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Regarding: Comments on *Dietary Guidelines for Americans, 2015* [FR Doc 2015-03552] from the North America Branch of the International Life Sciences Institute (ILSI – NA)

Dear Dr. Wright, Ms. Tagtow, and Dr. Jacobs-Young:

The North American Branch of the International Life Sciences Institute (ILSI-N.A.) appreciates the opportunity to share recently published scientific research and expert summaries supported by ILSI-NA. This body of research is a valuable contribution to understanding the importance of dietary recommendations to consider the **factors that impact food selection** and that dietary recommendations can be met by including foods of varying degrees of processing [1-3]; the **impact of fortified micronutrients** in the U.S. diet [4-7]; use of **low-calorie sweeteners to maintain calorie balance** over time to achieve and sustain at a healthy body weight [8-10]; both **differentiation and quantification of "added sugars"** [11-16]; and the importance of considering complete dietary patterns cumulatively incorporating **feasible sodium and potassium intakes** [17-20]; within the context of translating evidence summarized in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (*2015 Scientific Report*) into dietary guidance for Americans [21].

ILSI North America is a public, non-profit organization that actively collaborates with government and academia to identify and resolve scientific issues important to the health of the public. The organization carries out its mission by sponsoring relevant research programs, professional education programs and workshops, seminars and publications, as well as providing a neutral forum for government, academic, and industry scientists to discuss and resolve scientific issues of common concern for the well-being of the general public. ILSI North America's programs are supported primarily by its industry membership.

Comments provided herein correspond in five independent sections to critical themes addressed within the *2015 Scientific Report* [20] and were developed by ILSI North America's Technical Committees on Food Value Decisions, Fortification, Low-Calorie Sweeteners, Carbohydrates, and Sodium.

I. FOOD VALUE DECISIONS

The *2015 Scientific Report* recognizes that it is critical to understand that all consumers do not share the same system of values which influence their food purchasing decisions. ILSI NA developed a tool that allows nutrition education professionals to evaluate these factors when helping consumers reach dietary recommendations. The tool, the Food Value Analysis application, is publically accessible at www.foodvalueanalysis.org. The application compares cost, preparation time, nutrition, cooking skills, shelf life, and food safety among similar foods of varying levels of processing. This work aligns directly with many statements, identified research needs, and current evidence related to food choice and dietary patterns of Americans as outlined in the 2015 DGAC Report.

Specifically, the *2015 Scientific Report* [21] makes the following statements related to dietary patterns and the factors that influence such patterns, which are related to evidence obtained through the Food Value Analysis application bulleted below:

1. *The DGAC found that while diet quality varies somewhat by the setting where the food is obtained, overall, independent of where the food is prepared or obtained, the diet quality of the U.S. population does not meet recommendations.* (Part D, Chapter 1)
    - It is foods chosen, rather than the spectrum of processing that most affects diet quality, as HEI scores do not vary appreciably from home-prepared to processed menu items. [1]
    - Evaluation of the Food Value Analysis application shows that dietary guidelines can be reached using foods of varying levels of processing. [1]

2. *Household social & cultural influences on dietary patterns include food and beverage availability, cooking and storage facilities, family and shared meals, living situation, person(s) responsible for food purchases/preparation.* (Part B, Chapter 1)
    - Time-inclusive prices for home recipes were especially higher for the more time-intensive (e.g. washing, peeling, chopping, etc.) food groups, such as grains, vegetables, and fruits, which are generally under consumed relative to the guidelines. [3]
    - The Food Value Analysis application allows for these factors to be considered when a nutrition professional provides dietary recommendations to a consumer. [1, 2]

3. *Additional evidence indicates that individuals can be helped in their intentions to implement healthy lifestyles by targeting specific eating behaviors (e.g. meal patterns, cooking and preparation techniques).* (Part B, Chapter 2)

- It was demonstrated using two USDA 2010 Dietary Guidelines for Americans Sample menus for a 2000-calorie food pattern that it can take 2.5 hours longer of active preparation time for a day's worth of meals using home prepared recipes in comparison to using various processed versions of similar foods. [1, Table 1]
- The "true cost" of a food for consumers goes beyond price and nutrition, with preparation time being a significant factor. [1-3]
- The Food Value Analysis application allows nutrition professionals to target specific needs of the individual /family including cooking skills, budget, time availability, and nutritional needs to help construct dietary patterns that are sensitive to their needs and constraints, yet meet dietary recommendations. [1, 2]

4. *Participants (of Federal food assistance programs) should receive tailored counseling to choose foods with their limited budgets that meet Dietary Guidelines for Americans and to achieve or maintain a healthy lifestyle.* (Part D, Chapter 3)
    - Research using the dataset from the Food Value Analysis application has shown that budget should not only incorporate the monetary cost of a food product but also the cost associated with the time it takes to prepare a meal. [3] This is a critical concept when forming recommendations for consumers with varying budgets and time constraints. The Food Value Analysis tool allows for the comparison of price between similar food products while also considering the nutrient composition of those products.

5. *Efforts are needed to reduce sodium in commercially prepared and processed foods, as well as encouragement of home cooking using recipes with small amounts of sodium are needed to decrease intake toward recommended levels.* (Part D, Chapter 1)
    - Sodium is a component of Healthy Eating Index (HEI) scores, yet the differences in HEI scores varied little, whether fresh or processed items were included. The HEI score is a scoring metric used by the USDA. It is designed to capture key recommendations from the 2010 Dietary Guidelines for Americans and is used as a predictor of health outcomes. A manuscript on the Food Value Analysis tool shows menus containing processed food items routinely had higher amounts of sodium compared to home-prepared foods. [1]
    - A separate analysis done in conjunction with the Food Value Analysis application demonstrated that the inclusion of products developed specifically as "low or reduced" sodium can further help consumers lower their total sodium intake. [1]

This work, supported by ILSI North America, has been presented in three peer-reviewed publications. The first publication, "A web-based food value analysis application to compare foods at different levels of preparation and processing" [2], describes the methodology used in the development of the application while the second publication, "Utility of a New Food Value Analysis Application to Evaluate Trade-Offs When Making Food Selections" [1], presents the application of the tool. The second manuscript analyzes one day diet menus taken from USDA FNS and Thrifty Food Plan sample menus substituting different forms of foods using the Healthy Eating Index (HEI) to compare diet quality. A third manuscript that has been accepted for publication in AJCN, "Beyond the Sticker Price: Including and Excluding Time in Comparing

Food Prices" [3] uses the dataset that was used to build the Food Value Analysis application to examine the inclusion of the value of time in measuring the price of a food. This work was conducted at Virginia Tech.

The work of the three manuscripts provides the following, overarching conclusions:

- There is more than one path to adherence to dietary recommendations and foods of varying levels of processing can be used (including fresh through ready-to-eat versions of foods). [1]
- It is foods chosen, rather than the spectrum of processing that most affects diet quality, as HEI scores do not vary appreciably from home-prepared to processed menu items. [1]
- The "true cost" of a food for consumers goes beyond price and nutrition, with preparation time being a significant factor. [1-3]
- Full prices take into account the money price of a food and the time value associated with the food. Considerations of money prices alone give a misleading indication of the relative prices of foods and therefore can lead to misleading policy implications. [3]
- Time-inclusive prices for home recipes were especially higher for the more time-intensive (e.g. washing, peeling, chopping, etc.) food groups, such as grains, vegetables, and fruits, which are generally under consumed relative to the guidelines. [3]

Finally, the *2015 Scientific Report* identified the need for strategies that complement policies and support consumers to make dietary behavior changes. The Food Value Analysis application, supported by ILSI North America, fulfills this need and can be a valuable tool for nutrition professionals helping consumers to reach the *2015 Dietary Guidelines of Americans*.

II. FOOD FORTIFICATION

Given the number of consumers restricting foods and food groups, it is even more essential that the diet patterns recommended by the 2015 Dietary Guidelines consider not only ideal diets, but diets reflecting the reality of consumer choices, particularly while meeting calorie targets. Additionally, these Guidelines should take into account the potential role of enriched/fortified foods and dietary supplements among the increasing numbers of consumers who limit multiple foods and food groups (e.g., meat, dairy, egg, and gluten-containing products).

Trends Show Sub-Populations that Benefit from Fortified Foods are Growing

Dietary Guidelines for Americans 2010 states a basic premise, "…that nutrient needs should be met primarily through consuming foods." [22]. This concept is not specifically mentioned within the *2015 Scientific Report* [21] and it is important that the guidelines do recognize that enriched and fortified foods and dietary supplements may be useful in providing one or more nutrients that otherwise might be consumed in less than recommended amounts, and for certain sub-populations, and they note:

- "…fortification can provide a food-based means for increasing intake of particular nutrients, including by example, vitamins D and B-12 and folic acid."

- Women capable of becoming pregnant are advised to choose foods "that supply heme iron, which is more readily absorbed by the body, additional iron sources, and enhancers of iron absorption such as vitamin C-rich foods… and synthetic folic acid (from fortified foods and/or supplements) …"

- Individual's ages 50 and older are advised to "[c]onsume foods fortified with vitamin B12, such as fortified cereals, or dietary supplements."

- "In the vegan patterns especially, fortified foods provide much of the calcium and vitamin B12, and either fortified foods or supplements should be selected to provide adequate intake of these nutrients."

Enriched and Fortified Foods Help Americans Meet Nutrient Needs

Data from the National Health and Nutrition Examination Survey (NHANES) 2003-2006 indicate that fortified foods help the U.S. population meet the Estimated Average Requirements (EAR), set by the Institute of Medicine's Food and Nutrition Board, for several essential nutrients (including vitamins A, B-6, B-12, C and D, thiamin, riboflavin, niacin, folate and iron) [4]. Specific examples for Americans 2 years and older are noted below, with detailed data for these and several other nutrients in the attached manuscript by Fulgoni et al. [4].

- <u>Fortification decreases the % of US consumers below the EAR for vitamin D</u>. Average vitamin D intakes from all food sources (naturally occurring + enriched/fortified foods) were more than double the intakes from natural sources alone (mean intake 4.9 ± 0.1µg/day compared to 1.9 ± 0.4 µg/d). However, even with increased intakes through fortification, 93.3% of Americans consumed less than the EAR, suggesting the need for additional research on levels and vehicles for vitamin D fortification [4].

- <u>Fortification improved mean vitamin A intake and substantially reduced prevalence of intakes below recommendations</u>. Vitamin A intakes from all food sources (naturally occurring + enriched/fortified) were 46% higher than natural sources alone (601± 8 compared to 412 ± 5µg retinol activity equivalents/day). As a result of enriched/fortified foods, 45.1% of the population consumed less than the EAR compared to 74.4% had the food supply provided only naturally occurring sources [4].

- In summary, food enrichment and fortification results in fewer people in the U.S. consuming below the EAR for several essential nutrients, including vitamins A, B-6, B-12, C, D, and calcium.

Dietary supplement users are more likely to meet the EAR for most nutrients and several important "shortfall nutrients", but also have a higher prevalence of exceeding the Tolerable Upper Intake Level (UL) for niacin and zinc.

Most Americans meet recommended nutrient targets for the majority, but not all, of vitamins and minerals. However, far fewer individuals would do so without consuming enriched and fortified foods, and even fewer would do so without consuming dietary supplements, particularly among "shortfall nutrients" and "nutrients of concern" identified by the *2015 Scientific Report* [21].

- <u>Supplement users meet the EAR for all micronutrients (except potassium).</u> For dietary supplement users, the % of adults achieving EAR intake increases by ~7 % for iron, ~12% for zinc, ~ 30% for calcium, and ~45% for magnesium [5].

- <u>Very few U.S. adults reach the UL's for vitamins and minerals, with supplement users making up the majority of those who do</u>. Among adult mineral supplement users in the 2003-2006 NHANES study, intakes from food plus supplements combined exceeded the UL for calcium, iron, zinc and magnesium (approximately 6% prevalence above the calcium UL, 9% for iron, 9% for zinc and 6% for magnesium) [5]. Fewer than 0.5% of adults in this study exceeded mineral intake UL's from food sources alone [5].

- Using NHANES 2003-2009, Bailey et al. showed that U.S. adults (19+ years) "did not have usual dietary intakes of vitamins from foods alone that were above the UL," (specifically vitamins A, B-6, B-9 (folate), B-12, C, D, and E) [6]. Among adult dietary supplement users, only 7% exceeded the UL for folic acid when food and supplement intakes were combined. Among vitamin supplement users, the prevalence of adults exceeding the UL for vitamin A was greater than zero in all age groups, reaching ~5% among 50+ year age group. [6].

- <u>Among U.S. children and adolescents, fortification and supplement users had a lower prevalence of consuming <EAR for many nutrients – including some of the identified "shortfall nutrients", and slightly higher prevalence of consuming >UL for a few nutrients</u>. In a research article published in the *Journal of the Academy of Nutrition and Dietetics,* Berner et al. concluded that among children 2-18 years, "When nutrient intakes contributed from fortification were added, the % [consuming] <EAR for vitamins A, B-6, C, D, the five enrichment nutrients, and zinc shifted sharply lower." As in the general populations, dietary supplement use accounted for the largest reduction in % of children 2-18 years consuming <EAR for shortfall nutrients such as vitamin E and vitamin D. The prevalence of intakes above the UL's were particularly noteworthy for supplement use among children 2-8 years old (42% of the population), with 53% exceeding the UL for zinc, 30% for folate, and 28% for niacin [7].

- The evidence indicates that consumers of enriched/fortified foods and dietary supplements are more likely to achieve recommended intakes for key nutrients, including "shortfall nutrients" such as vitamin D, vitamin E, and calcium. Although, supplement use may create the potential for intakes above the UL for some nutrients (vitamins A, B-6, B-9, and C and calcium, iron, zinc and magnesium), this observation must be put in the context that supplement users tend to have greater nutrient intake from conventional foods than non-users [6].

In Summary

Evidence shows enriched/fortified foods and dietary supplements contribute to nutrient intakes and help meet key nutrient needs among specific life-stage groups [4-7]. Currently, more than 67 countries require fortification of specific foods staples (eg. milk, flour, sugar, salt) and commonly consumed foods (eg. ready-to-eat-cereals). Fortification has a long history of helping to address population nutrition needs and recently shifting consumer diets towards prepared or partially-prepared foods home and away-from-home must be considered. Approaches to fortification should continue to be effective and responsible, as well as flexible (or be able to evolve) in order to meet the changing needs of the population and current nutrition challenges.

III. LOW-CALORIE SWEETENERS

Calorie-Balance: Low calorie sweeteners offer potential to help manage body weight, BMI, fat mass, and waist circumference

Scientific evidence from a recently completed, comprehensive meta-analysis of randomized clinical trials shows the potential of low-calorie sweetened foods and beverages in helping maintain calorie balance [8].

Maintaining calorie balance is an issue for the majority of Americans, regardless of age [22]. In a recent comprehensive meta-analysis by Miller and Perez, evidence from 15 randomized clinical trials (RCT) indicates that substituting low-calorie sweeteners (LCS) for regular-calorie versions "results in a modest weight loss, and may be a useful dietary tool to improve compliance with weight loss or weight maintenance plans" [8]. Evidence from the body of RCT's is particularly important since it differs from observed associations in prospective studies among free-living, self-selecting subjects. In the observational studies (n=9), which lack randomization, it is not possible to completely adjust for the multiple biases and confounding factors associated with self-selecting LCS users.

For this meta-analysis, low-calorie sweeteners included nonnutritive and bulk sweeteners used in foods, beverages, tabletop or experimental capsule. Details on the study inclusion criteria, data extraction, and data analysis can be found in the full manuscript, which was published 19 June 2014 in AJCN. Pooled summary estimates are expressed as weighted group mean differences for the RCT and weighted group mean correlation for the prospective observational studies.

- Among randomized clinical trials (n=15), **low calorie sweeteners reduced body weight** (weighted group mean differences - 0.80 kg, 95% CI: -1.17, -0.43) relative to the comparator arm, **BMI** (-0.24 kg/m2, 95% CI: -0.41, -0.07), **fat mass** (-1.10 kg, 95% CI: -1.77, -0.44), and **waist circumference** (-0.83 cm, 95% CI: -1.29, -0.37). All were statistically significant at the $p<0.05$ level (as shown by the 95% CI).

- Results were directionally similar when stratified by children and adults. For example, body weight change among children was -1.06 kg (95% CI: -1.57, -0.56) and among adults -0.72 kg (95% CI: -1.15, -0.30).

- In contrast to randomized trials, prospective observational studies (n=9) among free-living subjects showed self-selected LCS use at baseline was not associated with fat mass, was modestly associated with positive change relative to the comparator arm in **BMI** (weighted group mean correlation 0.03, 95% CI: 0.01, 0.06) and directionally, but not statistically, for **weight gain** (0.02, 95% CI: -0.01, 0.06).

It is an important aspect of this meta-analysis that observational and RCT studies were evaluated in separate quantitative assessments. Observational results alone, as noted by Miller and Perez, are “not easily interpreted” and “may have biased the reported associations with body weight and composition” [8]. In contrast, the meta-analysis of RCT studies does clearly “indicate that substituting LCS for sugar modestly reduces body weight, BMI, fat mass, and waist circumference”.

The duration of RCT studies evaluated within the meta-analysis varied. The longest continuous study lasted for 18 months and determined that “Masked replacement of sugar-containing beverages with noncaloric beverages reduced weight gain and fat accumulation in normal-weight children” [9]. A second study included a three year follow-up which concluded aspartame, as a part of a multidisciplinary weight-control program, better facilitated “long term maintenance of reduced body weight” [10].

Constraints in participation, funding, and structure generally limit the feasibility of RCT studies to extend beyond this length, leading to some confusion over the *2015 Scientific Report* [21] statement from Chapter 6: “Since the long-term effects of low-calorie sweeteners are still uncertain, those sweeteners should not be recommended for use as a primary replacement/substitute for added sugars in foods and beverages.”

In summary, this meta-analysis shows that had prospective studies (with un-accounted for residual biases and confounding factors) been used as evidence for dietary guidance, the conclusions may have missed the potential benefit on body weight and composition shown in randomized clinical trials. Differing results are also suggestive that advice related to consumer behavior may be relevant to reinforce that LCS be used to replace higher calorie options, in order to realize the demonstrated potential to help maintain calorie balance for weight management. Based on findings from the meta-analysis of randomized clinical trials, Miller and Perez state that the findings “provide suggestive evidence that LCS do not, contrary to past hypotheses, increase the desire or inclination to consume more sweet foods.”

In Summary

Recently published and presented scientific evidence summarized herein, support the potential benefit of substituting low-calorie sweeteners for regular calorie sweeteners, to maintain calorie balance.

IV. ADDED SUGARS

Evidence summarized here is based on ILSI NA sponsored work relevant to the *2015 Scientific Report* as it relates to "added sugars" and indicates that the form of sugar is indistinguishable whether added or intrinsic, inadequate evidence exists to establish DRI upper levels, and the public-health benefit of focusing on added sugar has not been demonstrated.

"Added sugars" are not distinguishable structurally from sugar occurring naturally in a food and evidence does not support differentiating by health benefit [11,12].

- In a 2012 summary of dietary guidelines for sugars, experts in the field concluded: "Clearly, excess energy intake in any form results in weight gain; therefore, moderating sugar intake so as to not exceed daily energy requirements can help to reduce the risk for obesity. It is not clear; however, if diets lower in added sugars necessarily result in better or more balanced diets based on currently available scientific evidence." [11]

- To address the issue of whether added sugars leads to unbalanced micronutrient intakes, ILSI NA sponsored a project to update and expand data on intakes of selected micronutrients at 5% increments of added sugars (from 0 to >35% of energy intake) using NHANES 2003–2006 data [12]. As reported in the publication:
    - "Nutrient intake was less with each 5% increase in added sugars intake above 5-10% [of energy intake]."
    - "Higher added sugars intake were associated with higher proportions of individuals with nutrient intakes below the [Estimated Average Requirement] EAR, but the overall high calorie and low quality of the U.S. diet remained the prominent issue."
    - The authors concluded that "[h]igh levels of added sugars intake occur among only a small proportion of the population and cannot explain the existing problem of poor nutrient intake in the U.S. population as a whole."

Evidence is inadequate to quantify limits on added sugar intake.

The *2015 Scientific Report* "recommends limiting added sugars to a maximum of 10% of total daily caloric intake…supported by: 1) the food pattern modeling analysis conducted by the 2015 DGAC and 2) the scientific evidence review on added sugars and chronic disease risk conducted by the Committee" [21]. According to the report, the food pattern modeling analysis was based on a stated assumption that "empty calories allowances" be split such that "45% of empty calories are allocated to limits for added sugars, with the remainder (55 percent) allocated to solid fats" [21]. Additionally, the report describes that the "DGAC concurs with the World Health Organization's [WHO] commissioned systematic review that moderate consistent evidence supports a relationship between the amount of free sugars intake and the development of dental caries among children and adults. Moderate evidence also indicates that caries are lower when free sugars intake is less than 10 percent of energy intake." [21].

The WHO guidance used as primary scientific evidence to recommend 10% of energy limit for free sugars (note that free sugars includes fruit juices), is based on two evidence-based reviews related to dental caries and obesity/overweight. The conditional WHO recommendation to further reduce free sugars intake to 5 percent of total calories was based on evidence described in the DGAC 2015 report as "very low quality." Furthermore, the following ILSI supported literature reviews are relevant.

- ILSI NA reviewed data related to dental caries in September 2002 and the findings were published in 2003 [13]. An earlier review was conducted in 1994 and published in 1995 [14]. This second, earlier review addresses the issue of dental caries during wartime. Data cited by the WHO review were collected following World War II in Japan, where there were undoubtedly many confounding factors, e.g., undernutrition and lack of dental care. The authors of the 1994 ILSI review state: "Although sugar consumption rose rapidly after World War II and has been ~ 45 kg per capita during the past 40 y, the number of caries-free schoolchildren aged 7-15 y had risen to 65% b 1989 and the DMFT index for 12 y-old children had decreased to 1.0." The data cited come from Büttner 1991.

- An ILSI Europe concise monograph on this topic reviews studies showing that frequency of consumption of fermentable carbohydrates is a driver of dental caries along with oral hygiene, exposure to fluoride, and salivary flow and composition [15].

- Murphy and Johnson [16] reviewed the DRIs for carbohydrates and stated the following:

> "The panel extensively reviewed the literature examining potential adverse effects of overconsumption of sugars. This included the available data on dental caries, behavior, cancer, risk of obesity, and risk of hyperlipidemia. The panel concluded that there was insufficient evidence to set a tolerable upper intake level (UL) for sugars. A UL for sugars was not set because of the limitation in the UL definition that requires a specific endpoint for an adverse effect from excessive nutrient intake."

- In addition, as cited by Hess et al., a European Food Safety Authority panel concluded that “there are insufficient data to set an upper limit for (added) sugar intake. The basis for this conclusion was a review of the effects of sugar intake on the nutrient density of the diet, body weight, dental caries, and risk factors for cardiovascular disease and type 2 diabetes mellitus” [11].

The recommendation of the *2015 Scientific Report* to label added sugars is an instance of policy advocacy, not a matter of scientific evidence

The *2015 Scientific Report* [21] suggests specifically that: “The Nutrition Facts Panel (NFP) should include added sugars (in grams and teaspoons) and include a percent daily value, to assist consumers in making informed dietary decisions by identifying the amount of added sugars in foods and beverages” [21]. This text is an unfortunate inclusion in the report as it has no basis in a review of the literature or systematic review, but is rather an editorial opinion on regulatory policy.

- With respect to assisting consumers, the following excerpts from published papers are relevant:

> ”…discussions concerning the health effects of sugars must be framed rationally and be supported by scientific evidence. Underlying assumptions and expectations related to specific nutrient and food choices must be consciously made with the consumer in mind. For consumers to implement dietary recommendations, they must be provided with clear, relevant messages that are based on quality evidence. Such messages are critical to maintaining the trust and confidence of consumers in those who develop the recommendations and in those who deliver them” [23].
>
> “Clearly, excess energy intake in any form results in weight gain; therefore, moderating sugar intake so as to not exceed daily energy requirements can help to reduce the risk for obesity. It is not clear, however, if diets lower in added sugars necessarily result in better or more balanced diets based on currently available scientific evidence. All digestible carbohydrates contain 4 kcal [per] gram, so substitutions of refined starch for added sugars will not lower calorie intake or improve public health” [11].

In Summary

The published literature summarized herein suggests added sugars are indistinguishable from total sugars, that evidence is inadequate to quantifying upper limits, and questions whether a focus on added sugars will result in better or more balanced diets.

V. SODIUM

Sodium and potassium intake in the context of dietary patterns

The *2015 Scientific Report* [21] identifies 3,478mg/day as the current average sodium intake in the U.S. and suggests this should be reduced. Conclusions drawn for the general population set 2,300mg/day as the tolerable upper limit for sodium intake (in concurrence with the 2013 IOM Report Sodium Intake in Populations [17]). Individuals who would benefit from lowering blood pressure are encouraged to consume no more than 2,400mg/day; lower sodium intake to 1,500mg/day for greater reduction in blood pressure, or lower intake by at least 1,000mg/day if goals of 2,400 or 1,500mg/day cannot be achieved (in concurrence with the 2013 AHA/ACC Lifestyle Guideline [18]).

In contrast to sodium intake recommendations, potassium is identified as a nutrient of concern within the *2015 Scientific Report* [21]. From Chapter 1: "Nutrient intake data, together with nutritional biomarker and health outcomes data indicate that vitamin D, calcium, potassium, and fiber are under consumed and may pose a public health concern". Chapter 2 elaborates: "…research that includes specific nutrients in their description of dietary patterns indicate that patterns that are lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are beneficial for reducing cardiovascular disease risk". The *2015 Scientific Report* specifically "…encourages increased potassium intake through potassium-rich foods such as vegetables and fruits".

Apart from specific, although independent, recommendations to reduce sodium intake and increase potassium intake, when considering the question "What effect does the interrelationship of sodium and potassium have on blood pressure and cardiovascular disease outcomes?" the *2015 Scientific Report* concurs with the 2013 NHLBI Lifestyle Report that "Evidence is not sufficient to determine whether increasing dietary potassium intake lowers blood pressure" and "Evidence is not sufficient to determine an association between dietary potassium intake and coronary heart disease (CHD), heart failure, and cardiovascular mortality." Further elaboration within the *2015 Scientific Report* states that although a high ratio of sodium intake to potassium intake is hypothesized to be a stronger risk factor for hypertension than individual evaluation: "…the evidence base to support this hypothesis is insufficient for drawing definitive conclusions".

Despite the assessment of insufficient evidence to support an association with increased dietary potassium and lower blood pressure or risk of cardiovascular disease, the *2015 Scientific Report* concludes that strong evidence exists for increasing dietary potassium intake while decreasing dietary sodium intake; effectively lowering the sodium potassium ratio in the U.S. diet. In considering this recommendation, the availability of dietary patterns which allow for lowering the sodium and potassium ratio must be considered. In ongoing research performed in cooperation with the Food Research Survey Group at the United States Department of Agriculture the importance of food choices to lower the sodium to potassium ratio in U.S. diets has been highlighted [19]:

- Fewer than 2% of adults met the recommended Na/K ratio of 0.49 (based on 2300 mg Na/4700 mg K), in NHANES 2007-2010. Mean Na/K ratio was 1.5 (SEM 0.01) for adult men and 1.4 (SEM 0.01) for adult women

- "Among individuals with Na/K <1.0 vs. Na/K ≥1.0, milk and dairy foods contributed 8% vs. 6% of daily Na and 12% vs. 9% of daily K." Note that consumers with lower Na/K ratios (<1.0) had higher percent of both Na and K intakes from milk and dairy foods, compared to consumers with higher Na/K ratios. Because nutrient dense milk and dairy foods contributed importantly to potassium intakes, the individuals' overall dietary Na/K intake ratio was better, even though milk and dairy foods contributed a relatively greater portion of sodium to their diet compared to consumers with high Na/K ratios.

- Similarly, "…fruit and vegetables contributed 12% vs. 6% of total daily Na and 25% vs. 18% of daily K, respectively for individuals with Na/K

Additional challenges in achieving a lower sodium to potassium ratio are illustrated in a recent linear programming model developed using dietary data from the NHANES 2001-2002. Dietary patterns for six age, gender sub-groups and modeling scenarios were evaluated before and after an across-the board 10% reduction in sodium content of all foods in the Food and Nutrition Database for Dietary Studies [20]:

- "The 2300-mg/d sodium guideline was theoretically compatible with the potassium guidelines (4700 mg/d) for all sex-age groups." Notably, "…women older than 50 years could reach the 4700-mg/d potassium goal only at the maximum level of sodium. For the remaining women and younger men, only a few Na-K combinations were compatible with nutritionally adequate diets…"

- "The 1500-mg/d sodium guideline was theoretically compatible with the potassium guideline (4700 mg/d) only for men older than 50 years and no other group…"

- Across-the-board 10% Na reduction in the food database "had minimal impact on the low energy food patterns. The feasibility of reaching the sodium goals by women was not affected. By contrast, the reduction in sodium content of the food supply led to food patterns for men that were significantly reduced in sodium content; however, the sodium and potassium guidelines could not be met simultaneously."

- The authors concluded: "If the level of sodium is set too low, the other nutrient requirements cannot be met; hence the sodium goal becomes incompatible with nutrient adequate diets." And 10% across-the-board reduction in the food supply "proved to be ineffective."

In Summary

While the 2015 Dietary Guidelines Advisory Committees' conclusions about the nutrients sodium and potassium related to CVD were moderate, the conclusions about dietary patterns that are rich in potassium and not necessarily limited in sodium (DASH, Predimed) were rated as strong. ILSI N.A. supported research demonstrated that meeting current sodium recommendations is incompatible with meeting potassium recommendations within current dietary patterns [20]. Taken in concert, the Drenowski findings that a single nutrient focus is not feasible along with the *2015 Scientific Report's* strong recommendation on dietary patterns shows that a focus on increasing intakes of the 3 key food patterns is more achievable than focusing on sodium reduction across the food supply.

ILSI North America Technical Committees on Food Value Decisions, Fortification, Low-Calorie Sweeteners, Carbohydrates, and Sodium appreciate the opportunity to share comments from our scientific programs which relate to the *2015 Scientific Report* and looks forward to the consideration of this material in the final *2015 Dietary Guidelines for Americans*.

Sincerely,

Eric Hentges, PhD
Executive Director
ILSI North America

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