

August 25, 2015

Health Canada
Office of Legislative and Regulatory Modernization
Policy, Planning and International Affairs Directorate
Address locator: 3105A
1600 Scott Street, Ottawa, ON K1A 0K9

RE: Health Canada's Regulations Amending the Food and Drug Regulation – Nutrition Labelling, Other Labelling Provisions and Food Colours

Dear Madam or Sir,

The North American Branch of the International Life Sciences Institute (ILSI North America) appreciates the opportunity to share ILSI North America's supported scientific work published in peer-reviewed journals. Evidence submitted herein provides sound science and reasoning in response to Health Canada's Regulations Amending the Food and Drug Regulation – Nutrition Labelling, Other Labelling Provisions and Food colours, and accompanying documents, published June 13, 2015.

ILSI North America is a public, non-profit organization that actively collaborates with government and academia to identify and resolve scientific issues important to public health. 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 wellbeing of the general public. ILSI North America's programs are supported primarily by industry member companies. ILSI North America's Technical Committee on Carbohydrates developed these comments on sugars and fibre.

Given the growing concern and interest in having more information about sugars on food labels, and a need to update current daily values for nutrients, Health Canada has proposed:

- Establishing a Daily Value (DV) of 100 grams as the basis for the mandatory declaration of the percent (%) DV for total sugars in the Nutrition Facts table (NFt);
- and removal of the %DV currently required in the NFt for fibre.

Concerning the proposal to require a DV of 100 grams for total sugars on the Nutrition Facts Table, ILSI North America-sponsored work supports:

1. the conclusion that there is no valid or acceptable basis for establishing a Dietary Reference Value (DRV), and hence a Daily Value (DV), for total sugars



Concerning the proposal to remove the percent Daily Value (%DV) for fibre from the Nutrition Facts Table, ILSI North America-sponsored work supports:

1. the conclusion that fibre is a nutrient of public health concern, and hence a %DV on the NfT would be a benefit to the public

Specific Comments on Sugars and Fibre

ILSI North America has sponsored workshops, research projects, and scientific papers on sugars and fibre that focused on several of the items addressed in Health Canada's proposed changes. In the following comments, ILSI North America cites Health Canada's statements in its proposed regulation amendments and supporting documents, along with the associated page numbers. We then provide relevant and/or supporting comments from workshops, research projects, and publications that have been sponsored or co-sponsored by ILSI North America.

1. ILSI North America-sponsored work supports there is no valid or acceptable basis for establishing a DRV or DV for total sugars

Health Canada is proposing to establish a DV for total sugars of 100 grams and to mandate the declaration of the % DV in the NfT, in order to help consumers determine whether a serving of food is high in sugars. Currently, the US FDA has not proposed a DV for total sugars because no dietary reference value was set due to an absence of a biomarker of risk of disease or other public health endpoint. Nonetheless, Health Canada is proposing a DV for total sugars using an approach that would be compatible with all nutrients of public health concern related to excessive intakes. [Health Canada, 2014a, Health Canada's Proposed Changes to the Core Nutrients Declared in the Canadian Nutrition Facts Table, p. 16]

ILSI North America-sponsored work does not support the setting of a DRV for total 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 level 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. The 100 gram DV proposed by Health Canada was established by using simulated diets (menu modelling) compatible with Canada's Food Guide (CFG) and dietary survey data from Canadian Community Health Survey (CCHS) 2.2 (Health Canada, 2014a; Health Canada, 2015a). The lack of



scientific rigor with this menu modelling approach is highlighted in the Federal Register Vol 79, No 41 (Food and Drug Administration, 2014, p.11895):

“We do not consider the use of food composition data, menu modeling, or dietary survey data as a suitable approach to determine Dietary Reference Values (DRVs).”

“The approach to determine DRVs using food composition data, menu modeling, or dietary surveys has a number of deficiencies. Menu modeling is an approach, based on available foods in the marketplace, to design a set of food items for meals, which will meet certain nutrient or food intake pattern recommendations. Menu modelling, by its very nature, would not permit the selection of DRVs that are based on scientific evidence related to actual public health outcomes.”

“Based on these inherent limitations of menu modeling and the data sources used, we tentatively conclude that the menu modeling approach, as recommended in the IOM Labeling Report, is an unsuitable method for determining DRVs (or RDIs). Instead, we intend to continue using science-based recommendations to set DRVs and RDIs.”

More specifically, the menu modelling done by Health Canada to establish the Total Sugars DV used 8000 simulated diets consistent with the CFG, and showed a mean calorie contribution from total sugar of 21%, ranging from 17-24%, mainly from naturally occurring sources such as dairy, fruits and vegetables (St-Pierre, 2015). The dietary survey data (CCHS 2.2) had a mean intake of calories from sugars range from 82 – 173g depending on age and gender subgroup, with an overall mean of ~20% calories from sugars (Health Canada and Statistics Canada, 2009a; Health Canada 2015). Although these two sources have similar calorie contributions from sugars (~20%), the sugars sources from the modelling was primarily from naturally occurring sources such as dairy, fruits and vegetables, while the CCHS intake data had higher intakes from soft and fruit drinks, baked goods and foods fitting into the ‘others’ category of the CFG (St-Pierre, 2015; Health Canada and Statistics Canada, 2009a; Health Canada 2015). Health Canada’s rationale for setting DVs for nutrients of public health concern due to excessive intakes, in which sugars are captured in the proposal, is based on upper limit values (Health Canada, 2014a). The DV for fat for example is proposed to be increased to 75grams to reflect the upper end of the AMDR, and sodium is being set at the upper limit of 2300 mg per day. Following this rationale, if Health Canada moves forward with a DV for total sugars, it should be set at the upper end of intakes from the dietary survey and menu modelling data, rather than the mean currently being proposed.

2. ILSI North America-sponsored work supports the need for consumer research *before* declaring a % DV for total sugars

Consumer research is essential *before* a decision is made to declare a % DV for total sugars in order to determine how consumers will interpret and use such declaration. As indicated by Health Canada’s statements, the concern with 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 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—e.g., 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 statement was contained in another paper sponsored by ILSI North America (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.”

If a % DV for total sugars is listed on the NFt, will consumers focus more on total sugars content than on calorie and nutrient content? For example, will consumers avoid nutrient dense products such as dairy products and fibre rich cereals due to the declaration of a % DV for total sugars? If an objective of the proposal is to reduce energy intake and 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.

3. ILSI North America-sponsored work supports the health benefits of fibre, the need for further understanding of the potential benefits and consumption of added/novel fibres, and the use of a %DV on the NFt to encourage intake and close the gap between intakes and recommendations

Although debates about fibre definitions have arisen, there is global consensus on the health benefits of fibre intake, and this is supported in ILSI North America publications (Jones 2006, Jones 2012, Dilzer 2013, Marriott 2010). Through epidemiological studies, fibre has been proven inversely related to a myriad of diseases and risk factors including cardiovascular disease, cancers, high blood pressure, metabolic syndrome, obesity, and diabetes (Dilzer 2013, Jones 2006). The Institute of Medicine, when setting the DRI for fibre, highlighted the need for a diet rich in fibre,



stating *“A lack of these fibres in the diet can cause inadequate fecal bulk and may detract from optimal health in a variety of ways depending on other factors, such as the rest of the diet and the stage of the life cycle.”* (Institute of Medicine, 2006).

Despite the knowledge of the importance of fibre intake and public messaging encouraging consumption, there remains a gap between the recommended intakes and consumption (Dilzer 2013). In the United States, analysis of the NHANES 2003-2006 data by Marriott et al (2010) highlights the low intakes of both potassium, a nutrient Health Canada has identified as a nutrient of public health concern, and fibre (Marriott 2010, p 236, 246):

“Among nutrients for which there is only an AI, potassium and fiber has the lowest percent of the population across life-stage groups that exceed the AI”

“The estimated fiber intakes were very low. With the exception of older women (51+y), only 0 to 5% of individuals in all other life stage groups had fiber intakes meeting or exceeding the AI. The estimated total fiber in grams was lower in females (12 to 15g/d) than males (15 to 18 g/d) for all life-stage groups.”

“The Dietary Guidelines (DHHS/USDA, 2005) emphasized the selection of fiber-rich foods, and provided clear information on the multiple health values of a fiber-rich diet. However, clearly more public-health education is needed to address the low fiber intakes of our population.”

The Dietary Guidelines Advisory Committee (DGAC) for over a decade has emphasized the importance of a fibre rich diet, and the gap between recommendations and consumption in the United States (U.S. Department of Health and Human Services and U.S. Department of Agriculture 2005, 2015). This is highlighted throughout the 2015 DGAC report (p.2, 9):

“Of the shortfall nutrients, calcium, vitamin D, fiber, and potassium also are classified as nutrients of public health concern because their underconsumption has been linked in the scientific literature to adverse health outcomes.”

“A diet emphasizing a variety of nutrient-dense foods will help shift consumption towards the recommended intake levels of these shortfall nutrients. The U.S. population should increase consumption of foods rich in potassium and fiber.”

In Canada, the gap between fibre intakes and recommendations has also been established. Health Canada has commented on this, and encouraged food manufacturers to create innovative solutions to address the problem (Health Canada, 2010, p.4):

“In Canada, surveys of nutrient intakes from foods indicate that mean dietary fibre intakes ranged from 14.3 to 16.6 g/d for women and from 16.5 to 19.4 g/d for men, in 2002.”



“The discrepancy between fibre intake and recommendations has provided food manufacturers the opportunity to help the Canadian population meet target intakes by developing new fibre-like products such as non-digestible oligosaccharides, resistant starch, resistant malodextrin, and other modified and synthetic substances”

The initiative to introduce novel fibre sources into the Canadian food supply has been successful, but has introduced new knowledge gaps around the health benefits and intake level of these sources of fibre. This issue was discussed at an ILSI North America-sponsored session at the 2011 American Association of Clinical Chemistry International Annual Meeting (Jones 2012):

“Added fiber is often not reflected in current databases or diet assessment tools used in epidemiological studies, such as food frequency questionnaires; understanding the potential benefits and possible synergies achieved through this kind of supplementation requires much more research. Additionally, food composition databases are outdated and need to be kept current by the food industry”

The CCHS 2.2 data also shows that fibre intakes are below the current recommendations, with an average of 16.5 to 19.4 g/d for men and 14.3-16.6 g/d for women across age groups (Health Canada and Statistics Canada, 2009b) Summarized in Health Canada’s 2012 ‘Do Canadian Adults Meet their Nutrient Requirement through Food Intake Alone?’ document, Canadians are not meeting needs for potassium and fibre, similar to the US NHANES findings (Health Canada, 2012a). However, this document sheds light on the information gap of consumption of novel fibres, but maintains the overall message that fibre intake should be promoted in Canadians:

“For each of these age and gender groups, the median fibre intake fell below their respective AIs. Thus, an assessment of Canadian adults’ fibre intake is not possible. The AI is based on total fibre intakes which encompass both naturally occurring dietary and functional fibre. Since the Canadian Nutrient File does not contain data on functional fibre (ie. Isolated, extracted or synthetic fibre added to food), the estimated fibre intakes of Canadian adults in CCHS 2.2 only reflects naturally occurring dietary fibre intake”

It is important to note that although this information gap on Canadians’ consumption of novel fibre exists, Health Canada maintained the overall message in the 2012 document that it is a nutrient of public health concern, stating that “*Despite this likely underestimation of (fibre) intake, the importance of an appropriate fibre intake should still be promoted to the Canadian population*”. To our knowledge there currently remains no data on novel fibre consumption in Canada and this information will greatly assist in determining if fibre remains a nutrient of public health concern, and should be gathered before removing the %DV for fibre.

In the 2014 Proposal for Daily Values Changes (Health Canada, 2014b, p.11) and in the 2015 Proposed Changes to the Nutritional Information on Food Labels Webinar, Health Canada expressed that while fibre content of foods would no longer be conveyed through a %DV, they can be shown through content claims. While this approach does allow consumers to identify foods that provide a source of fibre, it does not allow consumers to distinguish between foods offering more than 6 grams of fibre per serving as the policy for “source of fibre”, “high source of fibre”, and “very high source of fibre” are set at 2, 4, and 6 g of fibre per serving, respectively (Health Canada, 2012b, p10).



Concluding Comments on Sugars

ILSI North America-sponsored work supports a lack of a scientific basis for establishing a DV or DRV for total sugars. Reducing sugars intakes alone will not necessarily result in diets that are nutritionally adequate or within estimated energy requirements. The presence of sugars in nutrient dense foods may actually improve diet quality. Consumer research will help inform a decision to require a %DV for total sugars in order to determine if consumers will comprehend and use the information appropriately and could be coupled with an emphasis on educating the consumer about selecting foods with greater nutrient density.

Concluding Comments on Fibre

ILSI North America-sponsored work supports the health benefits associated with fibre intake, and the need to better understand the effects of novel fibre. There is also a need to keep databases up to date to reflect the fibre content of current products on the market to allow better understanding of fibre consumption among Canadians. ILSI North America-sponsored work also supports the conclusion that fibre is a nutrient of public health concern due to inadequate intake based on survey data, and the continued need for promotion of fibre consumption through the use of a %DV for fibre on the NfT. Removal of the %DV for fibre may confuse consumers and reduce fibre intake. Further information on functional/novel fibre consumption in Canada will assist in determining if fibre remains a nutrient of public health concern, and should be gathered and analyzed *before* removing the %DV for fibre.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Hentges".

Eric Hentges, PhD
Executive Director
ILSI North America



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