



December 5, 2014

Richard D. Olson, M.D., M.P.H.
Prevention Science Lead and Designated Federal Officer, 2015 DGAC
Office of Disease Prevention and Health Promotion, OASH
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite LL100 Tower Building
Rockville, MD 20852

Angie Tagtow, M.S., R.D.
Executive Director, Nutrition Guidance and Analysis Division
Center for Nutrition Policy and Promotion
U.S. Department of Agriculture
3101 Park Center Drive, Room 1034
Alexandria, VA 22302

Filed electronically at: www.health.gov/dietaryguidelines/dga2015/comments/writeComments.aspx

RE: **Comments on for consideration by the 2015 DGAC**

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 by the 2015 Dietary Guidelines Advisory Committee (DGAC).

Dietary guidance recommendations intended to inform policy development and public health interventions must be based on the totality of available scientific evidence. The following comments address concerns with the current process being used, the need for a total dietary approach, the identification of future research needs, and low calorie sweeteners and weight management. We ask that these comments be considered in the deliberations of the DGAC as their work is being finalized.

GMA member companies have concerns with the process being used to develop the conclusion statements and implication statements

The DGAC must translate and distill current science into a set of practical, affordable and achievable dietary recommendations that can be used to develop the DGA. The DGAC recommendations must be based upon the weight of scientific evidence combined with strong scientific agreement. We request that the DGAC committee consistently apply the evidence based systemic review process across all the research questions the committee is charged to address. This would include an independent systematic

search of the literature and evidence related to the specific question. At this time, some subcommittees and working groups have relied solely on select reviews or previously published meta-analyses when answering research questions. Limiting the evidence reviewed to a select few reviews or meta-analysis as is being done by the Added Sugars and Sodium Working Groups may result in selection bias, excluding other relevant studies or additional meta-analysis from the review process, 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 evidence review process as is done with the Nutrition Evidence Library. GMA members also question 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.

GMA members question the application of the grading system for some of the conclusion statements. As noted in the USDA Nutrition Evidence Library Conclusion Statement Evaluation Criteria, a grading of strong is assigned to studies of strong design free from design flaws, bias and execution bias. Additionally a strong rating by the Nutrition Evidence Library 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 includes both RCTs as well as 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 members question the assignment of a strong rating to the conclusion statements that were developed solely upon epidemiological studies as these types of research can only identify associations which could be modified by intervention studies. GMA member companies urge the DGAC to reconsider the grading of their conclusion statements based upon the type of evidence that was used to develop the statements as mandated by the NEL criteria.

GMA member companies noted the implication statements were not developed consistently across the subcommittees. Some of the subcommittee developed implication statements that were directly related to the strength of the conclusion statement and scope of the question. Other subcommittees developed implication statements that went much broader than the scope of the research question and were not reflective of the strength of the conclusion statement. Additionally GMA members question the appropriateness of some of the implication statements as they include specific policy recommendations for taxation, suggest changes to the GRAS status of ingredients such as salt and advocate for changes to nutrition label regulations. GMA members encourage the DGAC to reconsider how the implication statements are developed and ensure that they are appropriately and consistently matched to each conclusion statement as well as supported by the current scientific literature.

GMA member companies are concerned with the development of conclusion statements that 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 Dietary Guidelines for Americans (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 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.

Sodium

For the majority of nutrients, GMA commends the work of the DGAC to assure that nutrient requirements, as evaluated through the DRI process, are translated into dietary patterns and recommendations that help guide consumers towards healthy diets. Despite the thoroughness of the DRI process, however, it is not fool proof. The Committees evaluating the science often have to use an imperfect evidence base to determine requirements that, in turn, are expressed more precisely than the data can support. For instance, a recent re-evaluation of the vitamin D DRI determined that that the RDA for adults is 15 mcg/day,¹ which is three-fold higher than the earlier AI of 5 mcg/day.² Similarly, the UL determined in 2011 (100 mcg/day) is double the UL determined in 1997 (50 mcg/day).

The current dietary recommendations for sodium are similarly based on an inadequate and outdated body of scientific evidence. The DRI Committee on sodium,³ in the absence of data on biological endpoints, based an AI on modeling a specific diet (Dietary Approach to Stop Hypertension (DASH) - sodium) rather than on a biological endpoint. Subsequent and more extensive diet modeling^{4,5,6} 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). Similarly, the DRI Committee¹³ did not have ideal data from which to derive a UL for sodium and chose blood pressure as the adverse effect, despite the continuous relationship between sodium intake and blood pressure. Thus the UL for sodium (100

¹ Institute of Medicine. (2011). *Dietary Reference Intakes for calcium and vitamin D*. Washington, DC: National Academies Press.

² Institute of Medicine. (1997). *Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride*. Washington, DC: National Academies Press.

³ Institute of Medicine. (2005). *Dietary Reference Intakes for water, potassium, sodium, chloride, and sulfate*. Washington, DC: National Academies Press.

⁴ Maillot, M., Drewnowski, A. (2012). A conflict between nutritionally adequate diets and meeting the 2010 Dietary Guidelines for sodium. *American Journal of Preventative Medicine* 42, 174-179

⁵ Drewnowski, A., Maillot, M., Rehm, C. (2012). Reducing the sodium-potassium ratio in the US diet: a challenge for public health. *American Journal of Clinical Nutrition* 96,439-444. <http://dx.doi.org/10.3945/ajcn.111.025353>

⁶ Maillot, M., Monsivais, P., Drewnowski, A. (2013). Food pattern modeling shows that the 2010 Dietary Guidelines for sodium and potassium cannot be met simultaneously. *Nutrition Research* 33, 188-194. <http://dx.doi.org/10.1016/j.nutres.2013.01.004>

mmoles or 2,300 mg) is at best an informed guess as to a threshold level that might indicate a change in one parameter associated with health risk. The IOM Committee further recognized the limitations of using blood pressure outcomes to set the UL for sodium because blood pressure can be influenced by other dietary factors, such as potassium, as well as by weight, exercise and genetic factors.

There is now an emerging body of evidence that shows that sodium is similar to other nutrients in that both high and low intakes are associated with increased mortality. Much of this newer evidence was reviewed by an 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 US population.*”⁷ The recent 2013 IOM Committee further concluded that low sodium intake may lead to greater risk of adverse health effects, with no evidence for benefit, when sodium intake levels are in the 1,500 mg/day to 2,300 mg/day range for population subgroups, specifically those with diabetes, chronic kidney disease, or CVD. The evidence for either benefit or harm imparted to these subgroups based on this range of sodium intake is not strong enough to indicate that these subgroups should be treated differently than the general population.¹⁷

Since the 2013 IOM committee issued their report, a meta-analysis by Graudal and colleagues, which included 25 separate studies encompassing over 250,000 participants, demonstrated that sodium intakes below about 2,600 mg/day were associated with increased risk for mortality.⁸ Studies by Pfister et al.⁹ in a healthy cohort of over 19,000 people in the U.K. and by O’Donnell et al.¹⁰ in over 100,000 subjects from 17 different countries found that sodium intake less than about 3,000 mg/day was associated with a higher risk of death and cardiovascular events. In the O’Donnell et al. study, the expected direct relationship between sodium and blood pressure was observed,¹¹ suggesting that at low sodium intakes factors other than blood pressure are impacting mortality and cardiovascular events. There are two relatively small longitudinal studies (combined n = 2,275) where the hazard ratio for cardiovascular disease increased 17% per 1000 mg/day increase in sodium.¹² The author’s graphical

⁷ Institute of Medicine. (2013). *Sodium intake in populations: Assessment of the evidence*. Washington, DC: National Academies Press.

⁸ Graudal, N., Jurgens, G., Baslund, B., and Alderman, M.H. (2014). Compared with usual sodium intake, low- and excessive-sodium diets are associated with increased mortality: A meta-analysis. *American Journal of Hypertension* 27(9), 1129-1137. <http://dx.doi.org/10.1093/ajh/hpu02>

⁹ Pfister, R., Michels, G., Sharp, S.J., Luben, R., Wareham, N.J., Khaw, K.T. (2014). Estimated urinary sodium excretion and risk of heart failure in men and women in the EPIC_Norfolk study. *European Journal of Heart Failure* 16(4), 394-402. <http://dx.doi.org/10.1002/ejhf.56>

¹⁰ O’Donnell, M., Mente, A., Rangarajan, S., McQueen, M.J., Wang, X., Liu, L...PURE Investigators. (2014). Urinary sodium and potassium excretion, mortality, and cardiovascular events. *New England Journal of Medicine* 371(7), 612-623. <http://dx.doi.org/10.1056/NEJMoa1311889>

¹¹ Mente, A., O’Donnell, M.J., Rangarajan, S., McQueen, M.J., Poirier, P., Wielgosz, A...PURE Investigators. (2014). Association of urinary sodium and potassium excretion with blood pressure. *New England Journal of Medicine* 371(7), 601-611. <http://dx.doi.org/10.1056/NEJMoa1311989>

¹² Cook, N.R., Appel, L.J., Whelton, P.K. (2014). Lower levels of sodium intake and reduced cardiovascular risk. *Circulation* 129(9), 981-989. <http://dx.doi.org/10.1161/CIRCULATIONAHA.113.006032>

presentation of the data and the small number of data points at the lowest intakes (about 230 subjects with intakes less than 2,300 mg day of sodium), call into question the ability of this study to seriously challenge conclusions based on over 370,000 individuals. This evidence must be considered by the DGAC to assure that their recommendations cause no harm.

Caffeine

GMA's position is that caffeine is not a nutrient. The DGAC should therefore allow the U.S. Food and Drug Administration (FDA) to make a safety determination based on sound evidence-based science. During previous meetings, conclusion and implication statements - especially those pertaining to so-called high caffeine consumption - did not appear to be based on the preponderance of scientific evidence. We would like to redirect the Committee to the GMA's earlier comments on caffeine (September 11, and October 31) to aid the Committee in achieving the objectives of its charter.

A total diet approach should be considered when addressing non-communicable disease such as obesity, rather than singling out any one nutrient or type of food

A total diet approach emphasizes the importance of a varied and balanced diet within calorie needs, and was endorsed by the Academy of Nutrition and Dietetics (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.¹³

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 Dietary Guidelines Advisory Committee 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.^{14,15,16,17} Calorie availability data from the Economic Research Service illustrates an

¹³ Academy of Nutrition and Dietetics. (2013). Position of the Academy of Nutrition and Dietetics: Total diet approach to healthy eating. *Journal of the Academy of Nutrition and Dietetics* 113, 307-317. <http://dx.doi.org/10.1016/j.jand.2012.12.013>

¹⁴ Bray, G.A., Smith, S.R., de Jonge, L., Xie, H., Rood, J., Martin...Redman, L.M. (2012). 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* 307(1). 47-55. <http://dx.doi.org/10.1001/jama.2011.1918>

¹⁵ de Souza R.J., Bray, G.A., Carey, V.J., Hall, K.D., LeBoff, M.S., Loria, C.M...Smith, S.R. (2012). 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. *The American Journal of Clinical Nutrition* 95(3): 614-625. <http://dx.doi.org/10.3945/ajcn.111.026328>

¹⁶ Hess, J., Latulippe, M.E., Ayoob, K., Slavin, J. (2012). The confusing world of dietary sugars: Definitions, intakes, food sources and international dietary recommendations. *Food Function* 3(5), 477-486. <http://dx.doi.org/10.1039/c2fo10250a>

increase in calories across all foods groups until 2000 that mirrors the rise in obesity rates. After this date, while obesity rates continue to increase, availability of calories from the different food groups fluctuated. Calorie availability from some food groups leveled off or decreased while others continued to rise before leveling off.¹⁸ This suggests that calorie increases in the diet come from a variety of food groups and thus a single food group or nutrient should not be singled out as the cause for increased obesity incidence. 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.¹⁹ 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. GMA members urge the DGAC to look at the total diet, rather than focus on single nutrients or foods when assessing obesity risk.

GMA Member Companies urge the DGAC to be mindful of gaps in data that may exist on food groups when developing conclusion statements

As part of the 2015 DGAC's evaluation of a range of dietary patterns that could help guide Americans to choose "better" options, food groups have been further differentiated to assess the impact on health and generate definitive recommendations. For example, dairy products have been evaluated as low/no-fat dairy separately from full fat options. Additionally, whole grains have been considered separately from refined grains. It would be appropriate to apply this approach across other key food groups and separate out sub-groups. As an example, the committee could evaluate red meat and processed meats separately. Furthermore, the impact of lean versus full fat offerings of red and processed meats should be distinguished in the evaluation of animal proteins. Additionally, low/no calorie beverage offerings could be evaluated separately from sugar-sweetened beverages. If the current databases do not allow for such evaluations we recommend this be identified as a future research needs. Any conclusion or implication statements developed on dietary patterns should take into account any gaps in data that may exist on certain food groups and thus not make broad recommendations.

Scientific studies support the use of low calorie sweeteners to aid in weight management

Low calorie sweeteners have been shown to be an effective weight management tool when consumed along with a healthful diet and regular physical activity. A recent meta-analysis of 15 RCTs and 9 prospective cohort studies on low calorie sweeteners and body weight and composition supports the

¹⁷ Lowndes J., Kawiecki D., Pardo S., Nguyen V., Melanson K.J., Yu Z., Rippe J.M.. (2012). The effects of four hypocaloric diets containing different levels of sucrose or high fructose corn syrup on weight loss and related parameters. *Nutrition Journal* 11(55). <http://dx.doi.org/doi:10.1186/1475-2891-11-55>

¹⁸ U.S Department of Agriculture Economic Research Service. (2014). Food Availability Data Set. 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)

¹⁹ Welsh, J.A., Sharma, A.J., Grellinger, L., Vos, M.B. (2011). Consumption of added sugars is decreasing in the United States. *American Journal of Clinical Nutrition* 94, 726-734. <http://dx.doi.org/10.3945/ajcn.111.018366>

conclusion that low-calorie sweeteners are an effective weight management tool.²⁰ There is additional evidence that may not have been considered by the DGAC, which demonstrates low-calorie sweeteners are also beneficial for long-term weight loss maintenance. A 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.²¹ Additionally a cross-sectional study of 434 members of the National Weight Control Registry found approximately 53% of successful weight loss maintainers consumed low calorie/no calorie sweetened 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.²²

Thank you for the opportunity to provide comments. GMA looks forward to regularly participating in the 2015 DGA development process through written comments.

Sincerely,



Leon H. Bruner, DVM, PhD
Executive Vice President
for Scientific and Regulatory Affairs
and Chief Science Officer
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

²⁰ Miller, P.E., Perez, V. (2014). Low-calorie sweeteners and body weight and consumption: A meta-analysis of randomized controlled trials and prospective cohort studies. *American Journal of Clinical Nutrition* 100 (3), 765-777. <http://dx.doi.org/10.3945/ajcn.113.082826>

²¹ Phelan, S., Lang, W., Jordan, D., Wing, R.R. (2009). Use of artificial sweeteners and fat modified foods in weight loss maintainers and always-normal weight individuals. *International Journal of Obesity* 33, 1183-1190. <http://dx.doi.org/10.1038/ijo.2009.147>

²² Catenacci, V.A., Pan, Z., Thomas, J.G., Ogden, L.G., Roberts, S.A., Wyatt, H.R., Wing, R.R., Hill, J.O. (2014). Low/no calorie sweetened beverage consumption in the National Weight Control Registry. *Obesity* 22(10), 2244-2251. <http://dx.doi.org/10.1002/oby.20834> [10.1038/ijo.2009.147](http://dx.doi.org/10.1038/ijo.2009.147)

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.