ Dror DK, Allen LH. Dairy product intake in children and adolescents in developed countries: trends, nutritional contribution, and a review of association with health outcomes. *Nutr Rev.* 2014 Feb;72(2):68-81.

³⁷ Huth PJ, Keigan MP. Influence of dairy product and milk fat consumption on cardiovascular disease risk: a review of the evidence. *Adv Nutr* 2012;3:266-285.

³⁸ Innovation Center for US Dairy and National Dairy Council. (2011) Cheese & Nutrition. Available at: http://www.nationaldairyCouncil.org/SiteCollectionDocuments/education_materials/cheese/Health%20Professional%20Cheese%20Nutrition%20Brochure%20Final.pdf

³⁹ Chowdhury, Rajiv, et. al. Association of dietary, circulating, and supplement fatty acids with coronary risk: A systematic review and meta-analysis. *Ann Intern Med* 2014;160(6):398-406.

⁴⁰ Siri-Tarino, et. al. Meta-analysis of prospective cohort studies evaluating the association of saturated fat with cardiovascular disease. *Am J Clin Nutr* 2010 Mar;91(3):535-546. <http://ajcn.nutrition.org/content/early/2010/01/13/ajcn.2009.27725.full.pdf>

⁴¹ Harland JI, Krul ES, Mukherjea R et al. (2012) Soy: nutrition, consumption and heart health. In A. Ahmad (Ed.) *Soy: Nutrition, Consumption & Health* (pp. 1-40). Nova Science Publishers.

⁴² Anderson JW, Johnstone BM, Cook-Newell ME. Meta-analysis of the effects of soy protein intake on serum lipids. *N Engl J Med.* 1995;333:276-282.

acknowledge the important role that dairy foods and dairy alternatives play in the American diet both as a source of important vitamins and minerals but also as important sources of protein as evidenced by its status as a meat alternative in the National School Lunch Program.

Clarity is Needed on Descriptive Terms for Lower-Fat Cheese and Dairy

GMA fully recognizes that the food category descriptors used in nutrition research studies often differ from the terminology utilized in food labeling. Furthermore, it is our understanding that the “low-fat” term used frequently by the DGAC to describe the dairy category is a broad descriptor and intended to include all lower-fat (fat-free, low-fat and reduced-fat) categories of cheese. The intention is to guide consumers toward cheese products that contain fewer calories and less saturated fat. This approach is consistent with a focus on reducing total calorie intake yet does not reflect research that has specifically investigated health outcomes associated with the intake of lower-calorie or lower-fat cheese products compared to full fat options. The DGA policy document should clarify the use of these terms due to the lack of alignment between regulatory standards for lower-fat claims and the use of these terms as broad descriptors in the scientific literature related to dietary patterns.

We noted that in the body of the 2010 DGA document, the term “reduced-fat” is not used to describe lower-fat cheese. We feel that the 2015 DGA policy document has an opportunity to be more consistent and precise with the lower-fat terminology used for dietary recommendations related to cheese. We recommend that all lower-fat cheese-related recommendations in the 2015 DGA include the “reduced-fat” descriptor. Ultimately, the result will be increased clarity for consumers in the general public and enable sound dietary choices when selecting food products from the cheese category.

Consumer research suggests that fat-free and low-fat cheese products are less desirable to consumers^{49,50} and thus, these cheese products only comprise a small portion of the overall cheese category. Furthermore, products in the cheese category with low/no/reduced fat claims greatly under-

⁴³ Zhan S & Ho SC. Meta-analysis of the effects of soy protein containing isoflavones on the lipid profile. *Am J Clin Nutr.* 2005;81(2):397-408.

⁴⁴ Balk E, Chung M, Chew P, et al. Effects of soy on health outcomes. Evidence Report/Technology Assessment No. 126. (Prepared by Tufts-New England Medical Center Evidence-based Practice Center under Contract No. 290-02-0022.) AHRQ Publication No. 05-E024-2. Rockville, MD: Agency for Healthcare Research and Quality. August 2005.

⁴⁵ Reynolds K, Chin A, Lees KA et al. A meta-analysis of the effect of soy protein supplementation on serum lipids. *Am J Card.* 2006;98(5):633-640.

⁴⁶ Harland JL & Haffner T. Systematic review, meta-analysis and regression of randomized controlled trials reporting an association between an intake of circa 25g soya protein per day and blood cholesterol. *Atherosclerosis* 2008;200(1):13-27.

⁴⁷ Solae Meta-Analysis, 2009 (unpublished)

⁴⁸ Anderson JW et al. Soy protein effects on serum lipoproteins: a quality assessment and meta-analysis of randomized controlled studies. *J Am Coll Nutr.* 2011;30(2):79-91.

⁴⁹ Childs JL, and Drake M. Consumer perception of fat reduction in cheese. *J Sensory Studies.* 2009;24:902-921.

⁵⁰ International Food Information Council Foundation. *Food & Health Survey*, 2014.

index when compared to the overall dairy category and other dairy subcategories (e.g., spoonable yogurt) (Table 1). Limitations associated with fat-free and low-fat cheese include reduced overall palatability, altered texture, reduced melting qualities, and increased browning.⁴⁹ Reduced-fat cheese is the largest segment of the lower-fat cheese category and much more widely purchased and consumed than either low-fat or fat-free cheese by the general public.

Table 1: Food Products With and Without Low/No/Reduced Fat Claims*^			
Category	Total Number of Products	Number of Products with Low/No/Reduced Fat Claims	% of Products with Low/No/Reduced fat Claims
All Food Categories	16,36	1,892	11%
Dairy	1,464	585	40%
Spoonable Yogurt	395	317	80%
Cheese	560	80	14%

*Source: Mintel Global New Products Database.
 ^Search Criteria: Products launched in the USA within last year. Search conducted on August 30, 2014.

We are concerned that it might be confusing to consumers if the 2015 DGA is not consistent in the descriptive terms used to describe the lower-fat cheese categories. In addition, we believe that aligning terminology in dietary guidance with terminology used in food labeling will make it easier for consumers to recognize and choose food products in the marketplace.

We urge the Departments to retain the distinction between “reduced-fat” and “fat-free” or “low-fat” within the dietary recommendations for the cheese and dairy category because it is important for consumers to receive clear guidance that reduced-fat cheese is also a recommended choice. We believe that this most accurately reflects the cheese products available to consumers in the marketplace while also aligning with appropriate food labeling regulations.

Fortified Foods

GMA agrees with the Committee’s findings that the typical use of fortified foods in a healthy dietary pattern rarely leads to overconsumption. We also agree with the committee’s findings that fortified foods can be part of an effective strategy to help Americans meet certain nutrient needs, especially shortfall nutrients. Fortified foods are often the very choices that can help children and adults “fill the gap” and meet recommended amounts of shortfall nutrients. For example, as the 2010 DGA notes, “In the United States, most dietary vitamin D is obtained from fortified foods, especially fluid milk and some yogurts. Some other foods and beverages, such as breakfast cereals, margarine, orange juice, soy milk

and other plant-based milks, also are commonly fortified with this nutrient.”⁵¹ Research has demonstrated the important contributions that enriched and fortified foods have made to dietary intakes.⁵² Historically, fortified and enriched foods have played a key role in reducing nutrient shortfalls in the population, particularly inadequacies in iodine, B-vitamins, iron, folic acid, vitamins A, C and D as well as dietary fiber. For these reasons, we encourage the Departments to recognize the benefits of fortification in helping the public achieve nutrient adequacy and improving the nutritional quality of the food supply and make recommendations that promote fortified foods, where appropriate, as part of a healthy dietary pattern.

Grains – Whole and Refined

GMA commends the DGAC on their due diligence in reviewing the evidence around grains and health, and supports their conclusions and recommendation to bring forward the 2010 recommendations. In light of the current negative consumer perceptions and confusion surrounding the benefits of grain-based foods, we encourage the Departments to provide clear and concise recommendations on this important food group as a whole, to help dispel the prevailing negative perceptions of grains and to help consumers understand the important place these foods have in their diets.

While GMA is supportive of the DGAC’s recognition of the importance of whole grains and the need to increase consumption among all Americans, we also encourage the Departments to note the crucial role of enriched and fortified grains in the diet which was supported by the findings in the DGAC report-- especially their contribution to folic acid consumption. Outlining and communicating the health benefits of enriched grains is necessary to minimize risks to the health of women of child-bearing age. Recent analysis⁵³ found that since 1998, when the Food & Drug Administration (FDA) mandated that enriched grains be fortified with folic acid, the incidence of neural tube defects (NTDs) in U.S. infants has decreased 36 percent. Enriched, fortified grains, such as ready-to-eat cereal, are the primary source of folic acid in Americans’ diets. This is particularly important for women of child-bearing age, the majority of which do not take folic acid supplements. In addition, recent data suggests that folic acid supplementation may reduce the risk for stroke across the adult population with hypertension.⁵⁴

Public perception of the health benefits and necessity of grains—in particular, refined grains-- in the diet has eroded over the last few years. However, with few exceptions, refined grains are enriched and fortified and contribute key nutrients to the diet. As stated in the glossary of terms of the DGAC

⁵¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. The Dietary Guidelines for Americans, 2010. Retrieved from:
http://www.cnpp.usda.gov/sites/default/files/dietary_guidelines_for_americans/PolicyDoc.pdf

⁵² Berner LA, Keast DR, Bailey RL, Dwyer JT. Fortified foods are major contributors to nutrient intakes in diets of US children and adolescents. *J Acad Nutr Diet* 2014;114:1009-1022.

⁵³ Centers for Disease Control and Prevention. Updated Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification – United States, 1995-2011. *Morbidity and Mortality Weekly Report* 2015;64(01):1-5.

⁵⁴ Huo Y, Li J, Qin X et al. Efficacy of folic acid therapy in primary prevention of stroke among adults with hypertension in China, The CSPPT randomized clinical trial. *JAMA* 2015 Apr 7;313(13):1325-35.

Scientific Report, “Many refined grains are low in fiber but enriched with thiamin, riboflavin, niacin, and iron and fortified with folic acid.” However, at least 95% of the refined grains in the U.S. are enriched and fortified and are labeled as such. As noted in the technical report, the dietary intake research on grain foods demonstrates that there is an imbalance in grain intake, with a high intake of refined grains and low intake of whole grains. This imbalance highlights an opportunity for the Departments to make clear recommendations around the benefits of grains—both whole and refined—and how Americans can balance them in their diet within calorie needs.

We are in full support of the continued recommendation by the DGAC for Americans to consume half of their total grain servings as whole grains as Americans have yet to achieve this goal. GMA is also in agreement with the Committee’s overall definition of whole grains. This definition has a solid foundation and has gained broad scientific and regulatory acceptance. Additionally, the acknowledgement that “many, but not all, whole grains are also sources of dietary fiber” is an important point that should be carried forward in consumer education messages regarding whole grain recommendations.

Fiber

As noted by the 2015 DGAC, fiber continues to be underconsumed by Americans. A 2013 IFIC Functional Foods Consumer Survey showed that 67% of those surveyed believe they are getting at least enough fiber to meet recommendations.⁵⁵ However, the DGAC report noted a significant shortfall with only approximately 5% of Americans are actually getting enough fiber.⁵⁶ GMA supports the DGAC recommendation of selecting high-fiber products, and choosing a wide variety of whole grains, fruits, vegetables and legumes to help consumers increase fiber intakes.^{57,58} In addition to highlighting the wide variety of food groups and products that provide fiber, encouraging consumers to check the Nutrition Facts Panel for grams of dietary fiber per serving prior to selecting products may also help consumers understand how to increase fiber intake.⁵⁹

⁵⁵ International Food Information Council Foundation. 2013 Functional Foods Consumer Survey.

⁵⁶ Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Part D, Chapter 1, Figure D1.2 Percent population with usual intakes above AI

⁵⁷ Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Part D, Chapter 1, pg 16 lines 593-595.

⁵⁸ McGill CR, Fulgoni VL, Devareddy L. Ten-Year Trends in Fiber and Whole Grain Intakes and Food Sources for the United States Population: National Health and Nutrition Examination Survey 2001-2010. *Nutrients* 2015;7:1119-1130.

⁵⁹ Mobley AR, et al. Identifying practical solutions to meet America’s fiber needs: proceedings from the Food and Fiber Summit. *Nutrients* 2014;6:2540-2551.

Added Sugars

The definition of added sugar should be reconsidered

GMA has noted in the Glossary of Terms that the DGAC utilized the proposed FDA definition of added sugars when conducting work. The use of this definition is premature as it has only been used in a proposed rule thus far and as such has not been finalized and is subject to change.

GMA has concerns with the process used to develop the added sugar recommendation

We ask that the Departments continue to follow the tenet identified in the 2005 DGAs that food guidance should encourage individuals to achieve the most recent nutrient intake recommendations or Dietary Reference Intakes (DRI) established by the IOM.

These intakes are intended to serve as a guide for good nutrition and provide the scientific basis for the development of food guidelines in both the United States and Canada. As noted in the 2005 DGA, “A basic premise of the Dietary Guidelines is that food guidance should recommend diets that will provide all the nutrients needed for growth and health. To this end, food guidance should encourage individuals to achieve the most recent nutrient intake recommendations of the Institute of Medicine, referred to collectively as the DRIs.”⁶⁰ However, it is important to acknowledge that most of the DRIs in 2005 were reflective of the latest scientific evidence. In contrast, for the 2015 Dietary Guidelines, the DRIs for most nutrients have not been changed since their last reviews 10-15 years ago. The exceptions being the DRIs for calcium and vitamin D which were revised in 2010. In the intervening years, scientific advances are such that other nutrients, including omega-3 fatty acids, sodium, magnesium, and vitamin E have been prioritized for scientific re-evaluation.

The IOM DRI Report on Macronutrients (2002)⁶¹ indicates that intakes of added sugars should be 25% or less of calories due to a concurrent reduction in nutrient intakes at higher added sugar levels. The IOM recognized at the time that there was insufficient evidence to set an upper level for sugar intake, based on data available on risk of dental caries, behavior, cancer, obesity and hyperlipidemia. GMA is cognizant of the newer scientific research on sugars and health outcomes and recommends that any re-evaluation of added sugar recommendations be done through a comprehensive rigorous process.

The 2015 DGAC’s work on added sugars resulted in a recommendation to keep added sugars intake below 10% of total intake is supported by food pattern modeling and existing reports. While we appreciate the DGAC’s interest in this topic, GMA is concerned that the DGAC did not use the more

⁶⁰U.S. Department of Agriculture and U.S. Department of Health and Human Services. The Dietary Guidelines for Americans, 2005. Retrieved from:

<http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter2.html>

⁶¹Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. Washington, DC: National Academy Press, 2002.

rigorous approach used by the IOM to develop recommended nutrient intakes. A key aspect of the IOM's DRI framework is the use of a bimodal approach which considers that there are risks of adverse effects associated with low or inadequate nutrient intakes as well as with high nutrient intakes. The DGAC acknowledged in the technical report that a "potential unintended consequence of a recommendation on added sugars might be that consumers and manufacturers replace added sugars with low calorie sweeteners. As a result, the Committee also examined evidence on low calorie sweeteners to inform statements on this topic."⁶² However, this does not constitute a risk assessment approach and thus did not fully consider unintended consequences or risks, such as a potential decline in consumption of certain recommended food groups, or nutrient inadequacies in order to meet a no more than 10% threshold, or the potential for increased consumption of other types of carbohydrates, fats or protein due to reformulation of products to reduce the amount of added sugars. Therefore, it would be appropriate for the 2015 DGA to reaffirm the 2010 DGA recommendation to reduce the intake of added sugars without a numerical target until such a target can be established through a comprehensive rigorous process.

The 2015 Dietary Guidelines should acknowledge added sugar in the context of a total diet and its importance in promoting the intake of nutrient-dense foods

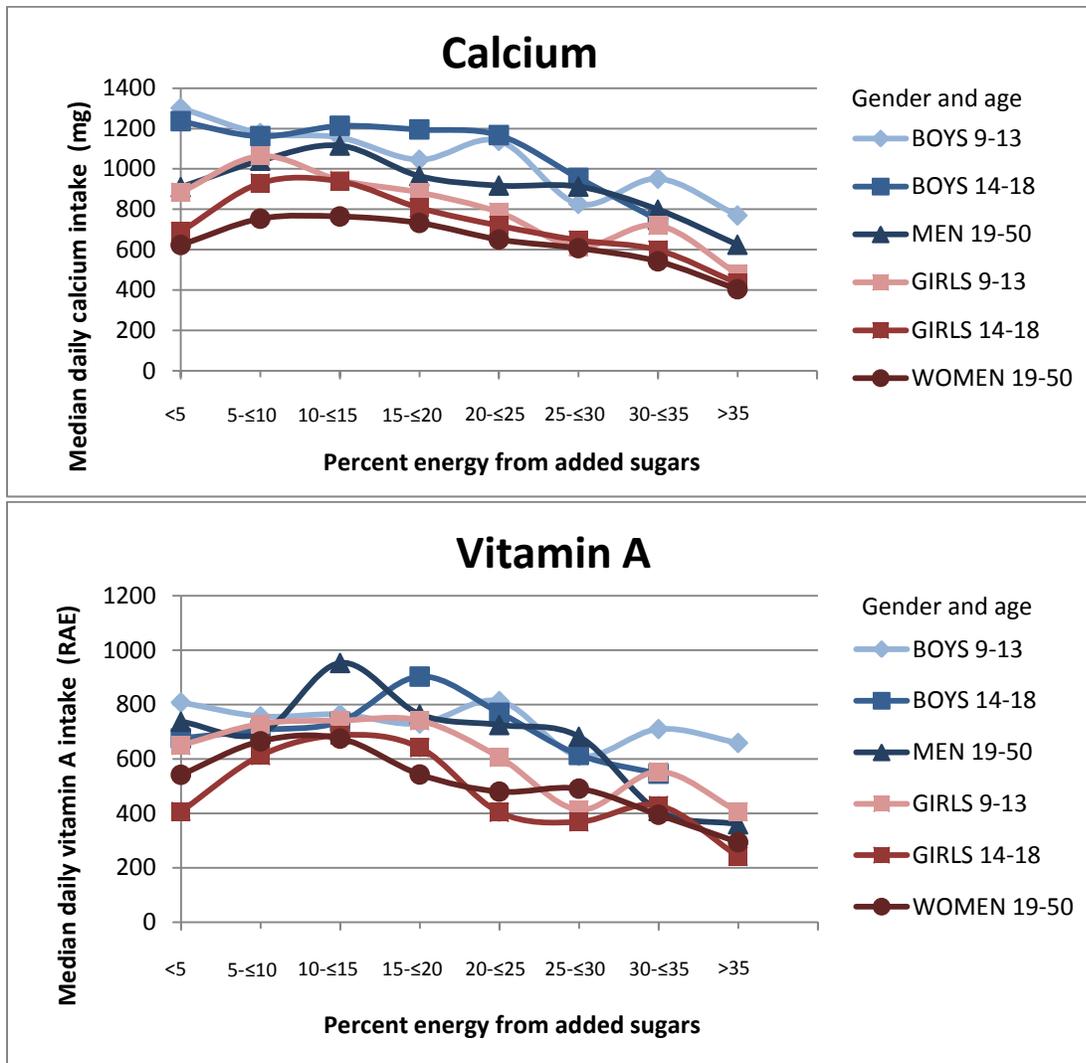
The 2015 DGAC Report has a strong emphasis on avoiding foods with added sugars. This is a departure from the 2010 Dietary Guidelines which recommended limiting intake of added sugars while acknowledging their value in increasing the palatability and enjoyment of nutrient-dense foods. GMA believes the lack of acknowledgment of the role of added sugars in the consumption of nutrient-dense foods reduces flexibility in diet planning as sugars are used in both manufactured and home-cooked foods to improve palatability and thus smaller sugar intakes may not automatically lead to improved nutrient intakes.

When average added sugar intake and median calcium, vitamin A, and iron intake for six age and gender groups were plotted using National Health and Nutrition Examination Survey (NHANES III; 1988-1994) shortfall intakes were noted at intakes at 5% or less of total energy as well as when levels exceed 25% of total energy as illustrated in the charts generated below.⁶¹ Analysis of data from the National Health and Nutrition Examination Survey (NHANES) 2003-2006 reinforces these trends. The shortfall intakes of these nutrients are most likely due to low intakes of fruits and vegetables (including juices), dairy products and fortified grains.⁶³ In a recent position, the American Academy of Pediatrics (AAP) also recognized that diet quality can be impacted by sugars intakes that are either too low or too high. The AAP recognized that when used in moderation and along with nutrient dense foods and beverages, added sugars can lead to improvements in the quality of child's diet. Caution was raised that including

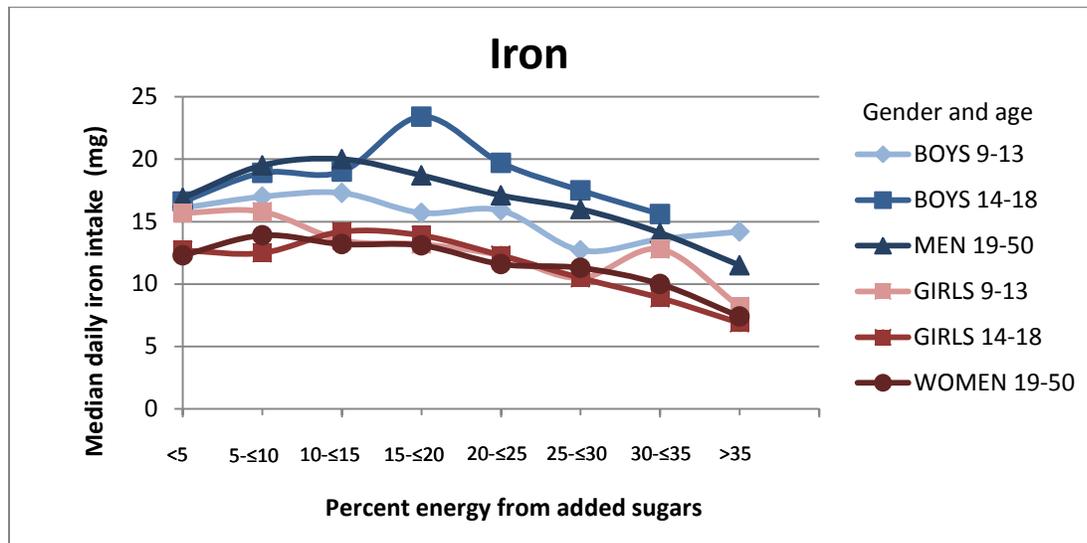
⁶² Scientific Report of the 2015 Dietary Guidelines Advisory Committee, Part D, Chapter 6, pg. 19, lines 687-690.

⁶³ Marriott BP, Olsho L, Hadden L, Connor P. Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003-2006. *Crit Rev Food Sci Nutr* 2010 Mar;50(3):228-58.

added sugars at levels of 25% or higher of energy intake can lead to excess calorie intake and displacement of other nutrients in the diet.⁶⁴



⁶⁴ American Academy of Pediatrics. Snacks, Sweetened Beverages, Added Sugars, and Schools. Pediatrics 2015;135(3):575-583.



Additional long term intervention studies should be conducted to ascertain that there are minimal effects on adequacy of nutrient intakes and diet quality when sugar reductions are recommended. GMA recognizes the importance of consuming energy-containing nutrients such as added sugars in moderation and within calories needs. GMA encourages the Departments to communicate to consumers the role of added sugars in promoting the consumption of nutrient-dense foods, as well as the importance of moderation and portion size instead of restriction or elimination of products.

Americans' intake of added sugars continues to decline

GMA appreciates that the 2015 DGAC acknowledged the reduction in calories from added sugar that has occurred and offers additional research that reinforces this point. Added sugars, although singled out as a nutrient of interest in relation to risk of obesity, have decreased as a percentage of total caloric intake by consumers. Welsh, et al. found energy intake from added sugars decreased from 18.1% in 1999-2000 to 14.6% in 2007-2008 across all age groups.⁶⁵ In addition, the amount of calories available from sources of added sugars has also been shown to have decreased during this same time period from 421 kcal/d in 1999 to 378 kcal/d in 2008.⁶⁶ Per the 2015 DGAC Final Report, added sugar consumption continues to drop and was estimated to be 13.4% of total calories among the total U.S. population ages 1 year and older.⁶⁷

⁶⁵ Welsh JA, Sharma AJ, Grellinger L, Vos MB. Consumption of added sugars is decreasing in the United States. *Am J Clin Nutr* 2011;94:726-734.

⁶⁶ U.S Department of Agriculture Economic Research Service. Food Availability Data Set. 2014. Retrieved from: [http://www.ers.usda.gov/data-products/food-availability-\(per-capita\)-data-system/.aspx](http://www.ers.usda.gov/data-products/food-availability-(per-capita)-data-system/.aspx)

⁶⁷ Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Part D, Chapter 1, pg 41.

Additional research should be taken into consideration when examining added sugar intake and body weight

Recently research using ecological modeling has been undertaken to elucidate the possible relationship between the availability of calories from a single source and obesity rates. Many studies and reports including the 2010 DGAC Report have shown that with respect to weight loss, reducing total caloric intake is essential and the source of calorie reduction may be of secondary importance because excess energy in any food form will promote body fat accumulation.^{68,69,70,71}

The 2015 DGAC concluded that there was strong and consistent evidence that intake of added sugars from food and/or sugar sweetened beverages are associated with excess body weight in adults and children. This work was heavily based on two recent meta-analyses examining added sugar and body weight. Reliance on pre-existing reviews does not ensure that the literature being used to answer the research question has undergone the rigorous and unbiased evidence review process as is done with the NEL. The use of such reviews/meta-analyses to form recommendations raises serious concerns that a review of the full body of science was bypassed. In regards to the scientific evidence base used to evaluate the relationship between sugars and body weight for the World Health Organization (WHO) “free sugar” dietary guideline, the interpretation of the WHO-commissioned systematic review and meta-analysis⁷² raises a number of concerns from a scientific perspective:

- The review confirms that any role of sugars on body weight results from its energy contribution to the diet overall and is not specific to sugars or “free sugars.” Many of the studies involved an explicitly counseled or mandatory consumption of an added energy load as sugars, and compared this to a lower-energy or energy-free load. Thus, it is not clear if these studies should be interpreted as a test of the role of sugars specifically or of supplemental energy in general from any macronutrient source. It cannot be inferred on the basis of these studies that increase in body weight is associated specifically with sugar intake, as opposed to distorted energy balance and the DGAC fails to properly qualify its conclusion statement for added sugars and body weight to reflect the scientific findings.

⁶⁸ Bray GA, Smith SR, de Jonge L, Xie H, Rood J, et al. Effect of dietary protein content on weight gain, energy expenditure, and body composition during overeating: A randomized controlled trial. *The Journal of the American Medical Association* 2012;307(1):47-55.

⁶⁹ de Souza RJ, Bray GA, Carey VJ, Hall KD, LeBoff MS, et al. Effects of 4 weight-loss diets differing in fat, protein, and carbohydrate on fat mass, lean mass, visceral adipose tissue, and hepatic fat: Results from the POUNDS LOST trial. *Am J Clin Nutr* 2012;95(3):614-625.

⁷⁰ Hess J, Latulippe ME, Ayoob K, Slavin J. The confusing world of dietary sugars: Definitions, intakes, food sources and international dietary recommendations. *Food Function* 2012;3(5):477-486.

⁷¹ Lowndes J, Kawiecki D, Pardo S, Nguyen V, Melanson KJ, Yu Z, Rippe JM. The effects of four hypocaloric diets containing different levels of sucrose or high fructose corn syrup on weight loss and related parameters. *Nutr J* 2012;11:55.

⁷² Te Morenga L., Mallard S., Mann J. Dietary sugars and body weight: Systematic review and meta-analyses of randomised controlled trials and cohort studies. *Brit J Med* 2013;346:e7492.

- The studies included in the systematic review utilized differing criteria for defining “free sugars.” The effect of “free sugars” on body weight was assessed without taking into account the effect of “total sugars” on body weight.
- There was no effect of sugar and measures of weight found in children based on the reviews of RCTs and only a small effect was found in cohort studies.
- There was no evidence of a dose-response relationship provided.

We ask that the Departments be mindful of these limitations of the evidence used to develop this conclusion when considering if or how to use it in the policy document.

Additional research is needed to examine added sugar intake and dental caries

The development of dental caries is complex and multifactorial. It is dependent on the concurrent presence of oral bacteria and fermentable carbohydrates (sugars and some starches). It also is influenced by the susceptibility of the tooth, the bacterial profile, the quantity and quality of the saliva, and the time during which fermentable carbohydrates are in contact with bacteria.^{61,73} The available evidence suggests that the frequency of sugar consumption, the stickiness of the food, and the length of time between sugar intake and tooth brushing plays a bigger role in the development of tooth decay than the quantity of sugar.^{73,74}

It was noted in the 2005 DGAC report “to address the problem of dental caries, the Committee recommended that “[d]rinking fluoridated water and/or using fluoride-containing dental hygiene products help reduce the risk of dental caries. A combined approach of reducing the frequency and duration of exposure to fermentable carbohydrate intake and optimizing oral hygiene practices is the most effective way to reduce caries incidence.”⁷⁵ The 2010 DGAC reaffirmed this conclusion while acknowledging that substantive research on the relationship of carbohydrates and dental caries has not occurred since the 2005 DGAC Report. Additionally, the USDA’s Food and Nutrition Service branch recently recognized the oral health benefits of chewing sugar-free gum and allow for it to be sold in schools as part of the Competitive Foods Program.⁷⁶

Thus GMA requests that the Dietary Guidelines should include language to reaffirm accepted oral hygiene practices including the use of fluoridated water and dental hygiene products as well as sugar-free gum, as contrary evidence for these practices has not been presented or reviewed. Given the lack of strong evidence available on the topic of added sugar intake and dental caries, GMA urges the

⁷³ European Food Safety Authority (EFSA). Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal March 2010;8(3):1462.

⁷⁴ Rugg-Gunn AJ. Dental caries: Strategies to control this preventable disease. Acta Medica Academica 2013;42(2):117-130.

⁷⁵ Dietary Guidelines Advisory Committee. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2005, to the Secretary of Agriculture and the Secretary of Health and Human Services. 2004. Retrieved from: <http://www.health.gov/dietaryguidelines/dga2005/report/>

⁷⁶ 78 Fed. Reg. 39079.

Departments to acknowledge this as a future research need. In addition, the Dietary Guidelines should acknowledge that the frequency and intake of added sugars is only one of many factors which contribute to oral hygiene and the risk of dental caries.

Consumer education is needed regarding added sugar

As noted by the International Food Information Council (IFIC) Foundation, “consumer research is a critical first step in determining Americans’ understanding of nutrition information and examining how consumer knowledge, perceptions and attitudes may impact behavior.” Findings from the IFIC Foundation’s consumer research entitled “Consumer Investigations into Nutrition Facts Panels and Sugars Labeling” found limited consumer understanding of what added sugars are as well as lack of clear understanding of the relationship between added sugars and calories.⁷⁷ Additionally, a heavy focus on one nutrient such as added sugars could lead to additional consumer confusion about the role of other nutrients such as intrinsic sugar and other carbohydrates that should be consumed within energy needs. More consumer education is needed on the topic of added sugars. We underscore the need for simple, clear and actionable consumer communications and messages that are evidence based.

Low and No Calorie Sweeteners

The DGAC concluded that moderate evidence supports the use of low calorie sweeteners (LCS) as a replacement for sugar containing sweeteners for short term weight loss. The long term effect of use of LCS was noted to be undetermined by the DGAC and thus the use of these sweeteners as a replacement for sugar-containing sweeteners was not recommended. GMA is concerned with this recommendation given that LCS have been shown to be an effective weight management tool when consumed along with a healthful diet and regular physical activity. Authoritative bodies such as the American Heart Association, Academy of Nutrition and Dietetics and the American Diabetes Association have conducted reviews of the literature and recommend the use of low and no calorie sweeteners (LNCS) to help people manage their weight and diabetes.^{78,79} A recent meta-analysis of 15 RCTs and 9 prospective cohort studies on LCS and body weight and composition supports the conclusion that LCS are an effective weight management tool.⁸⁰ There is additional evidence that may not have been considered by the DGAC, which demonstrates LCS are also beneficial for long-term weight loss maintenance. A

⁷⁷ IFIC Foundation. Consumer investigation into nutrition facts panels and sugars labeling. Published July 29, 2014. Available at: <http://www.foodinsight.org/sites/default/files/IFIC%20Foundation%20Preliminary%20NFP%20Survey%20Report%20072914.pdf>

⁷⁸ Gardner C, Wylie-Rosett J, Gidding SS, et al. Nonnutritive sweeteners: current use and health perspectives: a scientific statement from the American Heart Association and the American Diabetes Association. *Circ* 2012; 126:509-519.

⁷⁹ Fitch C, Keim KS. Position of the Academy of Nutrition and Dietetics: Use of nutritive and nonnutritive sweeteners. *J Acad Nutr Diet* 2012;112:739-758.

⁸⁰ Miller PE, Perez V. Low-calorie sweeteners and body weight and consumption: A meta-analysis of randomized controlled trials and prospective cohort studies. *Am J Clin Nutr* 2014;100(3):765-777.

comparison of dietary strategies between weight loss maintainers and always-normal weight controls found three times more daily servings of artificially sweetened beverages by weight loss maintainers which suggests these products may be an important strategy in supporting weight maintenance.⁸¹ Additionally a cross-sectional study of 434 members of the National Weight Control Registry found approximately 53% of successful weight loss maintainers consumed LNCS beverages one or more times per day. Notably, these participants also reported that consuming these beverages was beneficial in their efforts to control or reduce total caloric intake.⁸²

An NHANES analysis⁸³ between 1999-2008 compared the dietary patterns of consumers and non-consumers of low-calorie sweeteners. These data show that consumers of LCS had better diet quality as measured by Healthy Eating Index (HEI) and consumed more vegetables, whole-grains and low-fat dairy.

Moreover, more recent studies that were not included in the above meta-analysis evaluated the effects of LCS beverages or water on weight loss. The first is a randomized control trial of 303 subjects randomized to a LCS beverage or to water which reported that both groups lost weight but the LCS group had significantly greater (50% greater) weight loss compared to the water only group over 12-weeks.⁸⁴ The LCS group also reported less hunger compared to the water group. The authors stated that a 9-month follow-up study is underway. Piernas, et al.,⁸⁵ conducted a six-month weight loss randomized controlled trial (CHOICE, Choose Healthy Options Consciously Everyday) that which compared diet beverages or water, substituted for caloric beverages on weight loss and dietary patterns. Both groups were successful in weight loss, improved dietary patterns and reduced in caloric intakes but the diet beverage group had greater reductions in dessert consumption, implying that beverages sweetened with low-calorie sweeteners may help satisfy the desire for sweetness without added calories.

Research has shown the use of low calorie sweeteners can be used as a strategy to help reduce caloric intake and serve as a tool for successful weight loss. There are a large number of low and no calorie products on the market that can help consumers with successful weight loss and maintenance allowing people the flexibility to choose nutrient-rich foods and beverages within their caloric needs. The American Academy of Pediatrics recognized that offering low and no calorie sweetened beverages in schools reduced calories shipped to schools by approximately 90%.⁶⁴ GMA urges the Departments to

⁸¹ Phelan S, Lang W, Jordan D, Wing RR. Use of artificial sweeteners and fat modified foods in weight loss maintainers and always-normal weight individuals. *International Journal of Obesity* 2009;33:1183-1190.

⁸² Catenacci VA, Pan Z, Thomas JG, Ogden LG, Roberts SA, Wyatt HR, Wing RR, Hill JO. Low/no calorie sweetened beverage consumption in the National Weight Control Registry. *Obesity* 2014;22(10):2244-2251.

⁸³ Drewnowski A, Rehm CD. Consumption of low-calorie sweeteners among U.S. adults is associated with higher Healthy Eating Index (HEI 2005) scores and more physical activity. *Nutrients*. 2014;6(10):4389-403.

⁸⁴ Peters JC, Wyatt HR, Foster GD, et al. The effects of water and non-nutritive sweetened beverages on weight loss during a 12-week weight loss treatment program. *Obesity*. 2014; 22:1415-1421.

⁸⁵ Piernas C, Tate DF, Wang X et al. Does diet-beverage intake affect dietary consumption patterns? Results from the Choose Healthy Options Consciously Everyday (CHOICE) randomized clinical trial. *Am J Clin Nutr*. 2013;97:604-611.

recognize the role of low calorie sweeteners as a tool to aid in calorie management while meeting nutrient needs.

Sodium

GMA is pleased to see that the Scientific Report of the 2015 DGAC in Part D, Chapter 6, lines 219-231, acknowledges the findings and conclusions of the 2013 IOM Committee that the evidence is inadequate to conclude that lowering sodium below 2,300 mg/day either increases or decreases the risk of CVD or all-cause mortality in the general population. We are concerned, however, that the DGAC did not acknowledge another important conclusion of the IOM Committee that individuals with diabetes, Chronic Kidney Disease (CKD), or pre-existing CVD, do not need to be treated differently from the general U.S. population or require lower sodium intakes of 1,500 mg/day.⁸⁶ This conclusion is different from the 2010 DGA where a daily sodium intake of 1,500 mg was recommended for these individuals. The 2013 IOM conclusions should be reflected in the 2015 DGA.

In addition, other recommendations in the 2015 DGAC report do not consistently acknowledge new evidence since 2005 which shows that low sodium, in the range captured by the current DRIs, may not be compatible with minimal risk for mortality or cardiovascular disease as outlined in the 2013 IOM report on “*Sodium Intake in Populations: Assessment of Evidence*”⁸⁶ and other evidence not available at the time of the IOM evaluation.^{87,88,89,90,91} The DGAs should not apply recommendations for those with hypertension to the entire population until the scientific uncertainty about sodium intake and optimal health has been resolved by an independent evaluation.

The DGAC recommendations on sodium are inconsistent with one another

GMA concurs with the DGAC that emerging science indicates that sodium intake recommendations may differ between “adults who would benefit from blood pressure lowering” and the general population. Such an acknowledgement is important to accommodate the conclusions and recommendations of the

⁸⁶ Institute of Medicine. Sodium Intake in Populations: Assessment of Evidence. 2013. Accessed at <http://www.iom.edu/Reports/2013/Sodium-Intake-in-Populations-assessment-of-Evidence.aspx>.

⁸⁷ O’Donnell M, Mentz A, Rangarajan S et al. Urinary sodium and potassium excretion, mortality, and cardiovascular events. *New England J Med*. 2014;371:612-623.

⁸⁸ Pfister R, Michels G, Sharp SJ, Luben R, Wareham NJ, Khaw KT. Estimated urinary sodium excretion and risk of heart failure in men and women in the EPIC-Norfolk study. *Eur J Heart Fail*. 2014 April;16(4):394-402.

⁸⁹ Graudal N, Jurgens G, Baslund B, and Alderman, MH. Compared with usual sodium intake, low- and excessive-sodium diets are associated with increased mortality: A meta-analysis. *Am J Hypertens* 2014 Sep;27(9):1129-37.

⁹⁰ Cook NR, Appel LJ, Whelton PK. Lower levels of sodium intake and reduced cardiovascular risk. *Circulation* 2014; 129:981-989.

⁹¹ Joosten MM, Gansevoort RT, Mukamal KJ, Lambers Heerspink HJ, Geleijnse JM, Feskens EJ, et al., Sodium excretion and risk of developing coronary heart disease. *Circulation* 2014;129:1121-1128.

2013 *AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk*⁹² and the 2013 IOM Report on *Sodium Intake in Populations: Assessment of Evidence*.⁸⁶ The former report specifically evaluated data from subjects with elevated blood pressure and concluded that adults who would benefit from blood pressure lowering should consume less than 2,400 mg of sodium/day and preferably as low as 1,500 mg/day. The latter report concluded that in the general population there is insufficient evidence that lowering sodium intakes to the 1,500 mg/day to 2,300 mg/day range either increases or decreases risk of CVD outcomes or all-cause mortality.

Nevertheless, the DGAC Scientific Report does not explain how the DGAC can concur with the 2013 IOM Report that in the general population there is insufficient evidence to conclude that lowering sodium below 2,300 mg/day either increases or decreases risk of CVD outcomes or all-cause mortality (Chapter 6, lines 226 -231) and a little later urge the general population, ages 2 years and older, to rely on the recommendations of the IOM Panel on DRIs for Electrolytes and Water⁹³ (Chapter 6, lines 304-305), which specifies a desirable sodium intake range as between 1,500 mg/day and 2,300 mg/day. The potential for increased risk of CVD recognized by the 2013 IOM panel is also inconsistent with the general population goal of sodium intakes less than 2,300 mg/Day (Part A Executive Summary, line 339). In healthy populations, the 1,500 mg/day to 2,300 mg/day range has not been shown to be associated with any benefit and may cause harm as concluded in the 2013 IOM report and confirmed by a subsequent meta-analysis⁸⁹ and longitudinal studies.^{87,88}

The DRI for sodium⁹³ is an Adequate Intake (AI) as there was inadequate evidence to determine an Estimated Average Requirement (EAR). The AI was based on diet modeling using the very specific and unique Dietary Approach to Stop Hypertension (DASH) – Sodium dietary pattern, and it is the amount of sodium in this low-sodium diet that provided an adequate amount of other nutrients rather than on scientific considerations of sodium *per se*. More comprehensive diet modeling^{94,95,96} has indicated that the AI of 1,500 mg sodium is not attainable and, furthermore, is not compatible with potassium intake recommendations (4,700 mg/day). This same modeling also shows that the lowest sodium diets are only theoretically possible, especially when recommended potassium intakes are taken into consideration, and would require major changes to dietary patterns and the types of food available in the U.S. food supply.

⁹² Eckel RH, Jakicic JM, Ard JD et al. 2013 AHA/ACC Guideline on lifestyle management to reduce cardiovascular risk: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Accessed at <http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437740.48606.d1.full.pdf>

⁹³ Institute of Medicine. Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. National Academy of Sciences, 2005.

⁹⁴ Maillot M and Drewnowski A. A conflict between nutritionally adequate diets and meeting the 2010 Dietary Guidelines for sodium. *Am J Prev Med* 2012;42:174-179.

⁹⁵ Drewnowski A, Maillot M and Rehm C. Reducing the sodium-potassium ratio in the US diet: a challenge for public health. *Am J Clin Nutr* 2012;96:439-444.

⁹⁶ Maillot M, Monsivais P, and Drewnowski A. Food pattern modeling shows that the 2010 Dietary Guidelines for sodium and potassium cannot be met simultaneously. *Nutr Res* 2013;33:188-194.

Similarly, the 2005 DRI panel had limited data from which to derive an Upper Level (UL) for sodium. The Panel noted that the relationship between sodium intake and blood pressure is continuous and that there are other environmental factors affecting blood pressure making it difficult to set a precise UL. A recent large multi-country study calls into question the linear relationship between sodium and blood pressure, assumed by the 2005 DRI Panel, as there was no further decrease in blood pressure at sodium intakes below 3,000 mg/day.⁹⁷ Furthermore, a recent meta-analysis found that sodium intake within the range normally consumed has no effect on blood pressure in people without elevated blood pressure which is the majority of the population.⁹⁸

There is now a consistent body of evidence which documents that sodium is similar to other nutrients in that physiologic responses to intake are parabolic. The outcome at both high and low sodium intakes is increased mortality.^{87,88,89} Much of this newer evidence came after the IOM Committee which concluded in 2013 that “the evidence from studies on direct health outcomes is inconsistent 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 in the general U.S. population.”⁸⁶

While science is still evolving in the area of sodium, even the most nutritionally savvy consumer will be unable to decipher these nuances. The net result will be consumer confusion regarding their individual sodium intake goal, independent of their blood pressure level. GMA suggests the departments develop clear sodium guidance using information for the general population, in order to avoid consumer confusion.

The totality of evidence should be considered in order to help protect the health of the public

GMA acknowledges that randomized control trials (RCTs) established that selected subjects are sensitive to excessive sodium intake. This finding has been the basis for previous dietary guidelines and public health recommendations. Over the past decade, the science of sodium and health has expanded well beyond the simple paradigm of the past. Despite the evidence from RCTs that some but not all individuals will experience a decrease in BP in response to lowered dietary sodium,⁹⁸ that body of data reflects a one-dimensional view of the physiologic impact of dietary sodium restriction. Simply relying on blood pressure to set sodium nutritional policy ignores the known physiological effects of sodium reduction such as:

⁹⁷ Mente A, O'Donnell MJ, Rangarajan S et al. Association of urinary sodium and potassium excretion with blood pressure. *New England J Med* 2014;371:601-611.

⁹⁸ Graudal N, Hubeck-Graudal T, Jurgens G and McCarron DA. The significance of duration and amount of sodium reduction intervention in normotensive and hypertensive individuals: A Meta-analysis. *Adv Nutr* 2015;6:169-177.

- Only a subset of individuals are sodium sensitive (i.e. blood pressure decreases with restricted dietary sodium) with roughly an equal number experiencing a rise in blood pressure on a restricted sodium diet.⁹⁹
- Low sodium intakes increases renin and aldosterone to maintain homeostasis; increased renin is associated with increased risk of heart attack.¹⁰⁰
- Metabolic parameters such as insulin sensitivity, low density lipoprotein (LDL) generation and serum sodium regulation may be impaired.¹⁰¹
- Impaired perfusion of critical organs such the heart and kidney.
- Toxicity of several commonly used drugs is enhanced.¹⁰²

Only a measure of health outcomes can predictably integrate all the potential physiologic effects of sodium reduction.

Unfortunately the DGAC did not conduct a meta-analysis of all the evidence. They considered previous evaluations and did an analysis of the four most recent studies, but did not conduct a single analysis of all the data. In addition, the DGAC did not critically assess the relevance of various studies. For instance the DASH study is singled out for special attention, but some critical features that impact its applicability to the U.S. populations were not addressed, e.g., the DASH diet is very different to the current U.S. diet in terms of potassium intake.

GMA cautions against some of the strategies to lower sodium recommended by the DGAC. The strategies recommended by the IOM in 2010 were developed to implement the 2005 DGA recommending 1,500 mg sodium/day for about half the population. In 2005, there was also limited awareness of the insufficiency and inadequacy of the health outcome data to conclude that lowering sodium below 2,300 mg/day either increases or decreases risk of CVD outcomes or all-cause mortality in the general population.⁸⁶ These strategies are out of step with the current science of sodium intake and mortality, especially in the majority non-hypertensive population.

In the absence of a rational for the inconsistent conclusions, we recommend that the DGA rely on the 2013 IOM report⁸⁶, this being the most recent independent assessment applicable to a general population. Advice provided to the general population in the DGAs should use the conclusions from this report considering the uncertainty that decreases below 2,300 mg sodium/day confers any benefit to the general population. We advise that the DGA leverage recommendations well-represented in the ACC/AHA Guidelines⁹² for the segment of the population with elevated blood pressure.

⁹⁹ Luft FC, Weinberger MH. Heterogeneous responses to changes in dietary salt intake: The salt- sensitivity paradigm. *Am J Clin Nutr* 1997;65(suppl):612S-617S.

¹⁰⁰ Brunner HR, Laragh JH, Baer L, Newton MA, Goodwin FT, Krakoff LR, Bard RH, Bühler FR. Essential hypertension: renin and aldosterone, heart attack and stroke. *N Engl J Med* 1972; 286:441-449.

¹⁰¹ Graudal NA, Hubeck-Graudal T, Jürgens G. Effects of low-sodium diet vs. high-sodium diet on blood pressure, renin, aldosterone, catecholamines, cholesterol, and triglyceride (Cochrane Review). *Am J Hypertens* 2012;25:1-15.

¹⁰² Bennett WM. Drug interactions and consequences of sodium reduction. *Am J Clin Nutr* 1997;65 (Suppl):678S-681S.

Additionally, GMA applauds the Committee's recognition of the role of herbs and spices in helping consumers reduce sodium intake while maintaining taste preferences and flavor. Studies have also found that herbs and spices can also aid in increasing consumption of lower calorie and low fat entrees as well as vegetables.^{103,104,105,106} GMA supports efforts to provide additional consumer education to ensure consumers are able to use these seasoning options when cooking.

Potassium

The DGAC report is inconsistent in its potassium conclusions. In Part D, Chapter 1, line 570 it comments on the critical role that potassium plays in the regulation of blood pressure and other functions. Later in the same section (line 574), potassium is designated as a nutrient of public health concern due to its under consumption relative to the AI and its association with reduced risk of hypertension and cardiovascular disease. These statements appear to be inconsistent with the DGAC's concurrence with the NHLBI Lifestyle Report that: "Evidence is not sufficient to determine whether increasing dietary potassium intake lowers blood pressure."¹⁰⁷

We agree that potassium is an important nutrient and urge the Departments, as they develop the 2015 DGA, to consider the ratio of sodium to potassium. In view of the amount of research on the topic, we're surprised that the relationship between this ratio and blood pressure was not proposed for an NEL review. Nevertheless a recent systematic review shows that, in randomized controlled trials of hypertensive subjects, the sodium:potassium ratio is associated with blood pressure more strongly than either sodium or potassium alone.¹⁰⁸ Although this finding is corroborated in observational studies, the authors concluded that the effects in the general normotensive population need to be explored further. Nevertheless, the sodium to potassium ratio should be considered in dietary guidance for people with hypertension.

¹⁰³ Peters JC, Polsky S, Stark R, Zhaoxing P, Hill JO. The influence of herbs and spices on overall liking of reduced fat food. *Appetite* 2014;79: 183-8.

¹⁰⁴ Polsky S, Beck J, Stark RA, Pan Z, Hill JO, Peters JC. The influence of herbs, spices, and regular sausage and chicken consumption on liking of reduced fat breakfast and lunch items. *J Food Sci* 2014;79:S2117-26.

¹⁰⁵ Anzman-Frasca S, Savage JS, Marini ME, Fisher JO, Birch LL. Repeated exposure and associative conditioning promote preschool children's liking of vegetables. *Appetite* 2012;58(2):543-553.

¹⁰⁶ Li, Krak M, Zerlin A, Brahe LK, Rheinwald-Jones A, Thames G, Zhang Y, Tseng C-H, Heber D. The impact of spices on vegetable consumption: A Pilot Study. *Food Nutr Sci* 2015;March 30.

http://www.scirp.org/Journal/PaperInformation.aspx?PaperID=55188#.VRvsTfnF_kU.

¹⁰⁷ Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Part D, Chapter 6, pg 8, Line 269.

¹⁰⁸ Perez V, Chang ET. Sodium-to-potassium ratio and blood pressure, hypertension, and related factors. *Adv Nutr* 2014;5:712-741.

Caffeine

It is GMA's view that the DGAC should defer to the U.S. Food and Drug Administration on the topic of caffeine safety based on sound, evidence-based science. Given that the DGAC has assessed the benefits and safety of caffeine we are compelled to make the following remarks.

As has been noted throughout these comments guidance recommendations intended to inform policy development and public health interventions should be based on the totality of available scientific evidence. Following the 7th and final meeting of the DGAC on December 15, 2014, and the subsequent release of the Committee's technical report, it is apparent that the Committee did not take into consideration a significant body of scientific evidence available on the safety of caffeine. In particular, we refer to scientific information presented in GMA's comments submitted to the Committee on September 11, 2014, October 31, 2014, and December 23, 2014, as well as the European Food Safety Authority (EFSA) draft Scientific Opinion on the Safety of Caffeine that was released on January 15, 2015. The Draft EFSA Scientific Opinion which was adopted with only minor revisions on April 23, 2015 is expected to be published mid May. The EFSA Scientific Opinion contains pertinent and recent scientific data on caffeine safety, levels of daily moderate intake, and assesses caffeine from all sources.

GMA remains concerned that an incomplete review of the data has adversely influenced the DGAC's review of caffeine and the DGAC's definitions of high-dose caffeine exposure and "at risk populations." We base this on the observation that the Committee has not appreciated that caffeine concentrations in most mainstream energy drinks are comparable to equivalent amounts of coffee, and less than a consumer would consume in drinking premium coffeehouse coffees. Considerable intake data have been published demonstrating that caffeine intake must be assessed from all sources to understand the significance of any one source to the total dietary intake of caffeine. These same government-sourced data demonstrate that caffeine from energy drinks is the single-smallest contributor to the daily intake of caffeine for all age groups, including those identified by the DGAC as "at risk."

As outlined above, it is beyond the scope and expertise of the DGAC, or the mandate given by Congress for the DGAC to deal with the issue of caffeine safety. The FDA regulates food safety and food additives. FDA has extensively studied caffeine and holds the expertise to regulate caffeine.

GMA asks the Departments to carefully and thoughtfully review current science and to establish a set of practical, affordable and achievable dietary recommendations that can meet public health needs. As GMA expressed in our earlier comments, meaningful caffeine education efforts to help consumers make informed decisions must incorporate information on all sources of caffeine.

Sustainability

GMA recognizes the entire food supply chain, from production to consumption to disposal, has direct impact on the environment. Given limited natural resources, our members are committed to finding more sustainable ways of feeding another 2 billion people around the world by 2050. GMA also supports the stated goals of the DGAC, which are to provide recommendations that are actionable by consumers and based on robust evidence.

The complex field of science that bridges agricultural sustainability and nutrition is still emerging. Therefore, it may be premature to include such recommendations in the 2015 DGA. In order to ensure a thoughtful and thorough examination of the literature and development of informed recommendations, GMA strongly urges the appointment of experts in the area of sustainability and its impact on food supply and nutritional status to the DGAC in the future. Before firm guidance is included in the DGAs, consistent and uniform methodologies should be developed to permit a meaningful review of the scientific evidence. This section describes some of the challenges of defining sustainable foods or diet patterns, as well as how GMA is working to reduce the environmental impact of the food system every day.

Sustainable dietary patterns are difficult to define

Defining and measuring “sustainability” is a complex task. GMA appreciates the DGAC’s recognition that any discussion of sustainability must account for a variety of environmental factors including energy use, land use, water use, greenhouse gas emissions, and biodiversity. Economic and social criteria are also often included when defining a sustainable food system. However, when more and more factors are included for consideration, tradeoffs between these factors are inevitable and clear decisions become increasingly difficult to make.

Multiple environmental indicators should be addressed

The DGAC used life cycle assessments (LCAs) and modeling as the basis for its conclusions and recommendations on sustainable dietary patterns. These can be powerful tools to provoke discussion and further research, but many practitioners of such methodologies recognize the limitations of the current science to provide definitive answers. Furthermore, studies using such tools to evaluate the environmental impact of food choices often show that methodological decisions about basic metrics such as functional units, allocation procedures, and system boundaries significantly impact results.¹⁰⁹

In its report, the DGAC suggested the LCA is a standardized methodological framework. While the International Organization for Standardization (ISO) has developed principles for implementing LCAs,

¹⁰⁹ Caffrey KR, Veal MW. Conducting an Agricultural Life Cycle Assessment: Challenges and Perspectives. *Sci World J* 2013:1-13.

there is no widely accepted guidance for how this type of work should be conducted. This makes the task of relating different environmental outcomes to one another more difficult. For example, how would 1000 gallons of clean water correspond to a pound of pesticide sprayed? This complexity becomes even more pronounced when the uneven distribution of various natural resources around the world, or even regions within the United States, is taken into account.

In 2013, the Institute of Medicine (IOM)/National Research Council convened a committee tasked with developing a “framework for assessing the health, environmental, and social effects (positive and negative) associated with the ways in which food is grown, processed, distributed, and marketed within the U.S. food system.” Recognizing the food system is multifaceted, they have brought together interdisciplinary experts in agriculture science, food supply chains, economics, complex systems science, water resources, climate change, trade, consumer behavior, dietary patterns, food safety, as well as nutrition and health in order to start addressing some of these questions. This type of systematic approach to develop a framework takes years to carry out. The framework emanating from the IOM could provide much needed clarity and consistency to any discussion of sustainable dietary recommendations going forward.

Additionally, the Sustainability Consortium, a multi-stakeholder group made up of industry and non-governmental partners, is working to assess the sustainability of a wide range of products, including foods and beverages. Through their work, members have discovered how challenging it is to fully compare a simple commodity such as a bushel of wheat with a more complex product, such as a frozen meal. Often, GMA members struggle with the challenge of even comparing one bushel of wheat with another. Unsurprisingly, honest efforts to document and track environmental impact from a supply chain are complex and take time. GMA strongly urges the Departments to consider the fact that these efforts are already underway, and given a little more time, our members will have reliable data to advance such efforts.

Tradeoffs between the environment and health should be assessed

The DGAC found “moderate to strong evidence” that diets higher in plant-based foods and lower in animal-based foods are better for the environment and health. While animal-based foods had a larger impact on the environmental metrics of interest to the DGAC, such a general categorization may be too broad for both health and the environment.^{110,111,112,113} This potential conflict between health and the

¹¹⁰ Heller MC, Keoleian GA. Greenhouse gas emission estimates of US dietary choices and food loss. *J Ind Ecol.* 2014;0:1-11.

¹¹¹ Vieux F, Darmon N, Touazi D, Soler LG. Greenhouse gas emissions of self-selected individual diets in France: Changing the diet structure or consuming less? *Ecol Econ* 2012;75:91-101.

¹¹² Vieux F, Soler LG, Touazi D, Darmon N. High nutritional quality is not associated with low greenhouse gas emissions in self selected diets of French adults. *Am J Clin Nutr* 2013;97(3):569-583.

¹¹³ Macdiarmid JI, Kyle J, Horgan GW, Loe J, Fyfe C, Johnstone A, McNeill G. Sustainable diets for the future: can we contribute to reducing greenhouse gas emissions by eating a healthy diet? *Am J Clin Nutr* 2012;96:632-639.

environment is significant to any discussion of health and sustainability because no widely accepted methods have yet been established to balance concerns for public health with concerns about food's environmental impact in a consistent, systematic way.

Such inconsistencies are evident within the DGAC report itself. Notably, the healthy dietary patterns presented in Chapter 2 that include low-fat dairy, lean meats and fish significantly contrast with the plant-based pattern presented in Chapter 5. The full impact on health will depend on which types of foods are added and removed from the diet and in what quantities. The full impact on the environment will depend on how the foods added and removed are actually produced.

For example, the 2010 Dietary Guidelines for Americans suggested consumers reduce their intake of *trans* fatty acids from all sources in order to reduce their risk of cardiovascular disease. However, this dietary guidance did not seamlessly align with environmental goals. Partially hydrogenated oils (PHOs), which contain *trans* fats, are often replaced with tropical oils. The substitution of these ingredients can have a significant environmental impact. For example, palm oil is produced in the southern hemisphere where harvest methods both planting of palm trees and palm kernel harvest can be harmful to the rainforest environment. The food industry is committed and continues to work towards sustainable harvesting of tropical oils, but this example illustrates some of the complex environmental tradeoffs that occur when making recommendations for health, even when the products being compared are all plant-based.

The food industry is moving towards more sustainable production

While they work to meet a competing set of consumer expectations for variety, health, and convenience, GMA recognizes they have a responsibility to help reduce the environmental impact of food and beverages. In order to make progress, the industry is diligently working to gather the information needed to make environmentally-sound decisions and choose the correct metrics for assessing advancements. Furthermore, GMA members continue to work to source ingredients more sustainably and to improve production methods. Increasingly, they partner with third-party certifiers and non-governmental organizations to implement new practices for long-term food security.

The food industry is addressing food waste

In addition to their investment in more sustainable sourcing and production methods, GMA members are actively engaged in reducing the environmental impact of food at other points along the supply chain. In the United States, the USDA estimates that 31% of the food available at the retail and consumer level alone was wasted in 2010.¹¹⁴ Food waste must be more efficiently managed in order to

¹¹⁴ Buzby JC, Farah Wells H, Hyman J. The estimated amount, value, and calories of postharvest food losses at the retail and consumer levels in the United States. 2014. (ERS Publication No. EIB-121). Retrieved from <http://www.ers.usda.gov/ersDownloadHandler.ashx?file=/media/1282296/eib121.pdf>.

achieve a more sustainable food system because when food is wasted, so too are all of the resources used to produce, process, transport, and store it.

The Food Waste Reduction Alliance (FWRA) consisting of members of GMA, the National Restaurant Association, and the Food Marketing Institute focuses on reducing waste from the processing, transportation, and retail sectors of the food supply chain. The goals of the Alliance are to reduce waste overall, ensure that unavoidable waste is donated to those in need, and recycle food waste that cannot be donated to the needy. In the future, the FWRA plans to incorporate agricultural and household waste into their efforts, the two largest sources of waste in the food system. GMA members currently offer a variety of ways to encourage consumers to reduce their own food waste including split packs, re-sealable packs, and smaller portions. Reaching a level of zero food waste may not be feasible, but changes in agricultural production and consumption practices could have significant environmental benefits with minimal tradeoffs for nutrition and health.

GMA encourages the Departments to develop dietary guidance based upon the total diet approach which supports balance, variety and moderation

The DGAC's recommendation for a dietary pattern associated with positive health outcomes includes the reduction of specific food categories or products. GMA encourages the Departments to develop the final policy document on a total diet approach and to not single out individual food items. A total diet approach emphasizes the importance of a varied and balanced diet within calorie needs. The total diet approach was endorsed by the AND in 2013 as the most important focus of a healthful eating style. A total diet approach asserts that there are no inherent "good foods" or "bad foods." As such, there is no single food or type of food that ensures good health, just as no single food or type of food is necessarily detrimental to health.⁴ Guiding Americans on which nutrient-rich food choices to make versus not to make, and focusing on portion guidance to provide "how to" practical advice, can help people make wiser food choices within their taste and cultural preferences and within their calorie needs.

Conclusion

GMA has consistently supported both the DGAC process toward development of the DGAC report and the resulting DGA policy document. GMA appreciates the complexity of the DGAC's responsibility to translate and distill current science into a set of scientifically-sound dietary recommendations from which the DGA can be developed. While the 2015 DGAC report provides several recommendations firmly based within the scientific literature, this was not apparent for all topics addressed. As discussed above, GMA has concerns with the scope of work and methodology used by the DGAC in addition to the application of the selected scientific literature to develop some of the conclusion and implication statements. We ask the Departments to develop the final policy document on a total diet approach which emphasizes the importance of a varied and balanced diet within calorie needs. Thank you for the opportunity to provide comments.

Sincerely,



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Grocery Manufacturers Association

[‡] Based in Washington, D.C., GMA is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies, and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle. The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually, employs 14 million workers and contributes \$1 trillion in added value to the economy every year.