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Health Canada's Proposed Changes to the Core Nutrients Declared in the Canadian Nutrition Facts Table

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Canada

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List of Abbreviations

AI	Adequate Intake
CCHS	Canadian Community Health Survey
CHMS	Canadian Health Measures Survey
CFG	Canada's Food Guide
CV	Coefficient of Variation
DRI	Dietary Reference Intake
DV	Daily Value
EAR	Estimated Average Requirement
FDR	*Food and Drug Regulations*
IOM	Institute of Medicine
NFt	Nutrition Facts table
US FDA	United States Food and Drug Administration
WHO	World Health Organization

1. Executive summary

In response to a commitment identified in the *2013 Speech from the Throne* to consult with Canadian parents and consumers on ways to improve nutritional information on food labels, Health Canada is undertaking a broad review of the nutrition labelling regulations. This review has led to proposed revisions to the list of core nutrients, specifically micronutrients (except sodium) and sugars, to be declared in the Nutrition Facts table (NFt).

Intake data from the Canadian Community Health Survey (CCHS) 2.2 were used to identify inadequate micronutrient intakes. If available, biomarkers and/or evidence of clinical signs of deficiency were used to validate or further assess whether a micronutrient is of public health concern and therefore should be declared in the NFt.

Based on this examination, with respect to micronutrients subject to mandatory declaration Health Canada proposes to:

1) add vitamin D and potassium
2) remove vitamins A and C; and
3) retain calcium and iron.

The proposed core micronutrients would be aligned with those recently proposed by the United States Food and Drug Administration (US FDA).

The remaining core nutrients currently required in the NFt will not be discussed further in this document as Health Canada is proposing to maintain their mandatory declaration. However, given the growing concern and interest in having more information about sugars on food labels, three approaches will be discussed in this document:

1) adding the declaration of "added sugars" to the NFt, similar to what the US FDA is proposing;
2) using a Daily Value (DV) of 100 grams as the basis for the mandatory declaration of the percent (%) DV for total sugars in the NFt; and
3) grouping all sugars-based ingredients under one ingredient termed "sugars" in the list of ingredients.

2. Purpose

The purpose of this document is to outline Health Canada's proposed changes to the list of core nutrients in the NFt with the intent to make this section of the NFt more relevant to Canadian consumers and to solicit feedback from interested stakeholders.

3. Current Context

On January 28, 2014, the Minister of Health announced the launch of a consultation with Canadian parents and consumers on ways to improve nutritional information on food labels, in response to a commitment identified in the 2013 *Speech from the Throne*. The initial phase of the consultation consisted of an online questionnaire and face-to-face roundtable discussions with Canadian parents and consumers in selected locations across Canada. This phase of the consultation closed on April 30, 2014. A *What We Heard* report has been prepared to provide an overview of the feedback received.

Health Canada is now entering into consultations with the broader stakeholder community on other technical aspects of the NFt, including the proposed changes to the list of core nutrients described in this document. Separate consultation documents have been prepared on other aspects of the NFt, specifically serving size, reference amounts, the Daily Values (DVs), and format. Input from all of these consultations and earlier feedback received from Canadian parents and consumers, will be used in conjunction with other data sources in the development of proposed amendments to the nutrition labelling regulations.

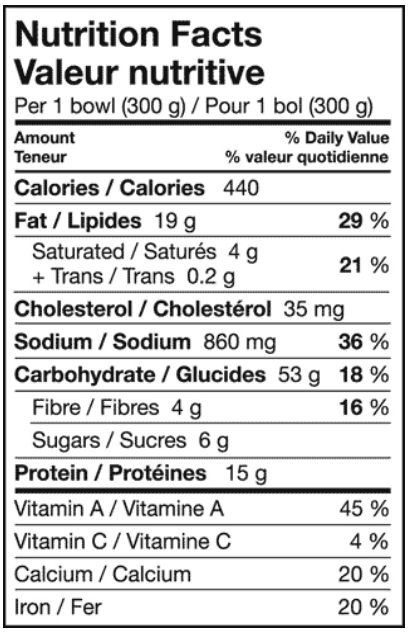
4. Background

4.1 Nutrition Labelling in Canada

On December 12, 2002, the Government of Canada promulgated regulatory amendments to the *Food and Drug Regulations* (FDR), requiring most pre-packaged foods to carry an NFt in a consistent format. The regulations on nutrition labelling aim at preventing injury to the health of Canadians, including those with special dietary needs, by providing product-specific nutrient information to assist in making informed food choices (see **Appendix A:** History of Nutrition Labelling in Canada). Nutrition labelling requirements include the declaration of the energy value and nutrient content as well as format considerations of the NFt (see Figure 1).

Figure 1. Example of the Current Nutrition Facts Table

- Core list of Calories and 13 nutrients always declared
- Actual amount of the nutrient in the stated serving of the food is listed for macronutrients and sodium



Nutrition Facts
Valeur nutritive
Per 1 bowl (300 g) / Pour 1 bol (300 g)

Amount / Teneur	% Daily Value / % valeur quotidienne
Calories / Calories 440	
Fat / Lipides 19 g	**29** %
Saturated / Saturés 4 g + Trans / Trans 0.2 g	**21** %
Cholesterol / Cholestérol 35 mg	
Sodium / Sodium 860 mg	**36** %
Carbohydrate / Glucides 53 g	**18** %
Fibre / Fibres 4 g	**16** %
Sugars / Sucres 6 g	
Protein / Protéines 15 g	
Vitamin A / Vitamine A	45 %
Vitamin C / Vitamine C	4 %
Calcium / Calcium	20 %
Iron / Fer	20 %

- The nutrient information is based on a specified amount of food as sold (serving size)
- % Daily Value (% DV) indicates the amount of the nutrient relative to the Daily Value

4.2 Core Nutrients on the Nutrition Facts Table in Canada

Core nutrients refer to the nutrients whose declaration is mandatory for most NFts (exceptions exist for Simplified Formats and Foods Intended Solely for Children Under two Years of Age). Currently, it is mandatory to declare calories and 13 nutrients: fat, saturated fat, *trans* fat, cholesterol, sodium, carbohydrate, fibre, sugars, protein, vitamin A, vitamin C, calcium and iron. In addition, all micronutrients that have been added to foods during processing or are the subject of a nutrient content claim must be declared.

5. Proposed Changes to the List of Core Micronutrients in the Nutrition Facts Table

Except for sodium, the declaration of all other micronutrients in the NFt was made mandatory because of public health concern related to inadequate intakes. Nutrients are considered to be of public health concern related to inadequate intakes if there is an indication that despite intervention strategies, for example, dietary guidance, labelling, and fortification programs in place: (1) the intakes of a significant proportion of the population is lower than the estimated average requirements (EARs) (see **Appendix B:** Lexicon for more information) and (2) this may have serious implications for the health of the general population.

The changes to the core nutrients proposed in this document focuses mostly on micronutrients that are of public health concern related to inadequate intake. Therefore, sodium, which is a

micronutrient of public health concern related to excessive intake will continue to be declared in the NFt and will not be discussed. Health Canada specifically examined micronutrients because a 2012 Health Canada survey of Canadian consumers found that, when comparing products, the least used elements within the NFt – used by about one-third or fewer respondents, included: calcium, iron, vitamin C and vitamin A [1]. Given that the declaration of vitamins and minerals is the least used part of the NFt by consumers, Health Canada plans to conduct some focus group testing to determine whether there is a need to improve the usability of this information through a more meaningful declaration or through specific education messages.

5.1 Approach Used to Determine Micronutrients of Public Health Concern Related to Inadequate Intake

Step 1. Identifying Shortfall Nutrients

Analysis of intake data from CCHS 2.2 was used to create a shortlist of nutrients with inadequate intake in a significant proportion of the Canadian population. Using a cut-off of more than 10% of intakes below the EAR, the following nutrients were identified as shortfall nutrients (see Table 1):

- Minerals: calcium, phosphorus, magnesium and zinc;
- Vitamins: folate, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C and vitamin D.

For nutrients without an EAR, if the mean intake was greater than the Adequate Intake (AI), low prevalence of inadequacy was assumed. Potassium intakes were below the AI for more than 80% of Canadians across all age and sex groups and therefore, this nutrient was further examined.

The estimation of iron inadequate intakes was carried out by full probability approach. Although, the intake data suggests that there is a low prevalence of inadequate intake, iron status was examined to determine whether there was still a rationale for retaining iron as a core nutrient.

Step 2. Determining if Nutrients are of Public Health Concern Related to Inadequate Intake

The status of these nutrients in the Canadian population was assessed using biomarker data and/or evidence of clinical signs of deficiency, if available, to validate or further assess whether a micronutrient is of public health concern. If a micronutrient is determined to be of public health concern, its mandatory declaration in the NFt could help addressing such a concern.

Table 1. Usual intakes from food, by Dietary Reference Intake (DRI) age–sex group, household population, Canada excluding territories, 2004. Intake percentages below the EAR.

Sex	Age Group	% < Estimated Average Requirement (EAR)									
		Vitamin A	Vitamin B_{12}	Vitamin C	Folate	Vitamin B_6	Calcium[1]	Vitamin D[1]	Magnesium	Zinc	Phosphorus
Both	**1-3 y**	3	3	3	2.9	3	2.6	59.8*	3	3	3
Both	**4-8 y**	2.5	3	3	3	3	18.7*	59.8*	3	3	3
Male	**9-13y**	11.6*	3	3	3	3	43.1*	66.4*	4.7	3	8.9
Male	**14-18 y**	38.3*	1.7	7.1	5.2	3	31.9*	67.7*	41.5*	5.6	4.9
Male	**19-30y**	47.4*	F	13.7*	3	F	25.4*	78*	34.8*	F	3
Male	**31-50y**	42.7*	F	24.4*	F	F	36.6*	78*	45.7*	13.3*	3
Male	**51-70y**	42.5*	F	24*	11.5*	10.9*	44.5*	64.9*	53.6*	24.6*	3
Male	**>70y**	49*	F	31.5*	23.1*	23.1*	69.4*	66.3*	65.3*	41*	F
Male	**19+y**	44.3*	2.7	22.5*	6.8			73.2*		16.8*	0.4
Female	**9-13y**	23.1*	F	3	F	F	65.4*	77.4*	18.3*	14.6*	30.2*
Female	**14-18 y**	42.2*	15.8*	6	20.1*	11.1*	67.8*	83.8*	66.3*	19.6*	35.1*
Female	**19-30y**	43.4*	F	10.8*	18.8*	9.6	41.6*	81.4*	36.6*	14.7*	3
Female	**31-50y**	34.1*	13.7*	19.9*	19.6*	15.9*	41.4*	70.6*	36.4*	14.2*	1.8
Female	**51-70y**	33.8*	F	14.2*	25*	19.4*	56.8*	57.6*	37.5*	F	1.8
Female	**>70y**	40.2*	15.3*	20.8*	47*	32.5*	63.1*	54.3*	51.1*	25.2*	3.3
Female	**19+y**	35.8*	11.1*	16.7*	24.6*			67.2*		14*	1.9

Source: Canadian Community Health Survey, Cycle 2.2, Nutrition (2004)

* >10% below EAR

values < 3 are indicated as 3

F Data with a coefficient of variation (CV) greater than 33.3% with a 95% confidence interval not entirely between 0 and 3%; suppressed due to extreme sampling variability.

[1] Data includes nutrient intake from food and supplements

Table 2. Usual intakes from food, by DRI age–sex group, household population, Canada excluding territories, 2004. Intake percentage inadequacy for iron and percent greater than the Adequate Intake (AI).

Sex	Age Group	% Inadequacy* Iron	% >AI Potassium
Both	**1-3 y**	1.4	15.9
Both	**4-8 y**	0.6	5
Male	**9-13y**	3	7.3
Male	**14-18 y**	3	19.2
Male	**19-30y**	3	13.8
Male	**31-50y**	3	13.4
Male	**51-70y**	3	9.4
Male	**>70y**	1.9	5.2
Male	**19+y**	0.4	11.8
Female	**9-13y**	3	3
Female	**14-18 y**	11.9	1.9
Female	**19-30y**	16.8	3
Female	**31-50y**	18.3	3.4
Female	**51-70y**	3	1.9
Female	**>70y**	2	1
Female	**19+y**		2.1

Source: Canadian Community Health Survey, Cycle 2.2, Nutrition (2004)

values < 3 are indicated as 3

F: Data with a coefficient of variation (CV) greater than 33.3% with a 95% confidence interval not entirely between 0 and 3%; suppressed due to extreme sampling variability.

* For iron, the probability approach was used to compare it to the EAR.

6. Micronutrients of Public Health Concern Related to Inadequate Intake

Based on the approach described above, the following micronutrients are currently of public health concern in Canada: calcium, iron, potassium and vitamin D. Therefore, their mandatory declaration in the NFt would support informed consumer choice and may assist in ensuring adequate intakes and improving health outcomes.

Although CCHS 2.2 data show that segments of the population have inadequate intakes for zinc, phosphorus, vitamin B_6, vitamin B_{12}, folate and magnesium, there was no biomarker or clinical evidence to suggest that there were public health issues related to the inadequate intake of these nutrients in the general Canadian population. Therefore, Health Canada proposes that the declaration of these nutrients in the NFt remains voluntary.

6.1 Rationale for Mandatory Declaration

Potassium

Potassium is the major intracellular electrolyte in the body, involved in neural transmission, muscle contraction and vascular tone. An AI for potassium was set at 4.7 g (120 mmol)/day for all adults. As presented in the IOM's DRI report, "this level of dietary intake (in other words, from foods) should maintain lower blood pressure levels, reduce the adverse effects of sodium chloride intake on blood pressure, reduce the risk of recurrent kidney stones, and possibly decrease bone loss." The effect that increasing potassium intakes has on reducing hypertension is additive to the effect of decreasing sodium intakes [2], making it relevant to consider the two nutrients together. Severe deficiency (with hypokalemia) symptoms include cardiac arrhythmias, muscle weakness and glucose intolerance. Moderate deficiency (without hypokalemia) is characterized by increased blood pressure, increased salt sensitivity, increased risk of kidney stones and increased bone turnover [3]. High blood pressure affects 20% of Canadian adults and another 20% have pre-hypertension [4] which is a risk factor for stroke and cardiovascular disease.

According to CCHS 2.2 data, less than 20% of Canadians have potassium intakes above the AI. It is noted that where the mean usual intake is below the AI, the population prevalence of inadequacy cannot be estimated [5]. In CCHS 2.2 (2004), a large proportion of Canadians did not consume the minimum recommended servings of fruits and vegetables or milk products, which are generally rich sources of potassium [6].

Serum and intracellular potassium levels are subject to efficient homeostatic control and departures from normal ranges are medically significant. As noted in Federal Register (79:11922) [7], in the absence of a sensitive biochemical indicator of potassium nutritional status, it was not possible to consider biomarker data to inform the prevalence of potassium deficiency.

Potassium is a nutrient of high public health concern in Canada, as in the U.S., given (1) probable low prevalence of adequate intakes, and (2) high prevalence of hypertension in the general Canadian population.

Presently, potassium must be declared on the NFt when the product contains added potassium salts and when there are claims relating to the salt or sodium content of the food (Section B.01.402 (5) and items 31 – 36 of the table following section B.01.513, of the FDR).

Vitamin D

Vitamin D, along with calcium, plays an important role in the development and maintenance of bone health. Vitamin D deficiency results in inadequate bone mineralization or demineralization of the skeleton, including rickets, osteomalacia and osteoporosis [8]. In 2009, 19.2% of women and 3.4% of men aged 50 or older reported having been diagnosed with osteoporosis in Canada [9]. Although there are suggestions that vitamin D may play a role in physiological responses and functions apart from its key role in bone health, the IOM concluded that the current scientific evidence is insufficient to support other benefits for vitamin D [8].

The CCHS 2.2 shows that of Canadians aged 1 year and over, 75-97% have vitamin D intakes from food alone below the EAR, and 54-84% have vitamin D intakes from food and supplements below the EAR (depending on age/sex classification). Using standardized serum 25-OH vitamin D values [10, 11] from the Canadian Health Measures Survey (CHMS) data [12, 13] from cycles 1 and 2 (unpublished data) and the IOM cut-off targets [8], between 1.6 – 8.5% of Canadians aged 6 – 79 years are at risk of deficiency (serum 25-OH vitamin D levels below 30 nmol/L), and 9.2 – 23.3% of Canadians aged 6 – 79 years have insufficient vitamin D blood levels (serum 25-OH vitamin D levels established as consistent with an intake below the EAR of 40 nmol/L). In summary, about 20% of Canadians have insufficient vitamin D blood levels.

Canadians meet some of their vitamin D needs through sun exposure as human skin uses ultraviolet radiation from the sun to synthesize vitamin D. The body's ability to produce vitamin D from sun exposure is affected by factors such as latitude, season, time of day, cloud cover, smog, clothing coverage, skin pigmentation and sunscreen use [14-16]. These issues provide further evidence for the public health significance of vitamin D status in Canada.

Vitamin D is a nutrient of public health concern because of (1) the high prevalence of inadequate intakes, (2) insufficient blood levels in about 20% of the population, and (3) the prevalence of osteoporosis in Canada.

Calcium

Calcium functions to maintain bone structure and it also plays critical roles in vascular contraction and vasodilatation, muscle function, nerve transmission, intracellular signaling and hormonal secretion. In setting requirements for calcium, the IOM concluded that adequate

calcium intakes are needed to allow for optimal bone mass development during childhood and young adulthood and to decrease the rate of bone loss in adults.

Based on CCHS 2.2 [17], a substantial proportion of the Canadian population had calcium intakes from food and supplements below the EAR (25–69% for adolescents/adults). There is no sensitive biochemical indicator of calcium status and therefore, no data on physiological calcium status. In 2009, 19.2% of women and 3.4% of men aged 50 or older reported having been diagnosed with osteoporosis in Canada [9].

Calcium is a nutrient of public health concern because of (1) the benefits of adequate calcium intake on bone health, (2) the large proportion of Canadians with inadequate intakes, and (3) the prevalence of osteoporosis in Canada.

Iron

Iron plays several key roles in oxygen transport and utilization and therefore iron depletion may impair many important biological functions. Iron deficiency anemia effects include reduced immune function and resistance to infection, impaired cognitive performance and behaviour, decreased thermoregulatory performance and energy metabolism, diminished exercise or work capacity, and increased incidence of preterm deliveries and low birth-weight infants [18, 19].

Based on CCHS 2.2 [20], the prevalence of inadequate dietary intake of iron by Canadians was generally low (less than 3%) for most age/sex groups; the exception was females aged 14 to 50 (12% to 18%) [20].

Based on data from cycle 2 (2009 to 2011) of the CHMS, the overall prevalence of anemia was low (3%) based on haemoglobin concentrations. However, depleted iron stores were detected among females 12-19 years (13%), while those 20-49 years of age showed lower iron sufficiency, indicating a higher risk of iron-deficiency anemia among both age groups [21]. For these reasons, iron is still a nutrient of public health concern.

6.2 Rationale for Removal from the Core Nutrient List

Vitamin A

Vitamin A is important for normal vision, gene expression, reproduction, embryonic development, epithelial differentiation, growth and immune function [22, 23].

According to CCHS 2.2 [17], for all regions of Canada excluding the territories, 11.6% - 49.0% of males and females from ages 9 to >70 years have an intake of vitamin A from food that is less than the EAR. Less than 5% of children aged 1 - 8 years had vitamin A usual dietary intake less than the EAR.

Studies performed with indigenous adults in communities in the Yukon, the Northwest Territories and Nunavut, found vitamin A dietary inadequacy rates commonly more than 10% and in some cases, as much as 100% below the EAR [24-32]. The prevalence of vitamin A dietary intake inadequacy in the Canadian territories is as high as or higher than that seen among the other Canadian populations surveyed under CCHS 2.2.

Vitamin A status was not measured in cycles 1 and 2 of the CHMS [12-13]. The limited number of studies available reporting serum retinol levels in Canadian adults has found little evidence of deficiency [33-38]. Thus, biochemical indicators suggest vitamin A deficiency may be limited to specific at-risk subpopulations in Canada. Also, there is no significant clinical evidence, such as for night blindness or for xerophthalmia, of vitamin A deficiency in Canada [39-41].

In conclusion, even though a high percentage of Canadian adults in every province and territory have a vitamin A intake below the EAR, there is no clinical evidence of vitamin A deficiency among the general population. These findings are similar to those of the US FDA review, which found that even though vitamin A intakes appear to be low, vitamin A deficiency based on an assessment of vitamin A status is rare in the U.S. population. Given the similarity of Canadian and U.S. evidence with respect to the lack of public health significance of vitamin A for the majority of consumers, Health Canada is proposing to change the status of the labelling of vitamin A on NFts from mandatory to voluntary. Declaration of vitamin A would still be required when it is added to a food or when a nutrient content claim is made.

Vitamin C

Vitamin C is required for the biosynthesis of collagen, L-carnitine and certain neurotransmitters; vitamin C is also involved in protein metabolism [42, 43]. Vitamin C is also an important physiological antioxidant [44] and has been shown to regenerate other antioxidants within the body, including alpha-tocopherol (vitamin E) [45]. In addition to its biosynthetic and antioxidant functions, vitamin C plays an important role in immune function [45] and improves the absorption of non-heme iron [46], the form of iron present in plant-based foods. Insufficient vitamin C intake causes scurvy, which is characterized by fatigue or lassitude, widespread connective tissue weakness and capillary fragility [42, 43, 45, 47-50]. The EAR for vitamin C is based on estimates of body pool or tissue levels of vitamin C that are required for antioxidant protection with minimal urinary loss, not on a public health endpoint.

The CCHS 2.2 showed that a substantial proportion of Canadian adults had vitamin C intakes below the EAR (11-32%); however, Canadians' average dietary intake of vitamin C was well above the IOM recommendations.

Presently, there is no Canadian biochemical data for vitamin C but serum vitamin C values are expected in late 2014 from the CHMS cycle 3 data. In the U.S., the prevalence of vitamin C deficiency is not apparent. Only about 6% of the general population had serum vitamin C concentrations below 11.4 micromoles (mmol)/L, a cutoff level that is used as an indicator of

vitamin C deficiency [51, 52]. There is no evidence to suggest that the Canadian situation would differ.

Today, vitamin C deficiency and scurvy are rare in developed countries but can still occur in people with limited food variety [53]. Overt deficiency symptoms occur only if vitamin C intake falls below approximately 10 mg/day for many weeks.

Vitamin C had historically been of important public health concern, however, despite the prevalence of inadequate intake of vitamin C, it is no longer a nutrient of public health concern given (1) the lack of evidence of overt vitamin C deficiency in the Canadian population, (2) an examination of U.S. data indicating minimal vitamin C deficiency, and (3) the rarity of overt vitamin C deficiency and scurvy in developed countries.

Based on the lack of evidence that vitamin C is currently a micronutrient of public health concern, Health Canada is proposing to change the status of the labelling of vitamin C from mandatory to voluntary.

7. Proposed Approaches to Enhance the Information Related to Sugars on Food Labels

Excess sugars intake, particularly from added sugars, can lead to excess calorie consumption, a contributing factor to overweight and obesity. Obesity is a public health concern in Canada because it is a risk factor for major chronic diseases such as cardiovascular diseases, type 2 diabetes and cancer [54]. As well, diets that are high in added sugar may be poor in essential nutrients that the body needs [55]. However, there is little evidence to suggest that added sugars have health effects independent of the effects of total sugars [56].

Sugars[a], referring to total sugars, are part of the core nutrients that must be declared in absolute amounts (grams) in the NFt. Consistent with the US approach at the time, Health Canada did not set a DV for sugars when nutrition labelling was introduced in Canada in 2002. This was because the evidence for setting an upper intake level was insufficient.

In March 2014, the World Health Organization (WHO) launched a public consultation and conducted an expert peer review of draft sugar guidelines. The draft guideline proposes that the intake of free sugars[b] not exceed 10% of total energy and suggests further reduction to below 5% of total energy intake. These levels were based on evidence related to dental caries. Health Canada will continue to follow the WHO process with interest, and will review the findings of the consultation and the eventual decision.

[a] The term refers to total sugars and includes all simple sugars that are added and naturally occurring in the product, such as sucrose, fructose, glucose, glucose-fructose, maltose, lactose, etc…

[b] Free sugars comprise all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus sugars naturally present in honey, syrups and fruit juices

Due to the growing public health concerns about the potential adverse effects of sugars, and given the current interest from consumers to better understand the sugar content of foods, as highlighted within the *Consulting Canadians to Modernize and Improve food Labels: What We Heard report*, Health Canada is proposing three approaches with respect to enhancing the information on sugar content on food labels. These approaches are not mutually exclusive.

7.1 Declaration of Added Sugars in the Nutrition Facts Table (Approach 1)

Recently, the US FDA proposed to require mandatory declaration of "added sugars" to the Nutrition Facts label in absolute amount (in grams). Health Canada is considering a similar proposal to help consumers identify foods with added sugars and choose foods with less or no added sugar.

Foods providing the highest amounts of added sugars are often foods with a low nutrient density; for example, sugar-sweetened beverages and desserts, whereas whole foods tend to have higher nutrient densities, such as unprocessed fruits and unsweetened milk [57]. Data on sugar consumption of Canadians show that a significant proportion of sugar in their diets comes from foods high in added sugars such as sweetened beverages, candies and desserts (CCHS 2.2) [58].

As per the US FDA, for the purposes of this proposal, we refer to "added sugars" as sugars and syrups that are added to foods during processing or preparation[c].

Health Canada is proposing the declaration of "added sugars" in grams and for this to appear as a separate indented line in the NFt, under "sugars", which would be re-named as "total sugars" for clarity, as described in *Health Canada's Technical Consultation on Proposed Changes to the Format Requirements for the Display of Nutrition and Other Information on Food Labels*.

This approach would address consumers' interest to better understand the sugar content of foods; would help consumers apply Canada's Food Guide (CFG) recommendations to limit foods and beverages high in sugar, fat and salt; may help consumers reduce their intake of excess calories; and would align with the United States proposal, which in turn would facilitate trade, if implemented in both countries.

This approach may however support the misbelief that added sugars per se are nutritionally different from naturally occurring sugars and would create enforcement challenges given that there is no analytical method to distinguish added sugars from total sugars.

[c] 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, for example fruit juice concentrates, and other caloric sweeteners.

7.2 Declaration of a % Daily Value for total sugars (Approach 2)

Health Canada is proposing to establish a DV for total sugars to help consumers determine whether a serving of food is high in sugars.

The US FDA did not propose a DV for total or added sugars because no dietary reference has been set on which to base a DV. No reference value was set due to an absence of a biomarker of risk of disease or other public health endpoint. However, the Committee on Use of Dietary Reference Intakes in Nutrition Labelling supported the labelling of percent (%) DVs for saturated fat, trans fat, and cholesterol and recommended that the basis of the DVs for these nutrients should be set at a level that is as low as possible in keeping with an achievable health-promoting diet. In order to establish DVs for these chronic disease-related food components, the committee recommends the use of food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes consistent with nutritionally adequate and health-promoting diets for diverse populations. Health Canada is proposing to extend this principle to total sugars. In doing so, Health Canada would adopt a DV approach that would be compatible with all nutrients of public health concern related to excessive intakes, in other words, values below which Canadians could realistically strive to be below, such as the proposed value for saturated fat, *trans* fat and sodium.

Australia-New Zealand (Food Standards Code 1.2.8), and the European Union (Regulation (EU) 1169/2011) have established, based on dietary intake data, a DV for total sugars of 90 grams to be used as the basis for the voluntary declaration of % DV on food labels. 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.

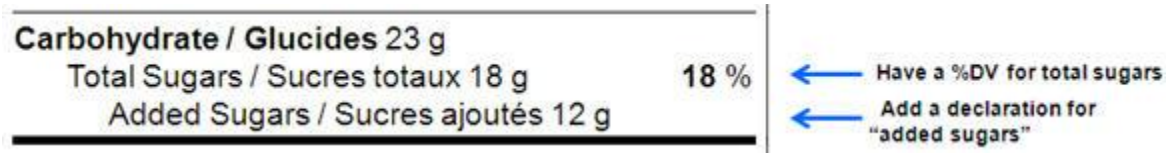
The proposed 100 gram DV is equivalent to 20% of energy based on a 2000 Calorie diet. According to dietary intake data (CCHS 2.2), approximately half of Canadians consume more than 20 % of their energy as sugars, with the highest intakes reported in younger age groups (<19 years).

This proposed approach could therefore support an overall reduction in sugar intakes for many Canadians, which is consistent with Canada's Food Guide recommendation of limiting foods high in calories, fat, sugar or salt (sodium); would address consumers' interest to better understand the sugar content of foods; may help consumers reduce excess caloric intake; and would be consistent with the approach for other nutrients of public health concern related to excessive intakes (e.g., fats, sodium).

Importantly, using the 15% DV benchmark for "a lot", foods and beverages containing 15 g or more of total sugars per serving would be identified as contributing a lot of sugars. In most cases, these foods and beverages contain free sugars (for example, sugar from sugar-sweetened beverages and fruit juices, added sugars in foods such as chocolate bars and desserts). Hence, it is expected that this approach would encourage Canadians to reduce their caloric intake from

free sugars to a level that approximates or is less than the 10% maximum daily intake of free sugars recommended by the WHO in its recent draft guideline.

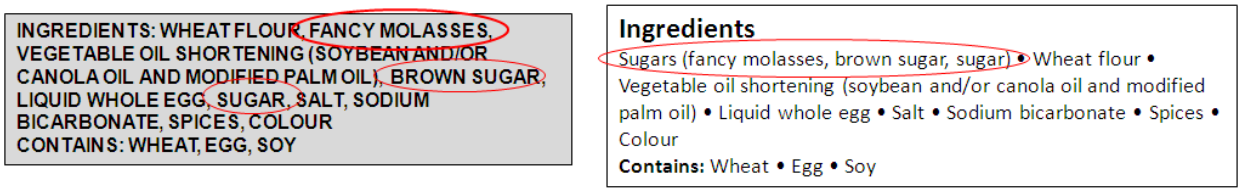
Figure 2. Proposed changes to the declaration of sugars in the Nutrition Facts table.



7.3 Grouping of Sugars-Based Ingredients in the List of Ingredients (Approach 3)

Currently, all sugar-based ingredients added directly to a food are listed separately in the list of ingredients and in descending order based on their proportion by weight to the food. Health Canada is proposing to require that these be grouped in parentheses under the common name "sugars" and be placed in the list of ingredients based on their total relative contribution to the food (see Figure 3).

Figure 3. Example of grouping sugars in the ingredient list. Example of current list of ingredients (left) and proposed format for the list of ingredients (right).



This approach would help consumers better estimate the relative contribution of added sugars to the food and apply Canada's Food Guide recommendation to limit foods high in sugar, fat and salt. However, it would not identify indirect additions of sugars to a food through the components (for example, the ingredients of an ingredient), such as the sugars in chocolate chips to a cookie.

8. Submitting Comments to Health Canada

Comments on the Revised Core Nutrients and Declaration of Sugars as outlined in this technical consultation document may be submitted in writing by regular mail or electronically at the address indicated below. If you are submitting your comments electronically, please use the phrase "**Revised Core Nutrients and Declaration of Sugars**" in the subject box of your email. Submissions must be received by 11:59 p.m. EST on September 12, 2014.

Bureau of Nutritional Sciences
Food Directorate
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Appendix A: History of Nutrition Labelling in Canada

In Canada, the *Food and Drugs Act* (R.S. 1985, c. F27) is the principal federal statute governing the labelling of food. The Act applies to all food sold in Canada at all levels of commerce. Regulations made under the Act cover ingredient listing, nutrition labelling and all types of claims.

Nutrition labelling guidelines were introduced in Canada in 1988, along with amendments to the FDR, concluding a process that was started in 1983. Application of the system, in whole or in part, was voluntary, with a few exceptions. *The Guidelines on Nutrition Labelling* [59] governed format, nutrient content information (core list and optional nutrients) and a declaration of serving size. Once applied, the nutrient declaration had to comply with the amended regulations [60], which stipulated nomenclature, units of measurement and expression on a per serving basis. Under the overall heading of "Nutrition Information," amounts of vitamins and minerals were required to be expressed in terms of a percentage of a single set of nutrient reference values, RDIs, per serving of stated size [61]. Amounts of macronutrients were expressed in terms of weight; no percentage information was provided.

The process that began in 1983 had proposed criteria for rating the nutrient content of food based on two reference standards: a nutrient density index and the percentage of a composite RNI derived from the Recommended Nutrient Intakes for Canadians [62, 63]. A reference set of RNIs expressed per megajoule was derived by dividing the RNI for each age and gender group by the average energy requirements of that group. When the RNIs were not based on energy and the nutrient to energy ratios were not constant among groups, the highest RNI/megajoule was selected. Relating all the RNIs to energy was criticized however, and the proposal was not pursued.

In 1986, Health Canada decided to set RDIs for nutrition labelling using the highest RNI from 1983 for each nutrient for each age and gender group, omitting supplemental needs for pregnancy and lactation [61]. Thus the values chosen were those for 19- to 24-year-old males (except for iron, for which the value was that of women of childbearing age). RDIs were established for 11 vitamins (vitamin A, vitamin D, vitamin E, vitamin C, thiamin, riboflavin, niacin, vitamin B_6, folacin, vitamin B_{12}, and pantothenic acid) and 6 minerals (calcium, iron, phosphorus, iodide, magnesium, and zinc). The list of RDIs was reviewed again in 2002 and updated to include two vitamins (biotin and vitamin K) and 6 minerals (selenium, chloride, copper, manganese, chromium and molybdenum). The *Guidelines on Nutrition Labelling* [59] specified the minimum nutrient content information, the label format and the serving size information that would constitute nutrition labelling for food sold in Canada.

In 1996, Canada's national action plan on nutrition, *Nutrition for Health: An Agenda for Action* [64], identified key strategies to reduce health risks to Canadians. The report supported the need for improving the usefulness of nutrition labelling, increasing its availability, and broadening public education on its use. In June 2001, Health Canada undertook a final consultation on

proposals to improve nutrition information on prepackaged food labels, including nutrition labelling.

On December 12, 2002, the Canadian government issued "Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Nutrient Content Claims and Health Claims)" [65]. The new regulations mandate nutrition labelling on most prepackaged food, update and consolidate permitted nutrient content claims, and introduce a new regulatory framework and process for diet related health claims.

The new regulations on nutrition labelling aim at preventing injury to the health of Canadians, including those with special dietary needs, by providing product-specific nutrient information to assist in making informed food choices. The Regulatory Impact Assessment Statement in *Canada Gazette Part II* stated the following objectives for the nutrition labelling regulations:

1. To enable consumers to make appropriate food choices in relation to reducing the risk of developing chronic diseases and permitting dietary management of chronic diseases of public health significance;
2. To encourage the availability of foods with compositional characteristics that contribute to diets that reduce the risk of developing chronic diseases;
3. To advance compatibility with the US system and further work towards mutual acceptance by Canada and the US of their respective nutrition labelling requirements; and
4. To provide a system for conveying information about the nutrient content of food in a standardized format which allows for comparison among foods and prevents consumers' confusion in respect of the nutrient value and composition of a food at point of purchase.

The declaration of the amounts of nutrients associated with risk of developing chronic diseases and the use of DVs to interpret the amounts present met the first and second objectives. The adoption of the term Daily Value and use of the US Daily Reference Values for all nutrients except vitamins and minerals met the third objective and the development of a rigidly standardized format of the NFt that included the DVs met the fourth.

Appendix B: Lexicon

Dietary Reference Intakes

The Dietary Reference Intakes (DRIs) are a set of scientifically based nutrient reference values for healthy populations. They were established by Canadian and American scientists through a review process overseen by the Institute of Medicine (IOM), which is an independent, non-governmental body in the US. The US and Canadian governments jointly sponsored the development of the DRIs since 1994.

The DRIs are an important part of the evidence underpinning government activities such as the development of regulatory standards, assessment of dietary intakes, food product safety assessment, and the development of dietary guidance for the general population and for specific life stage groups.

The main types of DRI reference values are the Estimated Average Requirement (EAR), the Recommended Dietary Allowance (RDA), the Adequate Intake (AI), and the Tolerable Upper Intake Level (UL).

- An EAR is the average daily nutrient intake that is estimated to meet the requirement of half the healthy individuals in a life-stage and gender group. A specific indicator of adequacy is used to determine the EAR. The EAR is used to calculate the RDA.
- An RDA is an estimate of the minimum daily average dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life-stage and gender group. The main use of the RDA is as a goal for usual intake of individuals. Since the RDA is calculated based on the EAR, an RDA can only be set for a particular nutrient if there is sufficient scientific evidence to establish an EAR for that nutrient.
- If sufficient scientific evidence is not available to establish an EAR and to subsequently set an RDA, an AI is derived for the nutrient instead. An AI is based on much less data and incorporates substantially more judgment than is used in establishing an EAR and subsequently the RDA. The issuance of an AI indicates that more research is needed to determine, with some degree of confidence, the mean and distribution of requirements for that specific nutrient. The AI is expected to meet or exceed the needs of most individuals in a specific life-stage and gender group. The AI can be used as the goal for an individual's intake when an RDA is not available for a nutrient.
- A UL is the highest level of continuing daily nutrient intake that is likely to pose no risk of adverse health effects in almost all individuals in the life-stage group for which it has been designed. The term "tolerable" intake was chosen to avoid implying a possible beneficial effect. Instead, the term is intended to specify a level of intake with a high probability of being tolerated biologically. The UL is not intended to be a recommended level of intake. As intake increases above the UL, the potential risk of adverse effects increases.

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