

August 1, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5360 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2012-N-1210 RIN 0910-AF22

Dear Madam or Sir,

The North American Branch of the International Life Sciences Institute (ILSI NA) appreciates the opportunity to share ILSI NA supported scientific research published in peer-reviewed journals and/or presented recently by experts in nutrition, dietary assessment and epidemiology. Evidence submitted herein provides sound science and reasoning in response to the Food and Drug Administration's (FDA) proposed revisions to the Nutrition and Supplement Facts labels that were published in the March 3, 2014 Federal Register (Docket No. FDA-2012-N-1210 RIN 0910-AF22).

ILSI NA 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 NA's programs are supported primarily by industry member companies. ILSI NA's Technical Committee on Carbohydrates developed these comments on added sugars and dietary fiber.

Concerning the proposal to require declaration of the amount of added sugars to the Nutrition Facts label, ILSI NA-sponsored work supports:

1. a need for added sugars definitions used by various federal agencies to be consistent;
2. the conclusion that added and naturally occurring sugars cannot be differentiated analytically or physiologically;
3. the conclusion that there is no valid or acceptable basis for establishing a Dietary Reference Value (DRV), and hence a Daily Value (DV), for added sugars;
4. a need for understanding the role of added sugars in selecting nutritionally adequate diets within estimated energy requirements; and
5. the need for consumer research *before* a decision is made to require added sugars labeling in order to determine if consumers will comprehend and use the information appropriately and must be coupled with an emphasis on educating the consumer about selecting foods with greater nutrient density.

Specific Comments on Added Sugars

ILSI NA has sponsored workshops, research projects, and scientific papers on sugars that focused on several of the items addressed in FR notice. For example, ILSI NA and ILSI Europe held a Sugars and Health workshop in 2002 (ILSI Sugars workshop) which involved a group of internationally recognized experts on selected topics relevant to sugars. The ILSI Sugars workshop followed a process pioneered by John Dobbing, Department of Child Health, University of Manchester, UK, to foster group consensus building. According to the Dobbing process, the experts were asked to write short review papers on specific topics posed to them in advance of the workshop. The papers were circulated to all of the authors, and each author was asked to review the papers and prepare written critical comments. The commentaries on each paper were given to those papers' authors before the workshop. Authors were asked to consider all published papers and reports with a focus on human health that had scientific validity. During the workshop, authors presented a 20-minute summary and discussion of their papers, and the remainder of the workshop was devoted to questions from and discussion by the other authors and invited participants. Comments from these discussions on the manuscripts were included in the final draft of the paper. The workshop proceedings were published in the *American Journal of Clinical Nutrition* in 2003. While there has been a significant amount of research added to the literature over the past 10 years, many of the issues that were raised in 2002 remain unresolved.

In the following comments, ILSI NA cites the FDA's statements in the FR notice along with the associated page numbers. We then provide relevant and/or supporting comments from workshops, research, and publications that have been sponsored or co-sponsored by ILSI NA.

1. ILSI NA- sponsored work supports a need for consistency in the added sugars definitions used by federal agencies as well as by scientists, health professionals, manufacturers, and others

Section II D 3 b of the FR notice [p. 11906] proposes a definition for "added sugars." In the FR notice, the FDA states:

"In proposed § 101.9(c)(6)(iii), we are proposing to define "added sugars" as sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners. This would include single ingredient foods such as individually packaged table sugar. Sugar alcohols are not considered to be added sugars. Names for added sugars include: Brown sugar, corn sweetener, corn syrup, dextrose, fructose, fruit juice concentrates, glucose, high-fructose corn syrup, honey, invert sugar, lactose, maltose, malt sugar, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose." [p.11906]

Consistency is needed in the definition of added sugars across federal agencies as well as by scientists, health professionals, manufacturers, and others. One of the ILSI Sugars workshop papers addressed defining and interpreting intakes of sugars that were relevant to the United States and the focus of the workshop. The following comments are relevant to FDA's proposed definition of added sugars (Sigman-Grant and Morita, 2003).

"Whereas there is concordance about the chemical definitions, these terms are not used to communicate information about sugars. Rather, in the United States, 4 distinctly different

terms—*added sugars, sugars, sugar, and caloric sweeteners*—are used by 2 government agencies. The US Department of Agriculture (USDA) issues dietary guidance, and the Food and Drug Administration (FDA) regulates foods and food ingredients. Each term is described in detail in Table 2.” [A copy of Table 2 from this paper follows.]

TABLE 2
Definitions

Term used	Source	Definition	Measurement
Consensus definitions used within workshop			
Sugars	Consensus	Refers to monosaccharides and disaccharides (1 and 2 monomers only); sometimes seen in the literature as simple sugars	
Sugar	Consensus	Refers strictly to sucrose	
Oligosaccharides	Consensus	Refers to compounds containing 3–9 monomers	
Commonly used definitions to describe sugars in food			
Added sugars	Food Guide Pyramid (US Departments of Agriculture and Health and Human Services; 8)	Eaten separately or used as ingredients in processed or prepared foods (such as white sugar, brown sugar, raw sugar, corn syrup, corn syrup solids, high-fructose corn syrup, malt syrup, maple syrup, pancake syrup, fructose sweetener, liquid fructose, honey, molasses, anhydrous dextrose, and crystal dextrose). May contain oligosaccharides	Teaspoon
Sugars	Food Label—in the <i>Nutrition Facts Panel</i> (Food and Drug Administration; 9)	All monosaccharides and disaccharides (includes naturally occurring sugars as well as those added to a food or drink, such as sucrose, fructose, maltose, lactose, honey, syrup, corn syrup, high-fructose corn syrup, molasses, and fruit juice concentrate). Any oligosaccharides present in these compounds are not counted.	Grams
Sugar	Food Label—in the <i>Ingredients Statement</i> (Food and Drug Administration; 9)	Indicates sucrose in ingredients statement	None
Caloric sweeteners	Food Disappearance Data (Economic Research Service, US Department of Agriculture; 10)	Sweeteners consumed directly and as food ingredients (such as sucrose (from refined cane and beet sugars), honey, dextrose, edible syrups, and corn sweeteners (primarily high-fructose corn syrup); contains oligosaccharides	Grams Teaspoons

Reprinted from Sigman-Grant and Morita (2003). Copyright 2003. Open Access.

“Added sugars (USDA) and caloric sweeteners [Economic Research Service (ERS), USDA] omit naturally occurring sugars, such as those in fruit and dairy products. Although the FDA includes only monosaccharides and disaccharides in its sugars category on the Nutrition Facts label, the ERS includes oligosaccharides present in the various high-fructose and nonfructose corn syrups in its caloric sweeteners category. Confusion exists about whether boiled (stripped, deodorized, and decolorized) fruit juices are included within the added sugars categories, but the FDA does include them as a component of total sugars for the Nutrition Facts Label. In addition, in 2002, the FDA issued a regulation that prohibits the claim of “no added sugar” for products containing any amount of sugars added during processing or packing or any other ingredient that contains sugars that functionally substitute for added sugars (eg, jam, jelly, and concentrated fruit juice).”

“In common vernacular, *sugar* refers only to table sugar (sucrose). The ultimate result of these multiple definitions is the potential for inconsistency and misinterpretation by consumers, scientists, and regulators alike. This is of major concern when addressing the issues of sugars and health because the body cannot distinguish naturally occurring monosaccharides and disaccharides from those added to food during processing, during cooking, or at the table or from those formed during the digestion of complex dietary carbohydrates.”

The ILSI Sugars workshop consensus (Sigman-Grant and Morita, 2003) was that *consistency of definitions across federal agencies is important*. Without a common language, accurate and precise measurements, and consensus among scientists, educators, regulatory agencies, and the public,

conversations regarding any health effects of sugars may lead to continued misunderstandings. Furthermore “...attempts should be undertaken to propose and adapt common terms used by regulators, scientists, manufacturers, and consumers alike. Agreement about which foods and ingredients to include and exclude would require commitment from all parties involved. Such efforts would open the path for better understanding, communication, and health.”

Fruit juice concentrate is one example of inconsistency among federal agencies that should be addressed. A paper supported by ILSI NA (Hess et al. 2012) contained the following statement:

“The USDA developed a database that estimates the added sugars content of over 2000 common foods. To compile the database, the USDA estimated added sugar values from sugars listed as label ingredients and nutrient values for total sugars and total carbohydrates. Sugar values were taken from the National Nutrient Database for Standard Reference. Fruit juice concentrates were counted as added sugars when used as an ingredient and not reconstituted as juice. If reconstituted pear juice was added to canned fruit, it was not counted as an added sugar.”

In the FDA’s proposed definition for added sugars, it is not clear if all fruit juice concentrates listed in an ingredient statement would be considered an added sugar or only those that are not reconstituted as full strength juice.

2. ILSI NA-sponsored work supports the conclusion that naturally occurring and added sugars cannot be differentiated analytically or physiologically

Section II D 3 a of the FR notice [p. 11902] proposes the mandatory declaration of “added sugars” but recognizes that added and naturally occurring sugars cannot be differentiated analytically or chemically. In the FR notice, the FDA states the following regarding the proposed declaration of added sugars, separate from total sugars, on the Nutrition Facts label:

“The IOM Report on Macronutrients stated that “although added sugars are not chemically different from naturally occurring sugars, many foods and beverages that are major sources of added sugars have lower micronutrient densities compared to foods and beverages that are major sources of naturally occurring sugars” (Ref. 68).” [p.11903]

“We understand that there are currently no analytical methods that are able to distinguish between naturally occurring sugars and those sugars added to a food.” [p.11905]

“We continue to recognize the lack of a physiological distinction between added and naturally occurring sugars.” [p.11905]

ILSI NA-sponsored work is consistent with the FDA’s recognition of the lack of physiological and analytical distinction between added and naturally occurring sugars. The ILSI Sugars workshop paper by Murphy and Johnson (2003) specifically addressed the question: *Should added sugars be distinguished from naturally occurring sugars when offering dietary advice to the public?* The following are excerpts from the paper:

“The DGAC’s discussion regarding added compared with naturally occurring sugars centered on several issues. First, the 2 types of sugars are indistinguishable chemically and physiologically.”

“Because added sugars cannot be chemically distinguished from naturally occurring sugars, label values for added sugars would be difficult to monitor with current analytic methods.”

“In the final section of the DGAC report, there is a call for a better definition of total sugars and added sugars and more research to determine whether there are reasons to distinguish between the 2 in the *Dietary Guidelines*.”

“Efforts to separate the effects of added sugars from those of naturally occurring sugars have been aided by the availability of the Pyramid Servings Database from the US Department of Agriculture (7), which gives the added sugars content of all foods reported during the 1994–1996 and 1998 Continuing Surveys of Food Intake by Individuals (CSFIIs). However, a complete investigation of the effects of the 2 categories of sugars would require analyses in which their comparative effects on health outcomes were examined. Unfortunately, the primary food-composition tables in use in the United States do not contain composition information for naturally occurring sugars, and thus it is has not been possible to directly compare the effect of these categories of sugars on health outcomes.”

3. ILSI NA-sponsored work supports there is no valid or acceptable basis for establishing a DRV or DV for added sugars

Section II D 3 c of the FR notice [p. 11906] does not propose a DRV for added sugars. In the FR notice, the FDA states:

“We reviewed scientific evidence and recommendations of consensus reports, and disagree with the petitioner and comments that there is currently a sound scientific basis for the establishment of a quantitative intake recommendation upon which a DRV could be derived.” [p.11906]

“Thus, we have no scientifically supported quantitative intake recommendation for added sugars on which a DRV for added sugars can be derived. Therefore, we are not proposing a DRV for added sugars. Accordingly, the proposed rule, if finalized, would declare added sugars on the Nutrition Facts label only in absolute amounts (in g), similar to the declaration of total sugars.”[p.11906]

ILSI NA-sponsored work is consistent with the FDA’s decision not to propose a 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.

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

Section II D 3 a of the FR notice [p. 11902] proposes the mandatory declaration of “added sugars” to assist consumers in maintaining healthy dietary practices and recognizes that small amounts of added sugars can increase palatability of nutrient dense foods. In the FR notice, the FDA states:

“Added sugars contribute an average of 16 percent of the total calories in American diets (Ref. 6). According to NHANES, the major sources of added sugars in the diet in descending order are soda, energy and sports drinks, grain based desserts, sugar-sweetened fruit drinks, dairy-based desserts and candy. Most of these foods are not nutrient dense and may add calories to the diet without providing dietary fiber or essential vitamins and minerals (Ref. 6). The consumption levels of added sugars alone exceed the discretionary calorie recommendations of 5 to 15 percent of calories from both solid fats and added sugars discussed in the 2010 DGA.” [p.11904]

“...we tentatively conclude that the declaration of added sugars is required to assist consumers in maintaining healthy dietary practices.” [p.11905]

“We recognize that small amounts of added sugars can increase the palatability of nutrient-dense foods, as suggested by a comment.” [p.11905]

“The IOM FOP report noted that small amounts of added sugars would be appropriate for foods to earn FOP points in their recommended labeling scheme, which suggests that small amounts would be appropriate in a balanced diet (Ref.29).” [p.11905]

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 sugars 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. This suggests that a more effective strategy to promote increased micronutrient intake would be to communicate that specific objective, as discussed further in comment 5.

5. ILSI NA-sponsored work supports the need for consumer research *before* requiring added sugars labeling as well as an emphasis on consumer education

Section II D 3 a of the FR notice [p. 11902] 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 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]

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 statement was 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* mandating added sugars labeling to determine if consumers will comprehend and use the information appropriately. In other words, if added sugars are listed 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.

Concluding Comments on Added Sugars

ILSI NA-sponsored work supports the need for a consistent definition of added sugars across federal agencies, the conclusion that added and naturally occurring sugars cannot be differentiated analytically or physiologically, and the lack of a scientific basis for establishing a DV or DRV for added sugars. Reducing added sugars intakes alone will not necessarily result in diets that are nutritionally adequate or within estimated energy requirements. Addition of sugars to nutrient dense foods may actually improve diet quality. Consumer research is needed *before* a decision is made to require added sugars labeling in order to determine if consumers will comprehend and use the information appropriately and must be coupled with an emphasis on educating the consumer about selecting foods with greater nutrient density.

References for Added Sugars Comments

- Hess J, Latulippe ME, Ayoob K, Slavin J. *The confusing world of dietary sugars: definitions, intakes, food sources and international dietary recommendation*. Food Funct 2012;3(5):477–86.doi:10.1039/c2fo10250a.
- Marriott BP, Olsho L, Hadden L, Connor P. *Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003–2006*. Crit Rev Food Sci Nutr 2010;50:228–258.
- Murphy SP, Johnson RK. *The scientific basis of recent US guidance on sugars intake*. Am J Clin Nutr 2003;78(4):827S–833S.
- Sigman-Grant M, Morita. *Defining and interpreting intakes of sugars*. Am J Clin Nutr 2003;78(4):815S–826S.
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Concerning the proposal to update the dietary fiber definition and its representation on the Nutrition Facts Label (Section II D 5 of the FR notice pages 11909-11912), ILSI NA-sponsored work is consistent with:

1. a single definition for dietary fiber that is equivalent to the IOM definition¹ for "total fiber" rather than separate definitions of "dietary fiber" and "functional fiber,"
2. adoption of a definition for total fiber that includes a DP of ≥ 3 , consistent with the definition established by the IOM,

3. with the inclusion of isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that have studies demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health,
4. acceptance of 'all-inclusive' methods of analysis (AOAC 2009.01 and AOAC 2011.25) to measure dietary fiber in foods,
5. the caloric value of soluble dietary fiber be no greater than 2 kcal/g with lower values accepted based on scientific evidence from properly designed studies (optionally supported by animal and in vitro data),
6. a regulatory definition for dietary fiber should be one that emphasizes its physiological effect that is beneficial to human health.

Specific Comments on Dietary Fiber

In the following comments, ILSI NA cites the FDA's statements in the FR notice along with the associated page numbers. We then provide relevant and/or supporting comments from workshops, research, and publications that have been sponsored or co-sponsored by ILSI NA.

1. ILSI NA work is consistent with the IOM definition for total fiber and has harmonized with key elements of the CODEX definition (Section II, 5, a. i, pg 11909)

A harmonized definition supports global consistency in research, dietary recommendation development, and labeling. For example, products from different countries (eg, the United States and Canada) could have different amounts of dietary fiber in their nutrition facts labels because of different local fiber regulations. Variation in the definition of dietary fiber prohibits comparison of research findings and inhibits building a body of scientific evidence that might support a health benefit. For this reason, organizations are working toward achieving global consensus to assist regions that are struggling to define fiber. (Dilzer, A., et al., 2013; National Research Council 2005; Codex Alimentarius, revised 2013)

In all definitions, fiber is considered a CHO polymer that resists digestion or absorption in the small intestine. Codex, Food Standards Australia and New Zealand, EFSA, EC, American Association of Cereal Chemists International, Health Canada, and IOM all agree that dietary fiber is resistant to human enzymes and is non-digestible/absorbable in the small intestine. These organizations also agree that dietary fiber includes polymers with degrees of polymerization of 3 or greater. (Dilzer, A., et al., 2013)

In addition, many contributors to the debate were of the view that to provide a discretionary approach at the national level to excluding or including carbohydrate fractions within the scope of the definition was undesirable. For nutrition research and assessment, the absence of a common definition creates difficulties for the comparison of fiber intakes across different geographic regions and in the interpretation of studies assessing possible beneficial physiological effects where datasets are drawn from different regions. (Howlett, J. F., et al., 2010)

2. ILSI NA work is consistent with adoption of a definition for total fiber that includes a DP of ≥ 3 , consistent with the definition established by the IOM (and in harmony with CODEX) (Section II, 5, a. i, pg 11909)

All those who spoke at the Ninth Vahouny Fiber Symposium regarding the physiological aspects argued that there was no basis for distinguishing between carbohydrates with a DP ≥ 10 and those

with $DP \leq 9$ because there were carbohydrates both above and below this cutoff point that exhibited one or more beneficial physiological effect(s) generally associated with fiber. The view was expressed that carbohydrates exhibiting beneficial physiological effects are distributed along a continuous spectrum of chain lengths with no clear differentiation at any particular DP. (Howlett, J. F., et al., 2010)

ILSI NA work is consistent with FDA's alignment with the CODEX definition (Codex Alimentarius, revised 2013) as follows: Dietary fiber consists of carbohydrate polymers of three or more monomeric units, which are not hydrolyzed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible Carbohydrate polymers naturally occurring in the food as consumed,
- Carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence,
- Synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence

3. ILSI NA work is consistent with inclusion of isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that have studies demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health (Section II, 5, a. i, pg 11909)

"...Codex Committee on Nutrition and Foods for Special Dietary Uses. The definition under consideration states:

Dietary fibre consists either of Edible, naturally occurring in the food as consumed, non-digestible material composed of carbohydrate polymers* with a degree of polymerization (DP) not lower than 3, or of Carbohydrate polymers ($DP \geq 3$), which have been obtained from food raw material by physical, enzymatic or chemical means, or of Synthetic carbohydrate polymers ($DP \geq 3$). Dietary fiber is neither digested nor absorbed in the small intestine and has at least one of the following properties:

- Increase stools bulk
- Stimulate colonic fermentation
- Reduce blood total and/or LDL cholesterol levels
- Reduce post-prandial blood glucose and/or insulin levels." (Jones, J. R., et al., 2006)

4. ILSI NA work is consistent with methods of analysis (AOAC 2009.01 and AOAC 2011.25) to measure dietary fiber in foods (Section II, 5, a. iii, pg 11910)

The AOAC analytical methods detect the fiber in food that comes from various sources: naturally occurring within the food, added fibers such as gums and pectins, and synthetic fibers or modified such as modified cellulose. These methods cannot distinguish dietary fibers by source. Despite this limitation, some organizations differentiate between that which is intrinsic (present within food as consumed) and that which is extrinsic (added to food). Codex considers both forms to be "dietary fiber." (Dilzer, A., et al., 2013)

5. ILSI NA work is consistent with the caloric value of soluble dietary fiber being no greater than 2 kcal/g with lower values accepted based on scientific evidence from

properly designed studies (optionally supported by animal and in vitro data) (Section II, 5, b.vi, pg 11912)

We agree that the caloric value of soluble dietary fiber be no greater than 2 kcal/g. (National Research Council, 2005)

6. ILSI NA work is consistent with a definition for dietary fiber should be one that emphasizes its physiological effect that is beneficial to human health (Section II, 5, a. i, pg 11909)

Although Codex requires demonstration of a physiological effect for certain types of fibers, the specific effects that can be included were not specified in the final definition. (Codex Alimentarius, 2013; Dilzer, A., et al., 2013)

Note: Health Canada from 2012 at <http://www.hc-sc.gc.ca/fn-an/legislation/pol/fibre-label-etiquetage-eng.php>

However, during the consultation, many stakeholders asked for more explicit guidance on the physiological effects recognized by Health Canada. In response to this request, Health Canada considers that the physiological effects listed below are functions of dietary fibre and are acceptable as a physiological effect of novel fibre sources. However, they are not exclusive and other effects attributable to dietary fibre may be recognized by Health Canada as science evolves.

Dietary fibre:

- improves laxation or regularity by increasing stool bulk;
- reduces blood total and/or low-density lipoprotein cholesterol levels;
- reduces post-prandial blood glucose and/or insulin levels;
- provides energy-yielding metabolites through colonic fermentation.

Research suggests that dietary fiber consumption may promote a host of physiological effects. During a discussion among international experts in fiber science at the Tenth Vahouny Fiber Symposium the following physiological effects received strong support: (Craig, S. A. S., 2014)

1. Reduced blood total and/or LDL cholesterol levels
2. Attenuation of postprandial glycemia/insulinemia
3. Reduced blood pressure
4. Increased fecal bulk/laxation
5. Decreased transit time
6. Increased colonic fermentation/short chain fatty acid production
7. Positive modulation of colonic microflora
8. Weight loss/reduction in adiposity
9. Increased satiety

Concluding Comments on Dietary Fiber

As noted in the paper from the Ninth Vahouny Fiber Symposium (Howlett, J. F., et al. 2010), "The results of this session are encouraging and indicated that the scientific community agrees on maintaining a worldwide consensus regarding the inclusion of non-digestible carbohydrates with \geq DP3 as dietary fiber and on a core, non-exhaustive list of beneficial physiological effects that dietary fibers have. These results are consistent with previous worldwide agreements." The consensus concept for harmonization of dietary fiber definitions, whether it is IOM, Health Canada, CODEX, or

the American Association of Cereal Chemists, has been prevalent throughout the body of work by ILSI NA and is consistent with FDA's proposals for the Nutrition Facts Label. Within the peer reviewed literature and across expert presentations at major workshops there is consistent agreement regarding a single definition for total dietary fiber, with inclusion DP of ≥ 3 , isolated and synthetic non-digestible carbohydrates, and an emphasis on physiological effect that is beneficial to human health.

References for Dietary Fiber Comments

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