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2015 Dietary Guidelines Advisory Committee

Dear Sirs and Madams:

The Sugar Association (Association) represents United States sugar cane farmers and refiners and sugar beet farmers and processors. Association members account for over 90% of sugar production in the United States. Founded in 1943, our mission is to monitor nutrition science, to educate consumers about sugar's role in a healthy diet and active lifestyle and to ensure that Federal nutrition and food policy regarding sugar is based on the preponderance of scientific evidence. Based on the totality of scientific evidence, we support and promote sugar in moderation as a safe and useful part of a balanced diet and healthful lifestyle.

These comments reflect our views as they relate to sugar/sucrose. The Association has long been on the record objecting to the use of the term "added sugars" as misleading and without scientific justification.

The Association has concerns with several aspects of how the 2015 Dietary Guidelines Committee (DGAC) evaluation process has progressed to date and would like to bring these to the Committee's attention prior to the completion of the scientific report to the Secretaries. The primary purpose of this comment is to request that the Committee's leadership, and the U.S. Department of Agriculture and U.S. Department of Health and Human Services staff, ensure that the systematic Nutrition Evidence Library (NEL) process has been consistently applied across the evaluation of all diet-disease relationships for all foods, nutrients and dietary patterns. Our concerns are outlined and discussed below for your consideration.

Added Sugars Working Group

There are numerous research questions for which the DGAC bypassed the formal NEL review and, instead, based its recommendations on previously published systematic reviews/meta-analyses.

The approach to evaluating evidence by the 2015 DGAC is inconsistent and is most evident by the fact its draft conclusion statements differ from other recent evidence-based conclusions to the same questions. **The Committee's use of pre-selected meta-analyses to form conclusions raises serious concerns that the Committee has bypassed a review of the full body of science and has selected science to support its pre-determined conclusions.**

The establishment of the NEL systematic reviews in 2006 was a critical step to assure that Federal dietary recommendations are based solely on the preponderance of scientific evidence, as mandated by Congress in Public Law 101.445. According to its developers, the NEL is a six-step process providing a standardized and systematic way to evaluate new research that has emerged since the previous guidelines. The NEL process is designed to minimize bias, ensure transparency and reproducibility and, when properly employed, the process should yield evidence-based conclusions.

Given the NEL process has not been consistently applied across all questions throughout the DGAC process, this brings into question whether the full body of literature has been evaluated, and raises questions about transparency and selection bias. The Committee has not disclosed the criteria it used for determining those questions that will be evaluated based on an NEL search versus those for which conclusions will be based upon existing reports. It is also unclear *how* the existing reviews were selected and how and why other studies and reviews have been excluded.

We raise concerns with the Committee's extensive use of pre-existing reviews because, as is widely known in the scientific community, the findings of meta-analyses differ based on the approach used by the researchers. These types of reviews are subject to multiple biases and methodological differences and thus, often contradict each other.¹ For example, the findings of the meta-analyses used by the Added Sugars Working Group contradict conclusions of other major evidence-based reviews conducted by authoritative scientific bodies on the same topic, such as reviews conducted by the European Food Safety Authority (EFSA)² and the United Kingdom's recently released Scientific Advisory Committee draft Carbohydrate and Health report (SACN)³ and contradict the positions and advice of U.S. professional organizations such

¹ Berlin JS. "Meta-analysis as Evidence Building A Better Pyramid." JAMA. August 2014. Vol. 312 (6)

² EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA). Scientific opinion dietary reference values for carbohydrates and dietary fibre (2010). *EFSA Journal* **8(3)**: 1462 [77 pp]. Available at <http://www.efsa.europa.eu/en/scdocs/scdoc/1462.htm>.

³ Scientific Advisory Committee on Nutrition (SACN), Draft Carbohydrates and Health Report. June 2014.

(https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/339771/Draft_SACN_Carbohydrates_and_Health_report_consultation.pdf)

as the American Diabetes Association,⁴ American Dental Association,⁵ and the American Heart Association/American Stroke Association.⁶

When properly employed, the NEL process yields evidence-based conclusions through a series of steps: the development of systematic review questions, defining search criteria, a thorough search and screening of relevant studies, data extraction and evaluation, and an assessment of the risk of bias of studies and evidence grading. Whereas when the NEL process is bypassed, and pre-existing reviews are selected, such as is occurring with the Added Sugars Working Group, this means that the Committee is basing conclusions that utilize questions, *search criteria*, studies, and evaluations that were determined not by the Committee and the standardized NEL review process, but by those reports' authors.

In many cases the processes employed by these authors don't incorporate the scientific principles and protocols outlined in the NEL process. In examining the pre-selected meta-analyses being used by the Added Sugars Working Group, there is significant variation with regard to study selection criteria. For example, there are inconsistencies across the health outcomes examined with regard to the criteria for the timeframe of studies included in these reviews, with studies from 1969 to present (body weight), 1950 to present (dental caries) and 1990 to present (diabetes) used to form the respective conclusions. This raises serious concerns about selection bias (even suggestive of 'handpicked' evidence) and forces questioning of the efficacy of using reviews for a process that is under a mandate requiring recommendations be based on the of the preponderance of scientific and medical knowledge at the time of the Dietary Guidelines for Americans report's release.

The scientific evidence relating to "added sugars" intake and health outcomes is a highly heterogeneous and often conflicting body of literature, a point frequently cited in the literature and a major factor as to why syntheses and conclusions in this area are extremely difficult. Given that the studies addressing these issues are so diverse, authors of a meta-analysis or systematic review must make decisions on inclusion criteria that are irrefutably *subjective* in nature. For example, the Working Group selected three existing systematic reviews/meta-analyses to form their conclusion on the relationship between "added sugars" intake and body weight. In total, there were 92 unique studies included in these three reviews. Only 21 of these studies were included in two or more of the reviews. This means that the study selection criteria for these three reports were so varied that 71 of the studies did not meet the criteria to be included in all three reviews *answering the same question*. This example highlights the inherent subjectivity of meta-analyses and systematic reviews, and warrants extreme caution when using these pre-existing reports as the sole basis for drawing evidence-based conclusions.

⁴ Evert AB, et al. Nutrition therapy recommendations for the management of adults with diabetes. Diabetes Care. 2014 Jan;37 Suppl 1:S120-43

⁵ Burt BA, Pai S. Sugar consumption and caries risk: a systematic review. J Dent Edu. 2001;65(10):1017-23

⁶ Meschia JF, et al. Guidelines for the primary prevention of stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2014 Dec;45(12):3754-832.

Supporting our concerns about the DGAC's heavy reliance on prior reviews, are many recently published papers that raise issues about use of meta-analyses in evidence-based dietary recommendations given the biases and errors inherent to conducting this type of analyses.^{7 8 9 10} At the bare minimum, given the weight that each of these pre-existing reports have in the DGAC conclusions, the limitations that are cited by each report's authors must be made transparent, as they ultimately are the limitations of the DGAC conclusions they 'inform.' For example, for the Added Sugars Working Group's body weight draft conclusion presentation at meeting 7, no limitations were presented for their conclusion of "strong" evidence associating "added sugars" and body weight. Yet, the following are statements made within each of the three reports used to form this conclusion:

- "The relatively high degree of unexplained heterogeneity observed in our analyses may limit the validity of our summary estimates."¹¹ (Malik, 2014)
- "Given the lack of feeding trial data and the inconsistencies in the results of the observational studies reviewed, it is unclear whether sugar-sweetened beverages intake is associated with obesity risk, other than contributing calories."¹² (Trumbo, 2014)
- "Assessment of dietary intake of sugars, whether by some method of recall as used in the trials, or by food frequency questionnaire as in cohort studies, was associated with a considerable degree of measurement error even when using validated methods."¹³ (Te Morenga, 2013)
- "The heterogeneity of the studies, especially in terms of the consequences of altering intake of sugars in ad libitum diets, resulted in difficulties in fully explaining the effects of different dietary changes."¹⁴ (Te Morenga, 2013)

The quality of studies used by the Added Sugars Working Group to form conclusions is in question.

Heavy reliance on observational data:

The evidence-basis for the Added Sugars Working Group draft conclusions linking "added sugars" intake with *serious* disease outcomes relies heavily on epidemiological data and,

⁷ Kicinski, M. "Publication Bias in Recent Meta-Analysis." PLOS ONE. November 2011: Vol. 8 (11)

⁸ *Op. Cit.* 1

⁹ Maki KC et al. "Limitations of Observational Evidence: Implications for Evidence-Based Recommendations." ASN Adv. Nutr. 5:7-15, 2014, doi:10.3945/an.113.004929

¹⁰ Rothstein HR. "Publication Bias in Meta-Analysis." *Prevention, Assessments and Adjustments* 2005 John Wiley & Sons, Ltd

¹¹ Maki KC, et al. Limitations of observational evidence: implications for evidence-based dietary recommendations. Adv Nutr. 2014 Jan

¹² Trumbo PR, Rivers CR. Systematic review of the evidence for an association between sugar-sweetened beverage consumption and risk of obesity. Nutr Rev. 2014. PMID: 25091794.

¹³ Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. Bmj. 2013;346:e7492. PMID: 23321486

¹⁴ *Op. Cit.* 13

as mentioned above, pre-selected meta-analyses and systematic reviews. These types of epidemiological studies, and even meta-analyses of RCTs, are considered observational data and their findings should be interpreted as associations as they are *not proof of cause and effect*. It is widely accepted in the scientific community that caution should be applied when making and communicating recommendations that are based primarily on observational data and not confirmed through well-designed trials.¹⁵

One of the major flaws in relying on observational studies is that the dietary intake assessment tools commonly used are subject to substantial measurement error, resulting in imprecise measures of exposure, or intakes.¹⁶ Of particular concern with regard to the Added Sugars Working Group is that there were numerous cohort studies used in forming the conclusions. These cohort studies predominantly examine (what are often called) sugar-sweetened beverage (SSB) intake in relation to health outcomes. The accuracy of food frequency questionnaires (FFQ) for determining soft drink (SSB) consumption ranges between only 30-80%, highlighting an imprecision that is well known across the nutrition field. Ten out of the twelve cohort studies used to evaluate the effects of “added sugars” on cardiovascular disease (CVD) used a FFQ tool that does not accurately capture exposure. This issue was noted in the 2010 DGAC report by the Carbohydrate Working Group, stating, “Drinks can include a wide range of macronutrients and artificial sweeteners, and are difficult to assess with food frequency instruments.” Adding to this established inaccurate assessment of SSB intake is the fact that in these cohort studies, dietary assessments are often performed several years (even decades) prior to the outcome measurement, with the *assumption* that the subjects’ diets did not change at all over the course of 5, 10, 20 years. This is a major assumption made worse by the fact that the initial intake assessment is only 30-80% accurate to begin with.

Given that the determination of causality between a food or nutrient and a health outcome has serious implications that are far-reaching, we encourage the Committee and staff to ensure that these conclusions are held to the highest standards of evidence evaluation. We ask that for each conclusion related to “added sugars” and health outcomes, the Hill criteria for judging causality be employed. These steps include an assessment of: strength and consistency of the association, evidence of dose-response, biological plausibility, and concordance with other data, particularly clinical trials.¹⁷

The limitations of observational data are real and must be recognized given the magnitude of impact of the Dietary Guidelines for Americans. The mandate of the Dietary Guidelines is to provide general dietary guidance for the American public. We contend that the Committee has not undertaken the rigorous scientific investigation needed to advance a validated

¹⁵ *Op. Cit.* 11

¹⁶ *Ibid.*

¹⁷ Hill, Austin Bradford (1965). "The Environment and Disease: Association or Causation?". *Proceedings of the Royal Society of Medicine* 58 (5): 295–300.

link or association between a dietary component and a serious disease outcome.

Recommendations that lead the American public to believe there is a link or association between any dietary component and a causal factor in a serious disease outcome should only be made based on significant scientific agreement due to a robust review of the entire body of scientific literature by experts in the field of investigation. Such scientific agreement does not exist for each of the ‘strong’ conclusions that have been stated by the Added Sugars Working Group thus far.

The use of “sugar-sweetened beverages” (SSBs) as a ‘proxy’ for “added sugars” in assessing their effects on health outcomes is inappropriate:

“Sugar-sweetened beverages” are a class of beverages that indeed contain “added sugars,” but SSBs do not represent the wide applications for sugars, reflect the intakes of “added sugars,” and further, evidence exists for differential metabolic and health effects of SSBs versus “added sugars” consumed in other varieties and modes. We strongly question the scientific validity of the Added Sugars Working Group’s use of SSBs as a ‘proxy’ for “added sugars” intake. The evidence being used to inform conclusion statements for evaluating health impacts from all “added sugars” intake indicates a heavy reliance on studies solely assessing SSB consumption. This reliance on SSB studies is evidenced by 10 of the 12 cohort studies and 3 of 11 trials used to evaluate CVD, 2 of the 3 systematic reviews/meta-analyses to evaluate body weight and obesity, and 4 of 5 studies/meta-analyses used to evaluate diabetes examining SSB intake, exclusively.

Given that SSBs are a unique source of “added sugars” intake, studies that examine potential health impacts from SSBs should not be generalized to infer similar metabolic impacts for all intakes of “added sugars.” SSBs are strictly a liquid source of intake, are primarily sweetened with high fructose corn syrup (HFCS) and unlike the majority of foods and beverages that contain sugar (sucrose), with only a few exceptions, do not contribute to intakes of fiber, protein and other essential micronutrients, as do other sugar containing foods and beverages such as cereals, other grain products and dairy products. With less than 50% of the US population consuming SSBs,¹⁸ scientific conclusions based on SSBs and not “added sugars” (as consumed by the whole population) adds to the argument that relying on SSBs as a ‘proxy’ is not valid.

Although we contend that the science the Committee has used to support its links and association between “added sugars” and serious disease outcomes in general is weak, we strongly contend that without the substantial inclusion of SSB studies, there would be little or no scientific evidence to support or imply an association between “added sugars” and disease outcomes. Other attempts to answer these same questions that the Added Sugars Working Group are answering have recognized these differences and separated analyses by ‘SSB’ and ‘added

¹⁸ Ogden, et al. Consumption of Sugar Drinks in the United States, 2005-2008. NCHS Data Brief. No.71, August 2011.

sugars' in relation to various outcomes. In fact, the 2010 DGAC performed their analyses this way, as did the recent SACN¹⁹ review in the U.K.

The required rigorous data and measurement tools do not yet exist for determining cause and effect relationships between “added sugars” and health outcomes:

The body of literature on the topic of “added sugars” has been reported as highly heterogeneous in published reports on multiple occasions. The lack of rigorous data, consistent definitions across studies and accurate measurement tools were concerns of the Carbohydrate Working Group of the 2010 DGAC.

As stated in the 2010 DGAC report²⁰ in the ‘Needs for Future Research’: “Studies of carbohydrates and health outcomes on a macronutrient level are often inconsistent or ambiguous due to inaccurate measures and varying food categorizations and definitions. The science cannot progress without further advances in both methodology and theory.” The 2010 DGAC report goes on to state that there is a need to, “Develop standardized assessment tools to determine the accurate intake of added sugars.”

The methodologies for making these determinations have not changed since 2010, therefore our ability to attribute a health effect to a type of carbohydrate remains no different or more reliable than it was in 2010.

The lack of rigorous and consistent data, including poor measurement tools and inconsistencies in definitions and designs are also critical reasons why meta-analyses and systematic reviews for this body of literature on “added sugars” are so difficult to perform. A quality meta-analyses or systematic review depends on a heterogeneous body of literature. This does not exist for “added sugars” and thus provides another important factor why their extensive and often sole use for evidence by the Added Sugars Working Group must be called into question.

Specific points are made below regarding the Added Sugars Working Group’s draft conclusion statements.

“Added Sugars” and cardiovascular disease:

The draft conclusion states that there is “Moderate” evidence that: “Evidence from prospective cohort studies indicates that higher intake of added sugars, especially in the form of SSBs, is consistently associated with increased risk of hypertension, stroke, and coronary heart

¹⁹ *Op. Cit.* 6

²⁰ Dietary Guidelines Advisory Committee. 2010. Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010, to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. Pages 311 - 312

disease in adults. Observational and intervention studies indicate a consistent relationship between higher added sugar intake and higher blood pressure and serum triglycerides.”

- The majority of studies included in this evaluation examined intakes of either “added sugars” or SSB intakes that, if even reported, were at least twice as high as current mean intakes in the U.S. Many of the studies did not even report total “added sugars” intakes, with several reporting only approximations of the number of SSBs consumed or only what the intake from “added sugars” intervention was.
- Over half of the studies included in this analysis were observational studies and over half of them examined SSBs exclusively, often not reporting intakes of total “added sugars,” total sugars, total carbohydrates, energy intakes, or other important dietary factors associated with CVD (i.e. fats, sodium).
- Additionally, very few of the eleven trials included employed isocaloric treatments, making evaluation of the role that sugars plays, independent of total energy or carbohydrate intake, impossible.
- The conclusion overstates what the evidence says. The study quality is generally weak, with poor control and with a heavy reliance on observational data. The CVD variables the Working Group chose to look at are numerous and a review of this nature, with studies of this quality and so few in nature, is not an evidence-based approach to making links between diet and disease. That said, consistent associations between “added sugars” intake and any of the CVD variables studied do not exist. For example, of the eleven trials, only two measured blood pressure and only one saw an effect of ‘added sugars’ intake – at an intake of 27% energy (twice the current average in the US). As is the case with each of the Working Groups’ conclusion statements, the scientific evidence does not support them.

“Added Sugars” and type two diabetes (T2D):

The draft conclusion states that there is ‘Strong’ evidence for: “Higher consumption of added sugars, especially “sugar-sweetened beverages,” increase the risk for T2D among adults and this relationship is not fully explained by body weight.”

- The evidence evaluated for T2D included four meta-analyses and systematic reviews and one cohort study. It is unclear how these five papers were selected for consideration. It is worthwhile to note that this question has not been previously evaluated by any DGAC, meaning that a formal NEL search and review of the literature on added sugars and diabetes has never occurred.
- Four of the five papers examined SSBs exclusively and the fifth was a meta-analysis that looked at both SSBs and sugars intake. ***This meta-analysis concluded that “The results were limited or inconsistent on the adverse effect of intake of total sugars, glucose or fructose on the incidence of type 2 diabetes.”*** [Emphasis added] This was the only paper

of the five to examine sugars other than SSBs, therefore the conclusion statement for diabetes, as written, is substantially overstating the findings.

- Two of the studies assessed the risk of T2D for *both* artificially and “sugar sweetened beverages” and found increased risk of T2D for *both*. These findings negate the conclusion that “added sugars” intake explains the observed associations between SSBs and T2B and provide support for questioning the utility of cohort data (and FFQs to assess soda intake) and also support the case that soda drinking has collinear diet and lifestyle behaviors that can’t be well controlled for, and thus impact findings.
- Importantly, this conclusion by the Added Sugars Working Group differs from those from the 2014 U.K. SACN draft report,²¹ an evaluation with access to the same body of literature as the DGAC given the similar timeline of their respective evaluations. In this SACN report, no association was found between sucrose, glucose, fructose and T2D (in fact, a borderline inverse association between sucrose and T2D was found). With regard to SSBs, which were studied separately, SACN found moderate, not “strong,” evidence for an association with T2D. This conclusion was not extrapolated to include all “added sugars” as stated by the DGAC.
- By declaring “strong” evidence, the Working Group ignores the limitations cited in the most recent of the five papers they examined, a meta-analysis by Greenwood et al. in June 2014, which states: “Overall, between-study heterogeneity was high. The included studies were observational, so their results should be interpreted cautiously....”
- In summary, the draft conclusion statement does not reflect the preponderance of science, let alone reflect the select body of science that was examined. To make such a strong statement linking added sugars intake to T2D based on weak scientific evidence is misleading, not evidence-based, and contradicts conclusions by other authoritative bodies and recommendations of the American Diabetes Association. The ADA states that sugar is not different than starch with respect to blood glucose and lipid levels, when consumed up to 35% of calories.²² Of note is that current intakes of “added sugars” are ~13% of calories and the DGAC is proposing a limit of less than 10%. Again, the scientific evidence presented by the Working Group does not validate its conclusion statement and does not provide a scientific basis for an intake recommendation.

“Added Sugars” and obesity

The draft conclusion states that: “Strong and consistent evidence indicates that intake of added sugars from food and/or SSBs are associated with unfavorable body weight in children and adults. The reduction of added sugars and SSBs in the diet reduces BMI in both children and adults. Comparison groups with the highest versus the lowest intakes of added sugars in cohort

²¹ *Op. Cit.* 3

²² *Op. cit.* 4

studies were compatible with a recommendation to keep added sugars intake below 10% of total energy intake.”

- These draft conclusions are based solely on three pre-existing meta-analyses and systematic reviews. Two of the three reviews examined SSBs and body weight, exclusively, and the third examined all “added sugars.”
- It is incongruent with the evidence to conclude a relationship that is “strong and consistent” when the authors of the three reviews state such limitations as:
 - “No intervention studies were identified from which scientific conclusions could be drawn about the relationship between SSB intake and BMI or risk of obesity. The evidence for an association between SSB intake and obesity risk, when adjustment for energy and physical activity was performed, was *inconsistent* for children, adolescents, and adults.” ²³ (Trumbo, 2014)
 - “The studies included in our meta-analyses varied substantially with respect to study design, exposure assessment, adjustment for covariates, and specific outcomes evaluated.” ²⁴ (Malik 2014)
 - “The data suggest that the change in body fatness that occurs with modifying intake of sugars results from an alteration in energy balance rather than a physiological or metabolic consequence of monosaccharides or disaccharides. Owing to the multifactorial causes of obesity, it is unsurprising that the effect of reducing intake is relatively small.” ²⁵ (Te Morenga, 2013)
 - “The extent to which population based advice to reduce sugars might reduce risk of obesity cannot be extrapolated from the present findings, because few data from the studies lasted longer than ten weeks.” ²⁶ (Te Morenga, 2013)
- It has consistently been reported in the scientific literature that the observed association between “added sugars” intake, particularly SSB intake, and body weight is related to increased overall energy intake and not a unique function of sugars. This was stated by the 2010 DGAC in its report and reiterated by the author of one of the three meta-analyses reviewed by this Committee: “We observed that isoenergetic replacement of dietary sugars with other macronutrients resulted in *no weight change*. This finding strongly suggested that energy imbalance is a major determinant of the potential for dietary sugar to influence measures of body fatness.” ²⁷ (Te Morenga, 2013).
- We contend that The Added Sugars Working Group’s draft conclusions oversimplify and inaccurately portray the scientific evidence that currently exists on “added sugars” and body weight.

²³ *Op. cit.* 12

²⁴ *Op. cit.* 11

²⁵ *Op. cit.* 13

²⁶ *Ibid.*

²⁷ *Ibid.*

“Added Sugars” and dental caries

The draft conclusion states that: “The DGAC concurs with the World Health Organization’s commissioned systematic review that there is moderate consistent evidence supporting a relationship between the amount of sugars intake and the development of dental caries among children and adults. There is also evidence of moderate quality showing that caries are lower when free-sugars intake is less than 10% of energy intake.”

- This conclusion was based on one systematic review. This review was not a meta-analysis because, according to the authors, variability in the data was too large to analyze as such.
- This one review studied only the amount of “added sugars” intake associated with dental caries and did not evaluate the role of frequency, total sugars or fermentable carbohydrates, all of which are considered to be cariogenic. This is an important point recognized in the 2010 Dietary Guidelines for Americans (DGAs), where it states that, “Both naturally occurring sugars and added sugar increase the risk of dental caries.” The DGAs also recognize additional factors involved in cariogenesis, “During the time that sugars and starches are in contact with teeth, they also contribute to dental caries. A combined approach of reducing the amount of time sugars and starches are in the mouth, drinking fluoridated water, and brushing and flossing teeth, is the most effective way to reduce dental caries.”
- Of note, this sole review used as the basis for this conclusion does not contain any publications more recent than 2010. This is also an important point because in 2010 EFSA concluded their review which included an evaluation of the role of sugars in dental caries, and concluded the following: “Frequent consumption of sugar-containing foods can increase risk of dental caries, especially when oral hygiene and fluoride prophylaxis are insufficient. However, available data ***does not allow setting an upper limit for intake of (added) sugars on the basis of a risk reduction for dental caries***, [Emphasis added] as caries development related to consumption of sucrose and other cariogenic carbohydrates does not depend only on the amount of sugar consumed, but is also influenced by frequency of consumption, oral hygiene, exposure to fluoride, and various other factors.”
- In conclusion, by selecting one pre-existing review, the DGAC’s shortcut to a conclusion on the role of “added sugars” and dental caries has bypassed an evidence-based approach to determine a diet and health relationship, and ignores the multifactorial nature of the role of all fermentable carbohydrates in the development of dental caries.

Subcommittee 2 Dietary Patterns

Subcommittee 2 use of hypothesis-based dietary patterns studies to link or associate dietary components with serious disease outcomes:

Guidance that suggests healthful dietary patterns, versus individual food or nutrient recommendations, may be a helpful tool for Americans to change dietary behaviors. However, we are concerned that such hypothesis-based research is being extrapolated to infer, or even state, cause and effect relationships between dietary components and disease outcomes that are not yet established by more traditional, experimental science.

The “hypothesis-based” methodologies used in these dietary pattern studies do not, and cannot, accurately isolate the positive or negative effects of individual components of the dietary pattern. In this methodology components of a dietary pattern are pre-assigned negative scores based on the presumptions they are detrimental, resulting in outcomes that are biased and *predetermined*. We contend that this methodology is not objective science and is not appropriate for use, particularly as the sole basis, in making evidence-based recommendations. Furthermore, examination of the science cited raises concerns that the conclusions drawn by the Committee do not accurately reflect what was represented in the actual scientific studies cited.

The majority of dietary pattern studies cited by the Committee did not include a total sugars or “added sugars” criteria yet the Committee implies that there is a link or association between added sugars and serious disease outcomes. In the Subcommittee conclusion statement for “The Relationship Between Dietary Patterns and Risk of Cardiovascular Disease” they state, *“There is strong and consistent evidence that in healthy adults increased adherence to dietary pattern scoring high in fruits, vegetables, whole grains, nuts, legumes, unsaturated oils, low-fat dairy, poultry and fish: **low in** red and processed meat, high-fat dairy, and **added sugars**; and moderate in alcohol is associated with decreased risk of fatal and non-fatal cardiovascular diseases, including coronary heart disease and stroke.”*

On pages 88 and 89 of the subcommittee’s initial report, 20 studies are identified as having assessed the association with ***individual food components*** of a dietary pattern score and ***CVD endpoint outcomes***. Of the 20 studies identified, 16 of those studies did not include an “added sugars,” sugars-sweetened food or sweetened beverage component in their scoring methodology. We strongly contend that the science cited does not support the association between lowering “added sugars” intake and a decreased risk of fatal and non-fatal cardiovascular disease, including coronary heart disease and stroke. This statement is not based on the science cited nor supported by a preponderance of scientific or medical knowledge.

Dietary guidance that links or associates any individual component of the diet with serious disease outcomes must be supported by a thorough systematic review of the full body of science (at the highest level of evidence available) to assure recommendations are based on a preponderance of scientific evidence. In some instances, the required scientific evidence for such conclusions does not yet exist. Therefore, this conclusion is another example of why serious concerns are being raised in the 2015 DGAC process that biases are influencing conclusions and not scientific evidence.

U.S. Department of Agriculture (USDA) Food Pattern modeling is being used for ‘recommended’ levels of intake:

The USDA Food Patterns and its mathematical construct do not have the scientific underpinning to be used as official recommendations. Yet, the USDA Food Patterns intake guidance is being reported and used by the DGAC as recommended intakes, even citing ‘limits’ that are not supported by the Institute of Medicine.

The Food and Drug Administration in its recent Proposed Rule, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels,” concluded that food modeling did not provide a scientific basis for setting a Daily Reference Value or intake recommendation for “added sugars.” Further, the 2010 Dietary Guidelines for Americans policy document clearly states USDA Eating Patterns is but one example of suggested eating patterns and that the USDA Eating Patterns “*have not been specifically tested for health benefits.*”

Subcommittee 1 asserted at meeting 6 that “The data from the intervention trials and the cohort studies provide empirical data that the USDA Food Patterns provide an evidence-based guide to food consumption.” The graphs provided by Subcommittee 1 to support this assertion call this statement into question. Below is a table that quantifies the information provided in these graphs that depicted the correlation between intakes in cited dietary pattern studies and USDA Food Pattern recommendations.

Dietary Component	Studies	Studies - Intakes Within USDA Food Pattern Range	Studies - Intakes Outside USDA Food Pattern Range	Lower	Higher
Vegetables	23	9	14	6	8
Fruit	23	5	18	3	15
Dairy	19	6	13	13	
Red & Processed Meat	20	1	19	6	13
Seafood	20	5	15		15

We are totally mystified by the Committee’s assertion, based on the table above. We question how their graphical depiction can be considered evidence-based and therefore grounds for empirical support that USDA Food Patterns are an evidence-based guide for food consumption. Furthermore, this quantified table shows that in fact the majority of food group intakes from these published dietary pattern studies do not actually fall within the recommendations of the USDA Food Pattern ranges as asserted by the Subcommittee.

Additionally, because the dietary pattern studies cited did not include “added sugars” criteria, there is no graph/empirical evidence to support the extremely low “added sugars” intake in the proposed “Healthy US-Style Patterns.”

Until the food pattern itself is tested, ‘empirical’ evidence for its efficacy does not exist. In the interim, such creative methods of portraying the science to support reporting the USDA Food Pattern “added sugars” intakes as official science-based recommendations misleads the American public. [Emphasis added]

We strongly assert that sugar is an important ingredient that contributes essential functional properties to food formulation, including safety as a natural food preservative. In fact, historic, as well as recent, analyses on “added sugars” intake confirm that sugar makes many nutrient-rich foods palatable which is a positive factor in the intake levels of many essential micronutrients.^{28 29 30 31 32 33 34} Consumption data dating back to the early 1900s show that “added sugars” intakes have never been at these extremely low levels suggested in the USDA Food Pattern/Healthy US-Style Patterns. The unintended consequences, including the impact on nutrient intakes, need to be strongly considered by the Committee.

In conclusion,

There is not a preponderance of scientific evidence for conclusion statements that link “added sugars” intake to serious disease or negative health outcomes or for a recommendation to limit “added sugars” intake to less than 10% of energy. Even in the WHO-commissioned review, the nexus that has empowered the DGAC to set an “added sugars” intake level, the authors 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.*” (Te Morenga, 2013) [Emphasis added]

Congress in its wisdom understood that the American public deserves science-based recommendations, no matter the issue. Therefore, we ask that the DGAC assure their recommendations to the Secretaries maintain the integrity of the Dietary Guidelines process and base their recommendations solely on the preponderance of scientific information.

We thank you for your consideration of this comment.

Sincerely,

Andrew C. Briscoe III



President

P. Courtney Gain, PhD, RD



Vice President of Scientific Affairs

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