December 22, 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

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

RE: American Beverage Association Comments in response to the 7th Meeting of DGAC

Dear Dietary Guidelines Advisory Committee:

The American Beverage Association (ABA) appreciates the opportunity to submit comments on behalf of its member companies to the 2015 Dietary Guidelines Advisory Committee (DGAC or Committee). The ABA is the trade association for America's non-alcoholic beverage industry. The ABA represents beverage producers, distributors, franchise companies and support industries that bring to market hundreds of brands, flavors and packages, including regular and diet soft drinks, bottled water and water beverages, 100 percent juice and juice drinks, sports drinks, energy drinks and ready-to-drink coffees and teas.

In general, the summary of the DGAC report presented at the December 15, 2014 meeting was concerning. Specifically, some of the DGAC committee members appeared to be biased toward pre-determined outcomes neglecting many of their own conclusions and the relevant studies and fact-based comments submitted relative to a number of topics. Problematic topics included: aspartame safety; benefits of no- and low-calorie sweeteners; lack of scientific basis on added sugars declaration; understanding the caffeine content in soft drinks and energy drinks compared to that in coffee; accuracy of intake estimates for caffeine from energy drinks, and benefits of caffeine from sources beyond coffee; suggested economic incentives to presumably encourage policies to either tax beverages or restrict choice within the Supplemental Nutrition Assistance Program. ABA submitted thorough comments March 7, 2014, and two additional sets of comments on September 10, 2014, which are incorporated here by reference.¹

1. Aspartame – No risk of cancer

The Dietary Guidelines for Americans have not heretofore addressed ingredient safety, which is outside the scope for the Advisory Committee’s consideration.² Rather, ingredient safety issues fall within the purview of the U.S. Food and Drug Administration (FDA). FDA, the authoritative agency of the United States government with the expertise to analyze food ingredient safety, has examined the safety of aspartame both when it was originally approved as a food additive and more
recently when concerns were raised of potentially elevated risk for cancer from aspartame consumption. As FDA’s review demonstrates, there is extensive literature on the issue of aspartame and cancer that spans decades and consists of hundreds of toxicological and clinical studies. Nevertheless, because of assertions made by DGAC Subcommittee 5 in its final public meeting and in prior meetings, we welcome the opportunity to submit the following supplemental comments.

The opinions expressed by DGAC Subcommittee 5 seem to have been drawn directly from the Center for Science in the Public Interest (CSPI) comments dated May 15, 2014, and November 20, 2014, relative to aspartame safety. CSPI references two main lines of research, the Ramazzini Institute rodent bioassays suggesting aspartame causes leukemias/lymphomas and the Schernhammer-Willet study, a prospective human cohort study suggesting an increased risk of incidence of lymphohematopoietic tumor types. However, the Ramazzini research has been criticized and dismissed by other researchers and leading health authorities worldwide. Many regulatory bodies around the world including U.S. FDA, Health Canada, the European Food Safety Authority (EFSA), and the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) among others have reviewed the body of research and repeatedly reaffirmed the safety of aspartame with no concern of adverse health outcomes at current levels of dietary intake. Importantly, FDA and EFSA reviewed aspartame safety since publication of the Ramazzini studies and still found aspartame safe at current levels of dietary intake.

In fact, the National Cancer Institute of the National Institutes of Health study encompassing approximately 500,000 men and women monitored over a five-year period to determine whether an association between aspartame and cancer exists concluded no increased risk of hematopoietic or brain cancers from aspartame consumption and that consumption of aspartame-containing beverages did not increase risk of leukemias, lymphomas or brain tumors. More recently, the American Cancer Society looked at intake of low-calorie (including aspartame) or sugar-sweetened carbonated beverages among 100,442 adult men and women who provided information on diet and lifestyle over a 10-year period in the Cancer Prevention Study-II Nutrition Cohort and concluded that moderate consumption does not increase non-Hodgkin lymphoma cancer risk.

In view of the weight of scientific evidence relative to lack of risk of cancer from aspartame consumption, ABA suggests that DGAC remove both its statement regarding a possible association between aspartame consumption and hematopoietic cancers and its recommendation for further research. Any questions regarding aspartame safety should be deferred to FDA as the leading authority on ingredient safety.

2. Aspartame – ADI

The DGAC’s representation at its final meeting regarding an ADI for aspartame was somewhat misleading. Noting that “If individuals choose to drink beverages that are sweetened with aspartame, they should stay below the aspartame Acceptable Daily Intake (ADI) of no more than 50 mg/kg/day (12-ounce diet beverage contains approximately 180 mg of aspartame),” as the Committee did, could mislead consumers to believe that one can of diet beverage contains over three times the ADI for aspartame. In fact, DGAC should replace the current language and clarify that for a 60 kg person, the safe daily levels of aspartame intake over the course of one’s lifetime is
ADI*60 kg (i.e., 50 mg/kg b.w./d * 60 kg) or 3,000 mg/day and one 12 ounce can of diet soda contributes only 180 mg aspartame.

3. **Low-Calorie Sweeteners**

The DGAC detailed their draft findings on low- and no-calorie sweeteners (LCS) and health outcomes at both the 6th and 7th meeting this past November and December. Their recommendations on LCS at the December 15 meeting are inconsistent with these findings.

A number of studies have documented the benefits of low- and no-calorie sweeteners (also called non-nutritive sweeteners or NNS) for weight management, including a survey of National Weight Control Registry members, published online in July 2014. The Academy of Nutrition and Dietetics affirmed that NNS can help consumers limit carbohydrate and energy intake. Aspartame-sweetened beverages reduced energy intake about 10 percent compared with control diets, according to a meta-analysis of 16 studies.

These benefits were reflected in both:

(i) the DGAC 6th meeting conclusions stating evidence from randomized controlled trials (RCTs) consistently indicates that LCS (versus sugar-containing foods and beverages) modestly reduces body weight in adults and modestly reduces body mass index (BMI), fat mass and waist circumference in both adults and children; and

(ii) the DGAC 7th meeting conclusions, reiterating the latter as moderate evidence.

However, the major recommendation at the final meeting - to not use LCS as a primary replacement/substitute for added sugars in foods and beverages - appears to be at odds with these findings. The recommendation appears to show "limited" rather than "moderate" evidence.

Furthermore, numerous studies have shown that LCS beverages are useful in weight reduction as well as weight maintenance. A systematic review of randomized controlled trials (RCT) found a consistent significant reduction in body weight, BMI, fat mass and waist circumference with LCS use. Although water is frequently cited as the beverage of choice for weight loss, Peters et al. from the University of Colorado and Temple University showed nearly 50 percent greater weight loss from baseline among LCS compared to water consumers in a 12-week weight loss program. Scientific research also shows that low- and no-calorie sweeteners do not cause sweet cravings, nor do they promote hunger. In the recent Choose Healthy Options Consciously Everyday (CHOICE) randomized control trial, low- and no-calorie beverages when compared with water did not cause food cravings, the diet beverage group consumed significantly fewer sweet foods and added sugars than did the water group.

ABA respectfully suggests that the DGAC recommendations should reflect its own conclusions and the body of evidence and thus ensure that recommendations provide Americans with options to achieve their weight management goals. The committee's recommendations should affirm its own findings that LCS as a primary replacement/substitute for sugar is a useful tool for weight management. Studies published since the 2010 DGAC recommendations reinforce that message.
4. **Added Sugars**

Relying on a WHO-commissioned review, DGAC suggested that a recommendation to limit “added sugars” intake to less than 10 percent of energy was appropriate. A preponderance of scientific evidence does not exist for limiting “added sugars” intake to less than 10 percent of energy. The authors of the WHO-commissioned review acknowledge the limitations of the evidence stating, “Although comparison of groups with the highest versus lowest intakes in cohort studies was compatible with a recommendation to restrict intake to below 10% total energy, currently available data did not allow formal dose-response analysis.” Moreover, WHO has previously recognized that no scientific basis exists to distinguish free sugars whether in beverages or otherwise from any other kinds of sugar. All sugars, whether free or intrinsic, are the same when it comes to the amount of calories they contain and the way they are metabolized by the body.  

ABA is concerned again that the DGAC is making recommendations that are more appropriately the responsibility of other authoritative bodies. In general, the appropriate body to set nutrient thresholds is the Institute of Medicine (IOM). IOM - charged with establishing Dietary Reference Intakes (DRIs) - failed to establish either a DRI or an Upper Limit (UL) for sugars or added sugars. Despite a rigorous analysis of the data, impact on diet quality (i.e. micronutrient consumption) was detected when sugars intake exceeded 25% of total energy. IOM also found negative impact on diet quality for some nutrients when sugars intake was at 5% or lower. Thus, there is no new or additional basis for DGAC to impose a DRI for sugars or added sugars. Even WHO, which attempted to tie numerous public health criteria in their attempt to severely limit sugar intake, found only dental concerns to rely on. Yet numerous experts have repeatedly shown that dental caries are caused and exacerbated by lack of fluoride and poor dental hygiene in addition to sugars intake.

Nevertheless, ABA does not support the proposed “added sugars” declaration on the nutrition facts panel and objects to DGAC’s recommendation that “added sugars” be added to food labels. ABA provided detailed information - incorporated herein by reference - in response to FDA’s request for comments on “Food Labeling: Revision of the Nutrition and Supplement Facts Labels.”

ABA respectfully requests that DGAC remove its recommendation to limit added sugars to a maximum of 10 percent of total daily caloric intake as they performed no analysis to substantiate this recommendation. The DGAC used the WHO analysis as their sole source for this recommendation which contradicts their own guidelines of including the body of scientific evidence.

5. **Caffeine**

Caffeine is one of the most widely studied ingredients in the food supply. The safe use of caffeine is supported by a long history of use and by extensive clinical and nonclinical studies. Whether caffeine is obtained from intrinsic sources such as from plants (i.e., coffee, tea, cocoa, guarana, yerba mate) or has been synthesized by man, the safety of the ingredient has been established by health authorities and international organizations worldwide. Currently, the U.S. Food and Drug Administration (FDA) is considering data related to caffeine-containing products, including energy drinks.

As noted in ABA’s comments on caffeine dated September 10, 2014, ABA questions whether the Dietary Guidelines process is the appropriate forum for the discussion of the safety and intake of food ingredients/components that are not nutrients given the lead role of the FDA in determining
food ingredient safety. The Advisory Committee failed to scientifically define “high-dose” caffeine consumption, narrowly and arbitrarily focused on a single category of products – i.e., energy drinks - when coffee (1) contains equivalent and often higher amounts of caffeine and (2) may contribute over four times as much caffeine to the American diet, inappropriately emphasized “young adults” as a vulnerable subpopulation without scientific justification and failed to evaluate the benefits of caffeine not associated with the consumption of coffee. In fact, by limiting the statements on the benefit of caffeine in the diet solely to consumption of coffee, the DGAC ignores the vast evidence of the benefits of caffeinated tea consumption including data on improved cognitive function when caffeinated tea is part of the diet. The DGAC is exercising an inconsistent approach by delving into assessments of specific products rather than addressing caffeine holistically and by investigating caffeine in combination with other products/ingredients (i.e., alcohol) without considering the preponderance of scientific and medical literature.

In general, the DGAC assessment of caffeine and energy drinks did not appear to evaluate the totality of the evidence associated with caffeine and energy drinks. Considerable scientific information and data exist that both already address the proposed research recommendations and demonstrate the safety of energy drink ingredients.

The ABA and its member companies are committed to practices that enhance consumer health and ensure transparency. In order to provide consumers with information on caffeine, ABA member companies who produce energy drinks have voluntarily committed to:

- Label and market their products as conventional foods/beverages, not nutritional supplements;
- Disclose the total quantity of caffeine (from all sources) in the container, on a per can/bottle basis and, for multi-serving containers, on a per serving basis (e.g., “caffeine content: xx mg/8 fl oz; yy mg/per can.”)
- Provide the following advisory statement, or its equivalent: “Not (intended/recommended) for children, pregnant or nursing women (and/or persons/those) sensitive to caffeine.”

For any meaningful education effort directed toward caffeine consumption to be sound, it must provide information on and address all sources of caffeine in the US diet. A narrow focus on only one type of caffeine-containing beverage will not serve to educate the public or improve public health.

6. Economic Incentives

Fiscal policy including taxation of food is not within the purview of the mission of the DGAC and should not be addressed in its recommendations. Economic research confirms such taxes are regressive and ineffective, harming those least able to pay the most. A 2009 Congressional Research Service report bears this out and a paper by University of Pennsylvania Economics Professor Jonathan Klick finds beverage taxes provide negligible effects on body weight.

Furthermore, it is not within the scope of the Dietary Guidelines for Americans Advisory Committee to make policy recommendations on what should and should not be eligible for purchase with assistance from the Supplemental Nutrition Assistance Program. Congress has already established policy declaring that all foods, with minor exceptions for hot prepared foods,
alcohol, and dietary supplements, are eligible for purchase with SNAP funds. It is not within the purview of the DGAC to redefine “food” for these purposes.

7. **Conclusion**

The ABA and its member companies are committed to practices that enhance consumer health and ensure transparency for the beverages produced by their member companies. Teaching children, teenagers and adults moderation in their consumption habits balancing calorie intake from all food and beverage sources, and the importance of exercise is an important public health goal. ABA and its member companies remain committed to that goal. For the reasons stated above, ABA encourages DGAC to refrain from providing recommendations on topics that clearly fall outside of their purview and that fail to reflect the relevant body of scientific evidence. We appreciate this opportunity to comment on the 2015 Dietary Guidelines for Americans.

Sincerely,

Amy E. Hancock
Senior Vice President and General Counsel
Legal and Regulatory Affairs
Endnotes

1 ABA Comments to the 2015 Dietary Guidelines Advisory Committee: “Food industry approaches to reducing sodium, added sugars, and fats - Request 2-1” (March 7, 2014), “Comments regarding non-alcoholic beverages and their ingredients” (September 10, 2014), “Evaluation of the Health Aspects of Caffeine as a Food Ingredient” (September 10, 2014)

2 2015 Dietary Guidelines Advisory Committee Charter: “Under Section 301 of Public Law 101-445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III) the Secretaries of Health and Human Services (HHS) and Agriculture (USDA) are directed to jointly issue at least every five years a report entitled Dietary Guidelines for Americans. The law instructs that this publication 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.” (emphasis added)


“FDA could not conduct a complete and definitive review of the study because the European Ramazzini Foundation (ERF) did not provide the full study data. Based on the available data, however, we have identified significant shortcomings in the design, conduct, reporting, and interpretation of this study. FDA finds that the reliability and interpretation of the study outcome is compromised by these shortcomings and uncontrolled variables, such as the presence of infection in the test animals... Additionally, the data that were provided to FDA do not appear to support the related findings reported by ERF. Based on our review, pathological changes were incidental and appeared spontaneously in the study animals, and none of the histopathological changes reported appear to be related to treatment with [the sweetener]. FDA believes that additional insight on the study findings could be provided by an internationally-sponsored pathology working group examination of appropriate tissue slides from the study... Considering results from the large number of studies on [the sweetener’s] safety, including five previously conducted negative chronic carcinogenicity studies, a recently reported large epidemiology study with negative associations between the use of [the sweetener] and the occurrence of tumors, and negative findings from a series of three transgenic mouse assays, FDA finds no reason to alter its previous conclusion that [the sweetener] is safe as a general purpose sweetener in food.” (emphasis added)


“In addition to a high background incidence of chronic inflammatory changes in the lungs and other vital organs and tissues there is uncertainty about the diagnoses of some tumour types, which rendered the validity of the findings questionable. Moreover, EPA has recently concluded that many of the malignant
neoplasms and the lymphoid dysplasias diagnosed in the studies from the European Ramazzini Foundation were hyperplasias related to unknown chronic infection in the animals and not related to aspartame intake. Furthermore, in the mouse study, the ANS Panel noted that the hepatic and pulmonary tumour incidences reported fell within the institute’s own historical control ranges for spontaneous tumours.” (emphais added)

“EFSA’s experts could rule out a potential risk of aspartame causing damage to genes and inducing cancer. Included in the risk assessment were the animal studies conducted more recently (including the studies performed by the European Ramazzini Foundation), which did not produce any scientific evidence supporting a carcinogenic effect of aspartame... Furthermore, there is no evidence to suggest that aspartame induces cancer according to existing large human population studies.” (http://www.efsa.europa.eu/en/corporate/doc/factsheetaspartame.pdf)

Specifically, the weight of scientific literature demonstrates that caffeine does not cause stroke, arrhythmia, or other alleged cardiac effects in healthy people, and that it is virtually impossible for a healthy person to consume a fatal dose of caffeine from food or beverages. In 2011, the “Third National Health and Nutrition Study (NHANES III)” conducted by the National Center for Health Statistics of the Centers for Disease Control and Prevention (CDC) concluded, as discussed by Zhang et al., that “the usual intake of caffeine-containing drinks does not affect QT interval duration”, a marker of cardiac health (Zhang, et al., PLoS ONE. 6, 2. 1-7. 2011).


2013 International Society of Sports Nutrition position statement on energy drinks - After a thorough review of the scientific literature, medical and clinical studies, the Society concluded that “the rate of adverse events [associated with energy drinks] appears low in the population of consumers” and that the current evidence “suggests that consumption of energy drinks and energy shots are safe in healthy populations and similar to ingesting other foods and beverages containing caffeine.” Accessed August 14, 2014.


April 24, 2009 Congressional Research Service report prepared by The Honorable John Barrow titled “Excise Tax on Sugar-Sweetened Beverages.”

“Assessing the USDA Report, “Taxing Caloric Sweetened Beverages: Potential Effects on Beverage Consumption, Calorie Intake, and Obesity” by Travis A. Smith, Biing-Hwan Lin, and Jonq-Ying Lee” by Jonathan Klick, Professor of Law, University of Pennsylvania Law School