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RE: Comments on Added Sugars from ILSI North America

Dear Dr. Olson and Ms. Rihane,

The North American Branch of the International Life Sciences Institute appreciates the opportunity to share ILSI supported scientific research and expert summaries relevant to added sugars. ILSI NA 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, 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.

In comments submitted to the 2015 Dietary Guidelines Advisory Committee (DGAC) on April 25, 2014, ILSI NA summarized research that addressed “overarching concepts” articulated in the Dietary Guidelines for Americans 2010 (namely, “maintain calorie balance over time to achieve and sustain a healthy body weight” and “focus on consuming nutrient-dense foods and beverages”) (USDA and US DHHS, 2010).

Comments presented here draw from work sponsored by ILSI NA’s Carbohydrates Committee and ILSI Europe Dietary Carbohydrate’s Task Force as they relate to specific components of the DGAC Draft Concluding Statements on body weight and dental caries and of the Draft Implications Statement presented by the DGAC Added Sugars Working Group on November 11, 2014. These components follow:

Added Sugars and Body Weight Draft Conclusion Statement
• “Comparison groups with the highest versus the lowest intakes of added sugars in cohort studies were compatible with a recommendation to keep added sugars intake below 10% of total energy intake.”
Added Sugars and Dental Caries Draft Conclusion Statement

- “There is also evidence of moderate quality showing that caries are lower when free-sugars intake is less than 10% of energy intake.”

Added Sugars Draft Implications Statement

- “In order to ensure a high quality, nutrient dense dietary pattern that is balanced in calories, the U.S. population should minimize their intake of added sugars.”
- “The Committee recommends limiting added sugars to no more than 10% of total daily calorie intake. The scientific evidence on added sugars and chronic disease risk coupled with the food pattern modeling supports this limit.”
- “The Nutrition Facts Panel should include added sugars (in grams and teaspoons) and include a percent daily value in order to assist consumers in identifying the amount of added sugars in foods and beverages to help them in making informed decisions.”

In brief, ILSI sponsored work addresses these draft conclusion and implication statements, by indicating...

1) lack of a scientific basis for a dietary recommendation to limit added sugars to no more than 10% of calories, and thus no acceptable scientific basis for establishing a Daily Value for added sugars;

2) need for better understanding the role of added sugars in selecting nutritionally adequate diets within estimated energy requirements; and

3) need for consumer research on the translation of added sugars as an effective means to improve diet quality before any recommendation is made to require added sugars labeling (on Nutrition Fact Panels or other) in order to determine if consumers will use the information effectively.

ILSI North America Comments

1) ILSI-sponsored work suggests the lack of a scientific basis for a dietary recommendation to limit added sugars to no more than 10% of calories, and thus no scientific basis for establishing a Daily Value for added sugars

Excerpts below are from comments submitted by ILSI on March 31, 2014 to the World Health Organization on the WHO Draft Guideline: “Sugars Intake for Adults and Children.”

*ILSI is not a standards-setting organization, but it has considerable experience in examining available data and is active in efforts to enhance the quality of research design and interpretation (Webb et al. 2013). Given that national governments worldwide are stretched to meet the health care needs of their populations, it seems important to provide guidance in which there is considerable confidence to avoid wasting valuable resources on implementing actions that will not result in effective outcomes.*
The WHO guidance is based on two evidence-based reviews related to dental caries and obesity/overweight. The new, conditional recommendation to further reduce free sugars intake to 5 percent of total calories appears to be based solely on data from several studies that are more than 50 years old. Even so, the findings of the evidence-based review are described by the review authors as of “very low quality” (Moynihan and Kelly 2014).

ILSI reviews of literature regarding sugars and dental caries
ILSI NA reviewed the data related to dental caries as recently as September 2002 and the findings were published in 2003 (Touger-Decker and van Loveren 2003). An earlier review was conducted in 1994 and published in 1995 (König K and Navia JM 1995). This second, earlier review addresses the issue of dental caries during wartime. The 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.

ILSI Europe published a concise monograph on this topic as well (van Loveren 2009). This monograph 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. The monograph cites studies showing a decline in dental caries in children from Germany and The Netherlands from the 1960s to 2005.

ILSI contributions to the understanding of the impact of added sugars consumption on Body Mass Index (BMI)

ILSI North America supported a re-analysis of “Appendix J: Association of Added Sugars Intake and Intake of Other Nutrients” published by the Institute of Medicine in 2002. Marriott et al. 2010 combined the 2003-2006 National Health and Nutrition Examination Survey (NHANES) data (15,189 respondents, ages 4 years and older, with the U.S. Department of Agriculture My Pyramid Equivalents Database to estimate individual added sugars intake as a percentage of total energy. Respondents were then classified into 8 added sugars percent energy intake categories. Table 1 in this paper shows that the majority of individuals had an estimated intake of >5 to <20 percent of energy from added sugars, with mean daily total energy intake of 2062 kcal to 2183 kcal. Controlling for total energy intake in their analysis, this represented an estimated range of 45 to 92 mean gram-equivalents of added sugar intake daily. There were no appreciable differences between male and female respondents across the 8 categories.

The BMI for the same nationally representative sample from the United States (US) was higher for individuals with low or high intakes of added sugars, thus there does not appear to be a linear relationship between BMI and intake of added sugars for this population. Those with low added sugars intake (≤ 5 percent of energy) had a similar BMI to those with high added sugars intake (≥ 35 percent of energy): 28.9 compared to 28.1, respectively. Of persons who were overweight or obese, the highest proportions reported consuming between 5 and 15 percent of their energy
from added sugars. With each 5 percent increase in added sugars intake above 15 percent added sugars intake, a lower prevalence of overweight and obese individuals was found, until the highest category of sugars intake was reached (>35 percent).

ILSI Europe published a concise monograph, Ziesenitz et al. 2012, that reviews the available data and found that sustained overconsumption of energy, irrespective of the energy sources, leads to weight gain. The most effective means of weight loss is to reduce energy intake and increase physical activity.

With respect to the DGAC specific draft recommendation that the Nutrition Facts Panel should include added sugars, the following excerpt is relevant from ILSI NA Comments on the FDA Proposed Revisions to the Nutrition Facts labels [Docket No. FDA-2012-N-1210 RIN 0910-AF22].

ILSI NA-sponsored work is consistent with the FDA’s decision not to propose a [Daily Reference Value] DRV for added sugars, given insufficient scientific evidence. The ILSI Sugars workshop paper by Murphy and Johnson (2003) 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. (2012), 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.

2) ILSI-NA sponsored work supports the need for understanding the role of added sugars in selecting nutritionally adequate diets within estimated energy requirements.

Excerpts from ILSI NA Comments on the FDA Proposed Revisions to the Nutrition Facts labels [Docket No. FDA-2012-N-1210 RIN 0910-AF22] regarding added sugars are relevant to the DGAC 2015 recommendations.

ILSI NA-sponsored work suggests that a focus exclusively on reducing added sugars intake may not necessarily result in an improvement in essential nutrient intake. The addition of sugars to foods such as whole grains and dairy products may actually improve diet quality. As cited by Hess et al. (2012):
“The IOM suggested that added sugars should comprise no more than 25% of total calories consumed. The rationale for this maximal intake level was based on ensuring sufficient intakes of essential micronutrients that are, for the most part, present in relatively low amounts in foods and beverages that are major sources of added sugars in North American diets. After a systematic review of observational and experimental data in humans, the IOM panel concluded that although the trends were not consistent for all age groups, reduced intakes of calcium, vitamin A, iron, and zinc were observed with increasing intakes of added sugars as a percentage of energy intake, particularly at levels exceeding 25% of energy. The panel noted that not all micronutrients were examined.”

ILSI NA sponsored a project to update and expand data in Appendix Table J in the IOM Macronutrient report. Appendix Table J contained data on median intakes of selected micronutrients at 5% increments of added sugars (from 0 to >35% of energy intake) developed from NHANES III (1988-1994) data. The ILSI NA-sponsored work was based on an analysis of NHANES 2003-2006 data (Marriott et al., 2010). 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 EAR, but the overall high calorie and low quality of the U.S. diet remained the prominent issue.”

“High 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.”

The data from Appendix Table J in the IOM Macronutrient report and from Marriott et al (2012) indicate that, even at lower levels of added sugars intake, Americans have relatively poor diet quality and nutrient intakes. A focus exclusively on reducing added sugar intake may not result in an improvement in essential nutrient intake and may risk unintended consequences in some individuals related to inadequate intake of some essential nutrients.

Although, one study is not sufficient to build recommendations, this study provides a cautionary note that driving added sugars intake very low may result in unintended consequences. Focusing on reducing added sugars intake may not result in an improvement in essential nutrient intake and may increase the risk of an inadequate intake of some essential nutrients in some individuals.

3) **ILSI NA-sponsored work supports the need for consumer research on the translation of added sugars as an effective means to improve diet quality before any recommendation is made to**
require added sugars labeling (on Nutrition Fact Panels or other) in order to determine if consumers will use the information effectively.

Excerpts from ILSI NA Comments on the FDA Proposed Revisions to the Nutrition Facts Labels [Docket No. FDA-2012-N-1210 RIN 0910-AF22], regarding added sugars is relevant to the DGAC 2015 prioritizing added sugars and recommending its addition to the Nutrition Facts panel.

[In] Section II D 3 a of the FR notice [p. 11902], [FDA] recognizes that added sugars are no more likely to contribute to weight gain than other sources of calories, that the declaration of added sugars on the Nutrition Facts label would assist consumers in maintaining healthy dietary practices, and that consumer research and education would be needed. In the FR notice, the FDA states:

“The [2010 DGA] report recognized that foods containing solid fats and added sugars are no more likely to contribute to weight gain than any other source of calories in an eating pattern that is within calorie limits. However, reducing the consumption of calories from solid fats and added sugars allows for increased intake of nutrient-dense foods without exceeding overall calorie needs.” [p.11903]

“As discussed in this document, a declaration of added sugars on the Nutrition Facts label would assist consumers in maintaining healthy dietary practices by providing them with information necessary to meet the key recommendations to construct diets containing nutrient dense foods and reduce calorie intake from added sugars by reducing consumption of added sugars.” [p.11904]

“Although foods containing solid fats and added sugars do not contribute to weight gain any more than another calorie source, they make up a significant percentage of the American diet and are a source of excess calories.” [p.11904]

“We are proposing mandatory declaration of added sugars on all foods because of (1) the variability in ingredients used, (2) the need for consumers to have a consistent basis on which to compare products, (3) the need for consumers to identify the presence or absence of added sugars, and (4) when added sugars are present, the need for consumers to identify the amount of added sugars added to the food. The mandatory declaration of added sugars may also prompt product reformulation of foods high in added sugars like what was seen when trans fat labeling was mandated (Ref. 58).” [p.11904]

“Thus, as pointed out in some comments, calorie declaration and ingredient listing do not provide enough information for consumers to determine the amount of calories derived from added sugars in the food.” [p.11905]

“We acknowledge that, if finalized, a requirement for declaration of added sugars on the Nutrition Facts label will need to be accompanied by consumer education on the role of added sugars, along with solid fats, and the use of the new information on the label in overall dietary planning. We will be conducting consumer studies that include questions regarding
Consumer research is essential before a decision is made to require added sugars labeling in order to determine how consumers will interpret and use such a declaration. As indicated by the FDA’s statements, the concern with added sugars intake is overconsumption of calories from low nutrient-dense foods while meeting energy and nutrient requirements. A paper from the ILSI Sugars workshop covered findings reported by the 2000 Dietary Guidelines Advisory Committee and the IOM report on DRIs for macronutrients (Murphy and Johnson, 2003). The paper contains the following statements concerning added sugars intakes, energy intakes, and nutrient density:

“From the existing evidence, we conclude that the most likely consequences of sugars consumption beyond the levels described by the food guide pyramid are overconsumption of energy and micronutrient inadequacies. However, excess energy from any source, not just from sugars, is detrimental to the maintenance of a healthy body weight.”

“Thus, a guideline that communicates the desirability of choosing foods with a high nutrient density (preferably not solely from fortification nutrients because many of the other healthful components of foods from the food guide pyramid—eg, carotenoids, flavonoids, fibers—may still be missing) might be more effective than advice that specifically identifies sugars as being responsible for overconsumption of energy and nutrient displacement. Perhaps we need a simple message that communicates the desirability of choosing foods with a high ratio of nutrients to energy.”

The following statements were contained in another paper sponsored by ILSI NA (Hess et. al., 2012)

“...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.”

“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.”

The above statements by the FDA in the FR notice and others support the need for consumer research before recommendation or mandating added sugars labeling to determine if consumers will comprehend and use the information appropriately. In other words, if added sugars are listed including added sugars on the Nutrition Facts label. We plan to use the results of these studies to help inform our future actions on this issue.” [p.11905]
on the Nutrition Facts label, will consumers focus more on added sugars content than on calorie and nutrient content? For example, will consumers avoid nutrient dense products such as dairy products and fiber rich cereals due to the declaration of added sugars? If an objective of the proposed rule is to improve selection of foods with higher nutrient density, a greater emphasis should be placed on educational campaigns about total calories in the diet and weight gain as well as what is a nutrient dense food.

The ILSI NA Carbohydrates Committee appreciates the opportunity to provide these additional comments and evidence for consideration in developing the Dietary Guidelines for Americans, 2015.

Sincerely,

Eric Hentges, Ph.D.
Executive Director
ILSI North America
References


