FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

International sugar labelling approaches

Executive summary

This report outlines approaches used in various countries for the labelling of packaged foods with respect to sugar, including ingredient and nutrition labelling. It forms part of the Stage 1 Sugar Labelling Program of Work that was agreed to by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) to develop the evidence base to support further investigation of labelling approaches for providing information on sugar.

The scope of this report has been limited to approaches that include specific reference to sugar. Front-of-pack (FoP) labelling systems that only provide information on the overall nutritional quality of a food were not included.

In general, requirements for having a nutrient declaration (for example, a nutrition information panel or nutrition facts label) and declaring sugar within that declaration are similar internationally. There are some differences including the basis for the declaration (e.g. per 100 g/100 mL and/or serving of the food) and for declaring nutrients as percentage daily value (% DV).

The general requirements for ingredient labelling are also similar internationally, in particular the requirement for ingredients to be declared in descending order of ingoing weight. The current European Union (EU), the United States of America (USA) and the Codex Alimentarius requirements for declaring sugar in the ingredient list align with the requirements in Australia and New Zealand with respect to the use of the generic name ‘sugar’. Differences occur in how ‘sugar’ is defined for this purpose; however, all definitions are based on forms of sucrose.

Although there are these similarities some countries have proposed or implemented specific labelling requirements for sugar that differ from the requirements in Australia and New Zealand. These include a requirement for added sugar to be declared in the Nutrition Facts label (USA), percentage daily intake values (% DV) to be declared for total sugars (Canada) and for added sugars (USA), grouping of sugar ingredients in the ingredient list (Canada), warning labels for foods that exceed specific limits for sugar, sodium, saturated fat and calories (Chile) and various other FoP schemes including one being proposed in Canada, that include the separate specific display of sugar information.

Detailed information is provided in Attachment 1 about the new requirement in the USA for added sugar to be declared in the Nutrition Facts label and in Canada for sugars-based ingredients to be declared in the ingredient list under the name ‘sugars’ and for % DV of total sugars to be declared in the nutrition facts table.

Table of contents

1. Introduction

This report outlines approaches used in various countries for the labelling of packaged foods with respect to sugar. Two case studies of new requirements for sugar labelling in the United States of America (USA) and Canada are included (Attachment 1).

This report together with a literature review on consumer knowledge, attitudes and behaviours relating to sugars and food labelling and an update of the policy context relating to sugars in Australia and New Zealand by the Australian Government Department of Health are all components of a Stage 1 Sugar Labelling Program of Work that was agreed to by the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) in April 2017[1]. This work provides the evidence base to support further investigation of labelling approaches for providing information on sugars. The program of work originated from the Forum's consideration of the technical evaluation and advice prepared by Food Standards Australia New Zealand (FSANZ) on Recommendation 12 (Ingredient labelling of added sugars, added fats and added vegetable oils) of *Labelling Logic: Review of Food Labelling Law and Policy* (Labelling Logic) (Blewett et al. 2011) at their November 2016 meeting.

Front-of-pack (FoP) labelling systems that provide information on the overall nutritional quality of a food (e.g. Nordic Keyhole system, France's 5-C Nutriscore logo) and which are not specific to sugar labelling, were not included in the scope of this report. Nutrition content and health claims were also excluded as these do not appear on all foods or in a consistent manner. Menu labelling and signage were also not included.

Some FoP labelling systems were identified that include the separate specific display of sugar information. Details of both the recently implemented system in Chile (section 4.1) and the similar system under development in Canada (section 4.2) are included along with a brief reference to systems in operation in other countries.

2. Generic nutrition list and ingredient labelling requirements including for sugar

2.1 Nutrition lists

Summary

- Current requirements for having a nutrition list and declaring the total amount of sugars within that list in the European Union (EU), Canada and the USA are similar to the requirements in Australia/New Zealand.

- The USA is transitioning to including a separate declaration for 'added' sugar in the Nutrition Facts table.

There are some differences including the basis for the declaration (e.g. per 100g/100 mL and/or serving of the food) and for declaring nutrients as percentage daily value (% DV) among Australia/New Zealand, the EU, Canada and the USA.

[1] Further information is available on the food regulation website (accessed 28 July 2017)

The requirement in Australia and New Zealand (*Australia New Zealand Food Standards Code*[2]) for having a nutrition declaration and declaring the total amount of sugars within that declaration is similar to current requirements in the European Union (EU), USA and Canada, and with the Codex Alimentarius Guidelines on Nutrition Labelling. Table 1 provides a summary comparison of Australia/New Zealand nutrition information panel requirements with requirements in the USA, EU and Canada, and the Codex Alimentarius, with a particular focus on sugar.

In the EU, sugars are required to be included in the nutrition declaration, expressed per 100 g or 100 ml of the food. In the USA, sugars are currently required to be declared on a per serving basis in the Nutrition Facts label, however a new requirement for also declaring the amount of added sugar is expected to be implemented[3]. In Canada, declaration of sugars is required in the Nutrition Facts table and there is a five year transition period (until 2021) for a new requirement to declare the total sugar content of the food as percent daily value (% DV). Although 'total' is not specified in the declaration, these declarations are based on the amount of 'total' sugars similar to the requirement in Australia and New Zealand (the total amount of monosaccharides and disaccharides). The Codex Alimentarius Guidelines on Nutrition Labelling recommend that total sugars are declared in the nutrient declaration (WHO, FAO 2016).

According to the World Cancer Council Research Fund International (2017), many other countries require mandatory nutrition lists on packaged foods. However, there are variations in what and how nutrients are declared among countries. For example, Japan only requires total carbohydrate to be declared and not sugars (Godo 2015). The basis for the amount declared also varies (e.g. per 100 g/100mL and/or per serving).

Other countries, such as South Korea and Malaysia, require a nutrition list on select categories of packaged foods only (e.g. confectionary and bread for both and other different categories for each country). Malaysia also requires mandatory nutrition lists for foods which make nutrition claims; products fortified with vitamins and minerals; and special purpose foods. Malaysia does not require the sugar content to be declared (carbohydrates is required), except for ready-to-drink beverages which must include total sugar (Ministry of Health Malaysia 2010). South Korea requires total sugar to be declared in the nutrition list (H Lee, pers. com.[4]).

[2] Requirements for nutrition information panels are in Standard 1.2.8 – Nutrition information requirements of the Australia New Zealand Food Standards Code, available at Federal Register of Legislation - Australian Government. Accessed 14 August 2017

[3] On 29 September 2017 a compliance date of 1 January 2020 for manufacturers with $10 million or more in annual food sales and 1 January 2021 for manufacturers with less than $10 million in annual food sales was proposed.

[4] H Lee, Senior Researcher, National Food Safety Information Service, Korea, personal communication, 31 May 2017

Table 1: Comparison of Australia/New Zealand nutrition list requirements with Codex, EU, USA and Canada

International Jurisdiction	General mandatory requirements	Key differences to Australia/NZ regarding sugar
Australia and New Zealand[5]	Requires declaration of energy, total fat, saturated fat, carbohydrate, [total] sugars, protein, sodium per 100 g or 100 ml and per serving of the food. Percentage daily intake of energy and the nutrients listed above can be provided voluntarily.	
Codex Alimentarius[6]	Recommends that where nutrient declaration is applied, declaration of energy, protein, available carbohydrate (i.e. dietary carbohydrate excluding dietary fibre), fat, saturated fat, sodium and total sugars are mandatory.	Does not provide for declaration of sugars as % DV.
European Union[7]	Requires declaration of energy, fat, saturated fat, [total] sugars, protein and salt, expressed per 100 g or 100 ml of the food. Nutrients also are provided voluntarily as a percentage of the reference intake.	Total sugars can also be provided on a per portion basis or per consumption unit.
United States of America (new rule)[8]	Requires declaration of calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fibre, total sugars, added sugars, protein, vitamin D, calcium, iron and potassium per serving of the food. Requires % daily value (% DV) for all of the above except for calories and total sugars.	Requires total and added sugars to be declared per serving. % DV required for added sugars. Neither total nor added sugar information on a per 100 g/100 mL basis is required.
Canada[9]	Requires declaration of calories, fat, saturated fat, trans fat, carbohydrate, fibre, [total] sugars, protein, cholesterol, sodium, potassium, calcium and iron per serving of the food. Requires % DV for fat, the total of saturated and trans fat, fibre, [total] sugars, sodium, potassium, calcium and iron.	% DV required for total sugars. Declaration of total sugar is on per serving basis. Total sugar information on a per 100 g / 100 mL basis is not required.

[5] Requirements for nutrition information panels are in Standard 1.2.8 – Nutrition information requirements of the *Australia New Zealand Food Standards Code*, available at Federal Register of Legislation - Australian Government *(*accessed 7 August 2017)
[6] Guidelines on Nutrition Labelling. CAC/GL 2-1985 (accessed 7 August 2017)
[7] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (accessed 7 August 2017)
[8] Information about the new rule can be found at United States Food & Drug Administration. (accessed 7 August 2017) Note a new date for commencement of this new rule is under consideration.
[9] Food and Drug Regulations (2016) C.R.C., c. 870, Part B, Division 1. Accessed 7 August 2017

2.2 Ingredient labelling

Summary

- The general requirements for ingredient labelling in the EU, Canada and the USA are similar to that required in Australia/New Zealand, particularly with respect to the requirement for ingredients to be declared in descending order of ingoing weight.

- The current EU and USA requirements and the Codex Standard for declaring sugar in the ingredient list align with the requirements in Australia/New Zealand with respect to the use of the generic name 'sugar'. Differences occur in how 'sugar' is defined for this purpose, however all definitions are based on forms of sucrose.

In Canada there is currently a five year transition period (until 2021) to the new requirement for sugars-based ingredients to be grouped in the ingredient list under the name 'sugars' (see Attachment 1).

Table 2 provides a summary comparison of Australia/New Zealand requirements for sugar ingredient labelling with the requirements in the USA, EU and Canada, and the Codex Alimentarius Standard.

The requirements for ingredient labelling in the EU, Canada and the USA are similar. The EU[10], USA[11] and Canada[12] share the same general requirement and specification as Australia and New Zealand (*Australia New Zealand Food Standards Code*[13]) where ingredients must be listed in descending order of ingoing weight. The Codex Alimentarius General Standard for Labelling of Pre-packaged Food also includes a similar approach[14]. The EU and USA include some exceptions to this requirement. For example, in the USA ingredients present in amounts of 2% or less by weight can be listed at the end of the ingredient statement following an appropriate quantifying statement, e.g., 'Contains _ percent or less of _'.

There are also similarities in the declaration requirements for ingredient names. The general approach is that the specific or common name should be used, unless a generic name is permitted. The generic names and the conditions for their use vary in the EU, Canada, the USA and the Codex Alimentarius standard.

The current EU and USA requirements and the Codex standard for declaring sugar in the ingredient list align with the requirements in Australia and New Zealand with respect to the use of the generic name 'sugar' (Table 2). Differences occur in how 'sugar' is defined for this purpose, however, all definitions are based on forms of sucrose. For non-sucrose sugar-type ingredients (e.g. maltodextrin or golden syrup), general naming requirements (e.g. a specific or common name) for these types of ingredients apply.

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[10] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. Accessed 7 August 2017

[11] Code of Federal Regulations (2017), Chapter I, Subchapter B, Part 101. Accessed 27 July 2017

[12] Food and Drug Regulations (2016) Food and Drug Regulations (2016) C.R.C., c. 870, Part B, Division 1. Accessed 7 August 2017

[13] Requirements for ingredient labelling are in Standard 1.2.4 – Information requirements – statement of ingredients of the *Australia New Zealand Food Standards Code*, available at Federal Register of Legislation - Australian Government (accessed 7 August 2017)

[14] Codex Alimentarius CODEX STAN 1-1985 General Standard for the Labelling of Prepackaged foods available at Codex Alimentarius - International Food Standards Accessed 7 August 2017

Codex and the EU allow the generic name ‘sugar’ to be used in the ingredient list for all types of sucrose. The USA specifies that ‘sugar’ shall refer to sucrose which is obtained from sugar cane or sugar beets.

In Australia and New Zealand, the generic name ‘sugar’ is permitted to be used to describe different forms of sucrose which are listed as: white sugar, white refined sugar, caster sugar, castor sugar, loaf or cube sugar, icing sugar, coffee sugar, coffee crystals, raw sugar. The term ‘sugars’ cannot be used to describe non-sucrose sugars and is prohibited in the statement of ingredients.

Health Canada has recently developed a requirement for declaring sugars-based ingredients in the ingredient list under the name ‘sugars’ (see the case study at Attachment 1). Until the end of the five year transition period for compliance with this new regulation (from December 2016), Canada will permit compliance with either these new requirements or the previous requirement for the name ‘sugar’ to be used for sugar, liquid sugar, invert sugar or liquid invert sugar (either singly or in combination).

No other mandatory international regulations were identified which currently require sugar ingredients to be identified as ‘added’ or to be grouped together in the ingredient list.

Table 2: Comparison of Australia/New Zealand sugar ingredient labelling requirements with Codex, EU, USA and Canada

International Jurisdiction	General mandatory requirements	Key similarities or differences to Australia/NZ regarding sugar
Australia and New Zealand[15]	Ingredients must be listed in descending order of ingoing weight. The generic name 'sugar' is permitted to be used in the ingredient list for all forms of sucrose (as listed in the Code). The term 'sugars' is not permitted. For non-sucrose sugar-type ingredients (e.g. maltodextrin or golden syrup), general naming requirements (i.e. a specific or common name) apply.	
Codex[16]	Ingredients must be listed in descending order of ingoing weight. The generic name 'sugar' is permitted to be used in the ingredient list for all types of sucrose. For non-sucrose sugar-type ingredients (e.g. maltodextrin or golden syrup), general naming requirements apply, i.e. the name must indicate the true nature and normally be specific and not generic.	Similar to Australia/NZ.
European Union[17]	Ingredients must be declared in descending order of ingoing weight (with variation allowed for ingredients constituting less than 2% of the finished product, which be listed in a different order after the other ingredients). The generic name 'sugar' is permitted to be used in the ingredient list for all forms of sucrose. For non-sucrose sugar-type ingredients (e.g. maltodextrin or golden syrup), a descriptive name must be used. 'Dextrose' and 'glucose syrup' are permitted for certain forms of dextrose and glucose syrups respectively.	Similar to Australia NZ except for the variation for ingredients constituting less than 2%.

[15] *Australia New Zealand Food Standards Code* (accessed 7 August 2017)
[16] Codex Alimentarius CODEX STAN 1-1985 General Standard for the Labelling of Prepackaged foods available at Codex Alimentarius - International Food Standards Accessed 7 August 2017
[17] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. Accessed 7 August 2017

International Jurisdiction	General mandatory requirements	Key similarities or differences to Australia/NZ regarding sugar
United States of America[18]	Ingredients must be listed in descending order of ingoing weight (with variation allowed for ingredients present in 2% or less by weight*[19]). A specific name shall be used and not a collective (generic) name. 'Sugar' must refer to sucrose, which is obtained from sugar cane or sugar beets.	Similar to Australia/NZ except for the variation for ingredients constituting less than 2%.
Canada[20]	Ingredients must be declared in descending order of ingoing weight. Ingredients must be declared by their common name. New requirement to declare sugars-based ingredients in brackets after the term 'sugars' in descending order of ingoing weight. There is a five year transition period from December 2016 during which time either the old or new regulations can be used. Old regulations do not require grouping of sugars-based ingredients. Permitted class/collective names: – sugar, liquid sugar, invert sugar or liquid invert sugar, singly or in combination, the collective name 'sugar' – sugar or glucose-fructose, singly or in combination the collective name 'sugar/glucose-fructose'.	Similar to Australia/NZ except for the new requirement to declare sugars-based ingredients in brackets after the term 'sugars'.

[18] Code of Federal Regulations (2017), Chapter I, Subchapter B, Part 101. Accessed 27 July 2017
[19] Variation permitted when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., "Contains _ percent or less of ___" or "Less than _ percent of ___.".
[20] Food and Drug Regulations (2016) C.R.C., c. 870, Part B, Division 1. Accessed 7 August 2017

3. Specific approaches for sugar labelling

Summary

- Some countries have proposed or implemented labelling requirements for sugar that differ from the requirements in Australia and New Zealand.

- In the USA requirements have been developed for added sugar to be declared in the Nutrition Facts label) and for % DV values to be declared for added sugars (as of 4 October 2017 the date of implementation was yet to be confirmed).

In Canada new requirements for % DV values to be declared for total sugars in the nutrition facts table and for grouping of sugars-based ingredients in the ingredient list have been implemented with a five year transition period ending in 2021.

Although there are a number of similarities in the requirements for the labelling of sugars internationally, approaches have been identified that differ to those currently required in Australia and New Zealand. This section outlines the following food labelling approaches that are specific to, or include, the labelling of sugar:

- new requirements for added sugar to be declared in the Nutrition Facts label and for % DV values to be declared for added sugars in the USA
- new requirements for % DV values to be declared for total sugars in the nutrition facts table and for grouping of sugars-based ingredients in the ingredient list in Canada (implemented in 2016 with a five year transition period)
- a Bill in the United Kingdom (UK) for added sugar content to be represented in teaspoons of sugar (no longer being considered).

3.1 United States of America

The FDA released a new Nutrition Facts label rule for packaged foods in May 2016 (FDA 2016). Amongst other changes, the new rule requires the amount of 'added sugars' in grams and as % DV[21] per serving to be included on the Nutrition Facts label. The added sugars content must be indented under 'Total Sugars' using the words 'Includes x g Added Sugars'. On 29 September 2017, the FDA released a proposed rule to extend the compliance dates for the new rule from July 2018 to January 2020 for manufacturers with $10 million or more in annual food sales and from July 2019 until January 2021 for manufacturers with less than $10 million in annual food sales. See Attachment 1 for a detailed case study about the new rule and the approach taken in its development.

3.2 Canada

The Canadian government launched a *Healthy Eating Strategy* in October 2016 (Health Canada 2016a) which includes initiatives relating to food labelling and claims. The following three aspects of these initiatives are relevant to this report:

- FoP labelling for foods high in sugars, sodium and saturated fats (section 4.2)

[21] The % DV is based on a Daily Reference Value (DRV) for added sugars. A DRV of 50 g for adults and children 4 or more years of age has been established by the FDA.

- new requirements for the grouping of sugars-based ingredients in the ingredient list under 'sugars'
- inclusion of % DV for total sugars in the Nutrition Facts table, with a footnote about the % DV must be added to the bottom of the Nutrition Facts table stating '5% or less is **a little,** 15% or more is **a lot'**.

The new requirements for the Nutrition Facts table and list of ingredients were announced by Health Canada on 14 December 2016 and are in the *Food and Drug Regulations*[22]. There is a five year transition period for the implementation of these new requirements.

See Attachment 1 for a detailed case study about these new requirements and their development.

3.3 United Kingdom

A Private Members' Bill entitled 'Sugar in Food and Drinks (Targets, Labelling and Advertising) Bill 2016-17'[23] was presented to the UK Parliament on 14 September 2016. The Bill proposed to require the Secretary of State to provide that *added sugar* content be represented on food labels and on any advertisement or promotional material in teaspoons of sugar, where one teaspoon equals 4 g of sugar. The Bill also proposed that the Secretary of State provide for prohibiting the use of language suggesting that a food is 'healthy' or 'low-fat' where the sugar content of the food exceeds 20% and to restrict advertising of these foods.

Under the Bill, 'sugar' would have the same meaning as in the *Food Labelling Regulations 1996.* The Food Labelling Regulations do not define 'sugar'; rather they define 'sugars' to mean *sugars, in the context of nutrition labelling, means all monosaccharides and disaccharides present in food, but excludes polyols.* This definition aligns with the definition of 'sugars' in the EU regulations[24].

The Bill proposed other measures in addition to labelling including that the government promote the World Health Organization's (WHO) guideline on sugars intake and to translate the recommended daily amount into teaspoon units, produce advice on sugar content by food category and publish targets for the total amount of sugar consumed in the UK (where different targets may be set for different consumer groups, e.g. age, gender). The purpose of the targets would be *to achieve, or help to achieve, an improvement in public health through an overall reduction in the amount of sugar ingested by consumers.* FSANZ notes that a contemporary official report published by Public Health England sets out daily maximum sugar intakes in teaspoon amounts for different age groups (Public Health England 2015).

A second reading of the Bill was originally expected to occur in the House of Commons on 4 November 2016, however, this was deferred until 12 May 2017. According to the UK Parliament website, as a General Election was called and Parliament was dissolved as of 3 May 2017, *the Bill falls and no further action will be taken.*

[22] Information is provided at Canadian Food Inspection Agency. Accessed 7 August 2017
[23] The Bill is available on the UK Parliament website at Parliament UK
[24] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers. Accessed 7 August 2017

A similar Bill with the same title, but dated '2015-2016', was also previously presented to the UK Parliament (in October 2015)[25]. This Bill proposed that the *sugar* content (rather than *added sugar* content) be represented on food labels in teaspoons. At the end of the 2015-2016 session of Parliament, the UK Parliament website stated that *this Bill will make no further progress.*

4 Front-of-pack labelling systems providing sugar information

Summary

- Several FoP and guideline daily amount (GDA) labelling systems that include the separate specific display of sugar information are in use around the world.
- A new requirement in Chile has been implemented for individual FoP warning labels for sugar, sodium, saturated fat and calories (energy) if any of these nutrients or energy in a food exceed specific limits.
- In Canada a mandatory FoP labelling scheme for foods high in sugars, sodium and saturated fats is being considered.
- In Ecuador, there is a requirement for 'traffic light' labels in which the levels of fats, sugar and salt are indicated by red (high), orange (medium) or green (low).
- GDA declarations including for sugar are required in Mexico and for certain snack foods in Thailand.
- In South Korea colour-coded labelling on the front of pre-packaged children's 'favourite food' is recommended.

4.1 Chile – warning labels for total sugar, sodium, saturated fat and calories

In June 2015, the Chilean Ministry of Health published new FoP warning labelling requirements for total sugar, sodium, saturated fat and calories (energy) which came into effect on 27 June 2016. The overall objectives of the FoP labelling together with related advertising/sales restrictions were to deliver clearer and more comprehensible information to consumers; and to protect the health of children by ensuring a food environment that facilitates healthy food choices. The main problem the combined new measures are intended to address is the increase of obesity and overweight of the Chilean population, particularly children. This labelling measure is also linked to restrictions for advertising to children and food for sale in schools.

The Chile Ministry of Health commissioned the University of Chile to undertake a qualitative and quantitative study to determine which warning label to use. The study measured the response of Chilean consumers to different warning label options to determine which performed best in regard to visibility, understanding and capability to modify purchase intention. No cost benefit analysis was undertaken.

[25] The Bill is available on the UK Parliament website at Parliament UK

Individual FoP warning labels are required if a food exceeds specific limits set in the regulation for total sugar, sodium, saturated fat and calories (energy). The warning label is a black and white stop sign-shaped label with the text 'High in' followed by 'sugar', 'sodium', 'calories' or 'saturated fat' (see Figure 1). One stop sign must be used for each of these in excess of the limits. This means that for some foods, up to four stop signs may be required. Specifications are provided for the size, font and placement of the warning message.

Figure 1: FoP warning symbols mandated in Chile

For sugar, the requirement applies to packaged foods when any of the following sugars (as defined in the legislation) are added as ingredients (and the food exceeds limits set for sugar as outlined in Table 3):

- sugar (sucrose) and other sugars (mono and disaccharides)
- honey
- syrups
- additives with mono and disaccharides, if added at or above a certain percentage
- ingredients that contain any of the above.

There are some exemptions to the FoP labelling requirement, including foods that are sold in bulk and Foods for Special Dietary Purposes (e.g. infant formula) (L. Rodríguez Osiac pers. com.[26]).

The Chilean Ministry of Health conducted public consultation and consulted internationally (with the World Trade Organization (WTO)). In general, consumers were supportive of the regulation and even asked for more strict measures, while industry were critical of the measures. Several WTO members raised concerns about the proposed labelling, in particular that it was not based on the relevant guidelines of Codex, that WTO principles relating to the preparation of technical regulations had been breached and that the measure would create unnecessary obstacles to international trade. Chile made some amendments to the original proposal presented to the WTO including changing the required size of the

[26] Dra. Lorena Rodríguez Osiac, Head of Department of Nutrition and Food, Ministry of Health, Chile, personal communication 7 June 2017

warning labels and allowing the use of stickers, however some concerns remained with the publication of the new requirements in 2015 (FratiniVergano 2015).

The limits for requiring the FoP labelling for total sugars, energy, saturated fat and sodium are being implemented using a phased-in reduction over a 3 year period; the objective of which is to encourage producers to reformulate their foods. The limits for total sugars for solid and liquid foods are set out in Table 3 below.

Table 3: Limits for total sugars in the Chilean FoP labelling system

Total sugars	From the date of implementation (27 June 2016)	24 months after implementation	36 months after implementation
Solid Food g/100g	22.5	15	10
Liquid Food g/100mL	6	5	5

Limits were set per 100 g or mL rather than per serving to provide a standard measure for all foods, to judge a food based on the nutritional quality rather than the way it is consumed, and to compare foods within and between categories.

A report on the evaluation of the new requirements was prepared 6 months after implementation (Undersecretary of Public Health 2017). This report includes an account of the evaluation carried out by the Ministry of Health on the implementation of the new requirements, the evaluation of reformulation carried out by the food industry, the results of a study on the perceptions and attitudes of consumers, and challenges facing Chile in relation to the implementation of the new law.

In terms of the perceptions and attitudes of consumers, a study found that 43.8% of respondents stated that they compare the warning labels when buying food, and of this group, 91.6% were influenced by the warning labels in their purchase (Undersecretary of Public Health 2017).

4.2 Canada – front-of-pack labelling for foods high in sugars, sodium and saturated fats

Health Canada is proposing to introduce mandatory FoP labelling for foods high in total sugars, sodium and saturated fats, due to excessive intakes of these nutrients and their association with increased risk of chronic disease (Health Canada 2016b). The objectives of the proposed FoP labelling are to:

- *provide quick and easy guidance to encourage consumers to make informed choices about foods in relation to sugars, sodium and saturated fats; and*
- *encourage the availability of foods lower in these nutrients, thereby reducing risks to health.*

Concurrent changes to nutrition content claims relating to sugars are also being proposed to ensure consistency across the regulations.

Health Canada released a consultation document seeking comments on the proposed changes in November 2016 (Health Canada 2016b). Further consultation is planned for later in 2017.

In selecting the proposed approach, Health Canada considered different types of FoP systems and international models, the Institute of Medicine of the National Academies (IOM) recommendations[27] and the intersection between various FoP systems and current Canadian food labelling policies. Health Canada concluded that evidence (referenced in the consultation document) shows that *FoP labelling can help consumers to make better food choices and that, in general, nutrient-specific FoP labels, rather than summary systems, more easily help consumers identify healthier products*.

Under the proposal, foods which exceed established thresholds for total sugars, sodium and saturated fats would be required to have a FoP symbol indicating that the food is high in the nutrient(s). Depending on the composition of the food, some foods could be required to display one or more symbols. For sugars, the proposed threshold for pre-packaged foods is ≥15 grams total sugars per reference amount[28] and per serving of stated size[29], which is based on a DV of 15%. The 15% DV was selected following testing of a range of DV's (from 10% - 25%) using a food composition database. It was considered that an appropriate threshold should trigger FoP labelling on foods that contain relatively high levels of one or more nutrients of concern, but not on foods that would be recommended as part of a healthy diet. In addition, the threshold is consistent with existing regulations for nutrition content claims and with the new messaging in the Nutrition Facts table which indicates that 15% or more of the DV is 'a lot' (see Attachment 1 for further information on the new messaging in the Nutrition Facts table). Higher thresholds based on 30% DV are proposed for pre-packaged meals (as these are consumed as a meal); and lower thresholds (7.5 g for sugars) are proposed for food intended solely for young children (aged 1 year and older but less than 4 years).

The FoP symbol for sugars would apply to pre-packaged foods containing free[30] sugars, including fruit juice. This means that unsweetened fruits, vegetables and dairy products would not be required to carry a FoP sugars label. Other exemptions to the FoP symbol would include foods in small packages and packages of sugar (e.g. brown sugar).

A range of FoP symbols are being considered as displayed in Figure 2 below (noting that the label would only include the nutrient(s) that exceed the proposed thresholds). Health Canada conducted consumer research (focus groups) in December 2016 to explore consumer access, understanding, appraisal and use of four FoP 'High In' labelling approaches (Sage Research Corporation 2017). Further research to refine the proposal is planned for later in 2017 and it is intended that a Regulatory Impact Analysis Statement also be published later in 2017 (C. Kuran. pers. com[31]).

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[27] An IOM committee recommended the use of a single, standardised FoP system and concluded that the best use of FoP labelling would be to help consumers identify and select foods based on the nutrients most strongly linked to public health concerns.

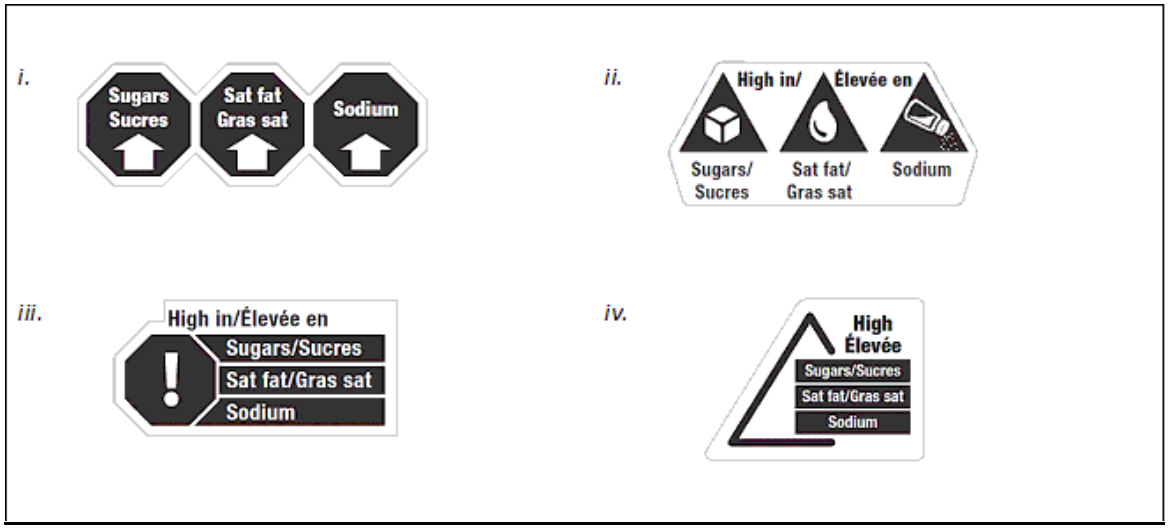
[28] Reference amounts represent the amounts of food typically eaten in one sitting and are set out in Canada's *Food and Drug Regulations*. A minimum reference amount of 50 g (or ml for liquids) is being proposed for the FoP labels for foods with reference amounts equal to or smaller than this amount.

[29] Serving of stated size is defined as follows: for multi-serving prepackaged products, serving of stated size will be based on the regulated reference amount; for single-serving prepackaged products (i.e., the quantity of food in the package that can reasonably be consumed by one person at a single eating occasion, or if the package contains less than 200% of the reference amount of the food), the serving of stated size will be the quantity of food in the package.

[30] Health Canada (2016b) note that free sugars are defined by the World Health Organization as *all monosaccharides and disaccharides added to foods by the manufacturer, cook or consumer, plus the sugars that are naturally present in honey, syrups and fruit juices.*

[31] C Kuran, Section Head, Nutrition Composition, Bureau of Nutritional Sciences, Health Canada, 23 July 2017

Figure 2: Examples of FOP 'high in' symbols under consideration by Health Canada



4.3 Other countries

In 2013, the UK Government published revised national guidance for a voluntary *Front of Pack Nutrition Labelling Scheme* for pre-packaged products (UK Department of Health, 2013). The guidelines are for colour coded labels which use green, amber and red to identify whether products contain low, medium or high levels of energy, fat, saturated fat, salt and sugar. All major UK retailers and a number of multinational food companies have voluntarily started using the traffic light labelling scheme.

According to the World Cancer Research Fund International (2017), a regulation in Ecuador requires packaged food to carry a 'traffic light' label in which the levels of fats, sugar and salt are indicated by red (high), orange (medium) or green (low). The new regulation was implemented in 2014. The Ecuadorian Health Minister has been quoted as saying that more than 20% of large and medium enterprises have decreased the amount of sugar, fat and salt in their products, following the implementation of the new system of labelling alerts on foods and beverages[32]. She noted that fat, sugar and salt contribute to chronic diseases which currently affect a large number of the population such as, diabetes and hypertension and that the new policy has been beneficial to the public and contains information in order to decide what kind of food you wish to eat.

In Mexico, a mandatory GDA system was established for all foods and beverages in July 2015. The GDA system includes icons for energy and various nutrients, including sugar, based on a 100 g serving of the food (Instituto Nacional de Salud Pública de México 2016).

In Thailand certain foods are required to carry a GDA label. The grams per package and percentage of recommended daily intake for energy, total sugar, total fat and sodium must be declared (Rimpeekool et al 2015). The label includes text aimed to help consumers understand the GDA.

The South Korean Special Act on Safety Control of Children's Dietary Life recommends colour-coded labelling for use on the front of pre-packaged children's 'favourite food' including cookies/candies/popsicles, breads, chocolates, dairy products, sausage (fish or meat based), some beverages, instant noodles and fast food (seaweed rolls, hamburgers,

[32] See the Andes accessed 9 August 2017

sandwiches). Guidance for the front-of-pack colour-coded labelling was issued by Public Notice (2011), and outlines three permitted designs using green, amber and red to identify whether products contain low, medium or high levels of total sugars, fat, saturated fat, and sodium (World Cancer Research Fund International 2017).

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Attachment 1 – Case Studies

1. United States of America – Added Sugars in Nutrition Facts Label

Snapshot

- A new rule requires the amount of *Added Sugars* in grams and as a percentage of the daily reference value (% DV) for added sugars in a serving to be declared as a subset of *Total Sugars* in the Nutrition Facts Label.
- The purpose is to provide factual information to help consumers understand the amount of added sugars in foods and construct a healthy dietary pattern.
- The new rule is based on scientific evidence underlying Dietary Guidelines for Americans, dietary recommendations, consumer research and comments from the public. This includes evidence that dietary patterns characterised, in part, by lower consumption of sugar-sweetened foods, are associated with reduced risk of cardiovascular disease.
- The new rule is not based on a direct relationship between added sugars and disease risk; or evidence of change in consumer behaviour and/or health.
- A Regulatory Impact Analysis was completed for combined rules; not specific to added sugars declaration.
- The United States Food and Drug Administration has proposed an extension of the original compliance dates for the new rule, until January 2020 for manufacturers with $10 million or more in annual food sales and until January 2021 for smaller manufacturers.
- A formal petition has been filed by the National Products Association to stop the new rule.

1.1 Overview of new labelling measure

The United States Food and Drug Administration (FDA) released a new Nutrition Facts Label Rule for packaged foods in May 2016 in the final rule (regulation) 'Food Labeling: Revision of the Nutrition and Supplement Facts Label'[33] (FDA 2016a, 2017a). Among other changes, the new rule requires the amount of *added sugars* in grams and as percent daily value (% DV)[34] in a serving to be included on the Nutrition Facts label.

The added sugars content is required to be indented under 'Total Sugars' (changed from 'Sugars') using the words 'Includes x g Added Sugars'. The added sugars statement is not required for products containing less than 1 g of added sugar in a serving if no claims about sugars, added sugars, sweeteners or sugar alcohol are made. In this case, the statement 'Not a significant source of added sugars' is to be included at the bottom of the Nutrition Facts label. If the added sugar content is required to be declared, it must be expressed to the nearest gram, except if a serving contains less than 1 gram the wording 'less than 1 gram'

[33] Referred to in this report as the 'Nutrition Facts Label Rule'

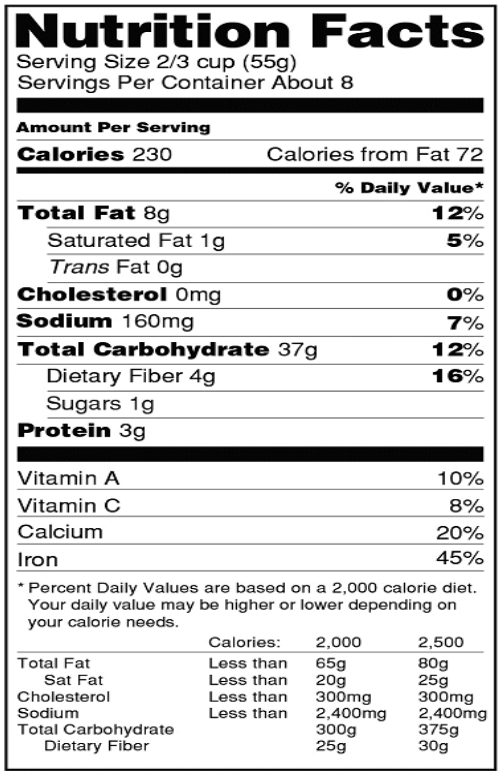
[34] The % DV is based on a Daily Reference Value (DRV) for added sugars. A DRV of 50 g for adults and children 4 or more years of age has been established by the FDA

may be used; and if the serving contains less than 0.5 grams, it may be expressed as zero.

Other changes to the Nutrition Facts label under the new rule include changes in the required font size and/or type, removal of the requirement to declare calories from fat, changes to the micronutrients that must be declared, and changes to the footnote that explains % DV. The changes to the Nutrition Facts label under the new rule are illustrated in Figures 1 and 2 below. A definition for dietary fibre was also introduced.

Figure 1: Original and new USA Nutrition Facts label

Original Label



Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving

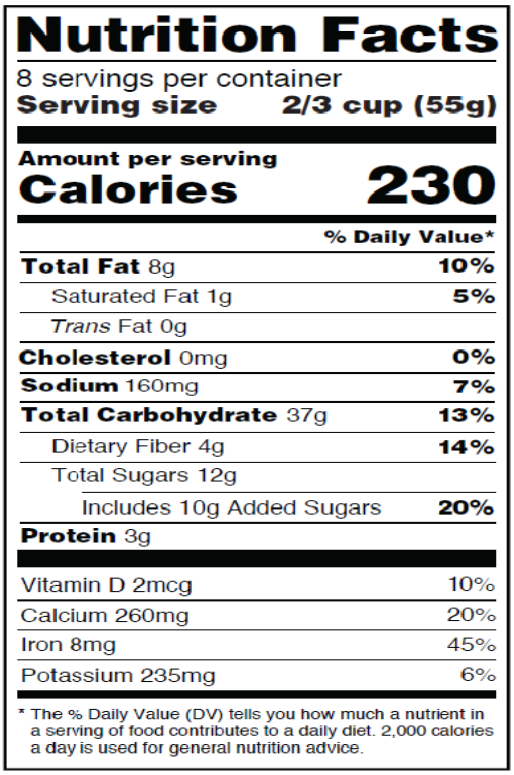
Calories 230 Calories from Fat 72

	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

New Label



Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Figure 2: Highlights of what's different on the new USA Nutrition Facts label

1.1.1 Declaration per serving and per container

In addition to the Nutrition Facts Label Rule, a separate Serving Size Final Rule was also released by the FDA in May 2016 which, among other changes, requires dual column labelling for certain products (FDA 2016b). To address packaged products that may be consumed in one or more sitting, certain products[35] are required to provide an additional column in the Nutrition Facts label that lists the amounts and % DV (including for added sugars) for the entire container, in addition to the column based on a serving.

1.1.2 Added sugars definition

A definition for 'added sugars' was developed by the FDA under the Nutrition Facts Label Rule which *includes sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. The definition excludes fruit or vegetable juice concentrated from 100 percent fruit juice that is sold to consumers (e.g. frozen 100 percent fruit juice concentrate) as well as some sugars found in fruit and vegetable juices, jellies, jams, preserves, and fruit spreads.* The full technical definition is provided in the Code of Federal Regulations[36].

[35] Those containing at least 200% and up to and including 300% of the applicable reference amounts customarily consumed

[36] The Code of Federal Regulations (refer Title 21, Chapter I, Subchapter B, Part 101) is available at Electronic Code of Federal Regulations
Accessed 27 July 2017

1.1.3 Records to verify added sugars amount

The FDA noted that there is no adequate analytical method to distinguish between added and naturally occurring sugars. As such, when naturally occurring and added sugars are present in food, manufacturers are required to maintain records to verify the added sugars declaration. These records must be kept for at least 2 years after introduction, or delivery for introduction, into interstate commerce. A similar requirement exists for added sugars in specific foods, alone or in combination with naturally occurring sugars, where the amount of added sugars is reduced through non-enzymatic browning and fermentation. The FDA stated that manufacturers of such foods who are unable to reasonably approximate the amount of added sugars may submit a petition to request an alternative means of compliance.

1.2 Purpose of new labelling measure

The FDA has stated that the nutrition information on the label has been updated *to assist consumers in maintaining healthy dietary practices*. They note that the current label is more than 20 years old and it is timely to make changes to ensure consumers have access to more recent and accurate nutrition information. The changes are based on updated scientific information, new nutrition and public health research, recent dietary recommendations and comments from the public (see section 1.3 below for further information on the evidence used) (FDA 2016a, FDA 2017a).

In relation to the added sugars declaration specifically, the FDA reports that this is intended to help increase consumer awareness and understanding of the quantity of added sugars in foods; and its contribution in the context of a total daily diet. The declaration provides information to assist consumers in constructing a healthy dietary pattern within the recommended daily limit of less than 10% of calories from added sugars (US Department of Health and Human Services and US Department of Agriculture 2015).In addition, it provides factual information and ensures consumers will not be misled in purchasing decisions as, without the declaration, consumers do not have information about the added sugars content and are not able to calculate the content based on the total sugars declaration or ingredient labelling.

The FDA also states that *consumers may or may not decide to reduce the consumption of certain foods with added sugars, based on their individual needs or preferences*. Additionally, *achieving specific changes in consumer behaviour and/or health are not the government interests.* The FDA states that there is no requirement for a threshold level of change in consumer behaviour before a nutrient can be required on the nutrition label.

1.3 Pre-implementation evidence

1.3.1 Scientific evidence and dietary recommendations

The evidence used by the FDA to support the decision to require the added sugars declaration included the scientific evidence underlying the 2010 and the 2015-2020 Dietary Guidelines for Americans (DGA), in particular, the recommendation to limit calories from added sugars. According to the FDA, the 2010 DGA included the concept that foods high in added sugars displace other nutrient-dense foods in the diet. If added sugars are consumed in excess it becomes more difficult to also eat foods with enough dietary fibre and essential vitamins and minerals and still stay within calorie limits (FDA 2016a).

The 2015 Dietary Guidelines Advisory Committee (DGAC) conducted a systematic review of the evidence related to dietary patterns and health outcomes (e.g. cardiovascular disease, body weight, type 2 diabetes) (FDA 2016a). The DGAC concluded that there is strong and consistent evidence that dietary patterns characterised, in part, by lower consumption of

sugar-sweetened foods and beverages relative to less healthy patterns, are associated with a reduced risk of cardiovascular disease. In referring to this evidence, the FDA noted that they are not establishing or relying on a direct relationship between added sugars intake and obesity, and that evidence of a direct relationship between added sugars and disease risk is still emerging. The DGAC also evaluated limits for added sugars in the diet based, in part, on food pattern modelling and recommended that intake of added sugars be limited to a maximum of 10% of total daily caloric intake.

The FDA also noted that expert groups (e.g. the American Heart Association, the American Academy of Pediatrics, the Institute of Medicine and the World Health Organization) recommend decreasing intake of added sugars (FDA 2017a).

The FDA considered that the scientific evidence provides support for the mandatory declaration of the amount of added sugars in a serving of a product and the % DV of added sugars on the label. The FDA has stated that they are not basing a mandatory declaration of added sugars for the general population on a direct relationship between added sugars intake and risk of disease, but on the need to provide consumers with information to construct a healthy dietary pattern that is low in added sugars. They intend to monitor the evidence in this area and will consider how any new evidence may impact regulations in the future (FDA 2016a).

1.3.2 Consumer research

In developing the new rule, the FDA conducted four consumer studies which explored consumer responses to modifications of the Nutrition Facts label (FDA 2016a). The overarching purpose of these studies was to explore how, and to what extent, different presentations of the Nutrition Facts label and its components may affect consumer responses. The FDA noted that they did not aim to use these studies to develop a label that will be understood by all consumers and recognised that, regardless of how well a label is designed, there is always a certain proportion of consumers who encounter challenges in understanding and using the label. The FDA also noted that as the study samples are not nationally representative the findings cannot be applied to the general population.

The four consumer studies, conducted in 2014 and 2015, were randomised controlled experimental studies with English-speaking adult consumers. Apart from the eye-tracking study, each of the studies were web-based experiments. The four studies were as follows:

1. Experimental study on consumer responses to Nutrition Facts labels with declaration of amount of added sugars (the ‘added sugars study’)

2. Experimental study on consumer responses to Nutrition Facts Labels with various footnote formats (the ‘footnote study’)

3. Experimental study of proposed changes to the Nutrition Facts Label formats (the ‘format study’)

4. Eye-tracking experimental study on consumer responses to modifications to the Nutrition Facts label outlined in the FDA’s proposed rulemaking (the ‘eye-tracking study’).

1.3.2.1 Added sugars study

The ‘added sugars study’ was undertaken to explore consumers’ potential responses to ‘added sugars’ declarations on Nutrition Facts labels to help inform the FDA’s future educational efforts. Nutrition Facts labels were presented in one of three formats. In one format an ‘added sugars’ declaration was indented below a ‘Sugars’ declaration; in another format, an ‘added sugars’ declaration was indented below a ‘Total Sugars’ declaration; and the current Nutrition Facts label (which has a ‘Sugars’ declaration) was used as the third format.

The study did not include a % DV for added sugars on the label and therefore did not provide data on how this information would affect consumer responses.

The study showed that while added sugars declarations increased the ability of some participants to identify those products with less added sugars and to determine the quantity of added sugar in a food, the added sugar declarations in both label formats decreased the ability of some participants to correctly identify the quantity of total sugars in a food (i.e. some participants summed the amount of total sugars and added sugars in the product). The findings of this study are further discussed in FSANZ’s broad literature review on consumer knowledge, attitudes and behaviours relating to sugars and food labelling (section 2.2).

As a result of these findings and comments received on the consumer research, the FDA revised the declaration to include the word ‘Total’ before ‘Sugars’ and used the phrase ‘Includes x g Added Sugars’ indented below ‘Total Sugars’ to clarify that added sugars is a component of total sugars.

1.3.2.2 Footnote, Format and Eye-tracking studies

The ‘footnote study’ explored consumer responses to modified formats for the footnote that explains % DV, including various definitions of % DV, a statement about daily caloric intake, and general guidelines for high and low nutrient levels or nutrients to limit. The study found that all modified footnote options resulted in similar perceptions and judgements of healthiness and nutrient levels relative to the current footnote and no-footnote control. However, all were rated as easier to understand than the current footnote.

The ‘format study’ explored consumer responses to different formats of the Nutrition Facts label (i.e. current label format, the proposed format with an ‘added sugars’ declaration indented below a ‘Sugars’ declaration and alternative format which included the heading ‘Quick Facts’ above a ‘sugars’ declaration together with an ‘Avoid too much’ heading above an ‘added sugars’ declaration). The study did not show many significant or consistent effects of these label variations. However, there were some statistically significant differences, for example, respondents were more accurate in identifying the grams of *sugars* per serving using the current label compared to other formats; respondents were more accurate in identifying grams of *added sugars* with the proposed label compared to the alternative label (respondents assigned to view the current label were not asked this question).

The 'eye-tracking study' explored the potential impacts of the proposed changes, in their totality, on consumer attention to various label elements and consumer effort in searching for specific label information. Different label formats were used, which were borrowed or adapted from the ‘format study’ above. Participants viewed the formats on a computer screen and their eye-movement was recorded. The study showed few statistically significant differences between the different label formats. No single format stood out as the ‘best’ in terms of degree of participant attention to label information, level of effort in using the information, or accuracy of information search or dietary choices.

1.3.2.3 Additional research submitted

The FDA reported that several submitter comments addressed further consumer research on Nutrition Facts labels with added sugars declarations. This included findings from two studies on cranberry and other fruit products; and an online experiment co-sponsored by five trade associations where half of the respondents viewed control labels that only included the amount of 'sugars', and the other half viewed labels with the amount of 'added sugar's in grams and % DV. Comments on the findings of these studies and the FDA's response are reported in the FDA's Final Rule report (FDA 2016a, page start 33820).

1.3.3 Stakeholder views

The FDA received nearly 300,000 comments collectively to the proposed rules (FDA 2016c). This included a significant number of comments specifically about the proposed added sugars declaration.

FSANZ notes there was significant media attention in the USA in relation to the proposed changes for added sugar labelling (before release of the final rule). Critics were cited as questioning whether there is sufficient evidence to require an 'added sugars' declaration because there is no difference in how the body metabolises naturally occurring versus added sugars, and the scientific basis for establishing a daily reference value (DRV) for added sugars is extremely weak. Some stakeholders believed an 'added sugar' declaration would adversely affect consumer understanding of the total sugar content of products. Others noted there is no accurate analytical method to distinguish added from naturally occurring sugars (important for compositional analysis in the Nutrition Facts label). Some nutrition scientists also raised concerns that highlighting added sugars on labels may divert attention away from total calories and other important contributors to weight gain.

In contrast, media reported that many public health stakeholders supported the proposed labelling changes. These stakeholders agreed that naturally occurring sugars and added sugars have the same physiological impact, but note the difference is significant when considering dietary quality. They believe the additional label information will assist consumers in making dietary decisions that would reduce their consumption of added sugars. Some industry stakeholders also expressed strong support for the proposed changes on the basis that they reflect the dietary guidelines to reduce calorie intake from added sugars. However, some of these industry stakeholders qualified their support by stating that certain ingredients (for example, lactose, and mono and disaccharides from any pure fruit ingredient such as juices, concentrates, fruit pieces, pulps and purees) should not be counted as 'added sugars' provided that these ingredients are not added for sweetening purposes.

1.4 Pre-implementation analysis of the cost and benefits

A Final Regulatory Impact Analysis (RIA) has been published by the FDA. The RIA considers the total changes made under the Nutrition Facts Label Rule, along with the Serving Size Final Rule (see section 1.1.1 above) (FDA 2016d). The following provides a summary of the analysis in the Final RIA.

The FDA prepared the RIA for the two final rules together, since they both involve some form of a label change. These new rules comprise a substantial number of changes; the costs and benefits specific to the added sugars declaration have not been individually considered in the RIA.

As with all pre-implementation regulatory analysis, there is uncertainty in the quantification of costs and benefits. The RIA includes sensitivity analysis and multiple discount rates to test the results given the uncertainty. Costs and benefits included in this summary are means of the estimated total costs or benefits over a 20 year period, displayed in 2014 US dollars, using a 3% discount rate. More detail can be found in the FDA's published final RIA (FDA 2016d).

The estimated means of the costs and benefits used to quantify the expected net benefit of implementing the two rules with implementation periods of three years for small businesses and two years for large businesses are provided in Table 1 below.

Table 1: Quantified costs and benefits for US labelling changes (US$)

Costs	Costs over 20 years[1]	Benefits	Benefits over 20 years[2]
Changing the labelling on products	2,720 million	Consumer welfare gains from more informed consumption choices. (Further described below.)	33,100 million
Reformulation costs	1,446 million		
Recordkeeping costs	21.4 million		
Research and additional labelling costs related to the new dietary fibre definition	434 million		
Labelling costs associated with future Universal Product Code (UPC) growth.	135 million		
Total	**4,756 million**		**33,100 million**

[1] Costs are aggregated estimated mean costs over a 20 year period using a 3% discount rate and expressed in 2014 US dollars.
[2] Benefits are aggregated estimated mean benefits over a 20 year period using a 3% discount rate and expressed in 2014 US dollars.

Multiple options for implementation timelines were considered in the RIA. The two year implementation period for large businesses and three-years for small businesses was preferred by the FDA as they believed that this would provide industry time to revise labelling to comply with the new requirements, while balancing the need for consumers to have information in a timely manner. The figures in Table 1 above indicate that this implementation approach was estimated to generate a $28.3 billion dollar net benefit (calculated from total benefits less total costs i.e. $28,344 million). The option involving a four year implementation period for both small and large businesses was estimated to provide the greatest net benefit at $28.5 billion dollars. Since completing the RIA the FDA have proposed a new implementation period in response to stakeholder comments (refer to section 1.5.1 below).

The major benefit of the new rules was predicted to be generated from the more relevant and salient information assisting consumers to make better informed consumption choices. This was predicted to result in gains to consumer welfare primarily due to increases in health and longevity generated by improvement in overall diet. The consumer welfare gains are calculated from the consumers' willingness to pay for the additional nutrient information[37].

[37] The RIA states that these results *are extrapolated from the welfare effects estimated in a retrospective study on the impact of the Nutrition Labelling and Education Act of 1990 by Abaluck 2011).*

Willingness to pay implicitly captures and reflects the fact that individuals account for the effects of their current diet on their future health status in their consumption choices. Because there was a lack of data and information on how consumers would substitute between foods in response to the labelling changes, it was noted that the quantified benefits may over- or understate the realised effects of the new rules.

The RIA notes that the new rules may incentivise food manufacturers to provide additional products with healthier formulations, or reformulate existing products. Due to the limited data available, the potential for reformulation that reduces added sugars to affect measures of health was not able to be verified, and therefore, not quantified. It was also noted that the potential benefits from reformulation may also be somewhat offset if consumers prefer the taste of relatively less nutritious foods, so when they switch consumption to healthier products, or reformulated versions of the existing products, they incur some utility loss.

The RIA states that *changes in label use could reduce the risk of morbidity and prolong life to the extent consumers use such changed label information to maintain healthy dietary practices*. In particular, poor diet and excess body weight has been linked to cardiovascular disease, type 2 diabetes, some cancers, cognitive decline, osteoporosis, and dental disease. Due to data limitations, the direct impact the new rules might have on incidences of these diet-related diseases was not able to be quantified. Thus the direct benefits, such as reduced medical costs beyond those paid by the consumer, associated with reduced incidences of diet-related diseases, were not quantified. Consumers' value in avoiding these diseases is implicitly captured in the quantified benefits through the willingness to pay estimates, as noted above.

The major costs are outlined in Table 1 above, and include:

- changing the labelling on products
- recordkeeping costs associated with making and keeping records sufficient to verify the label declaration for the amounts of dietary fibre, soluble fibre, insoluble fibre, vitamin E and folate/folic acid and added sugars
- reformulating products in order to continue to make certain health and nutrient content claims or as a result of the requirement to display new information on the product label
- labelling costs associated with future Universal Product Code (UPC) growth (see below)
- research and additional labelling costs related to the new dietary fibre definition.

Changing the labelling on products includes labour, material, inventory and recordkeeping costs. All packaged foods subject to FDA regulation would have to undertake some form of label change. The labelling costs include those attributable to the added sugars declaration; however no sugar specific costs were noted in the RIA.

The new Nutrition Facts Label rules require manufacturers to make and keep records to verify the amounts of dietary fibre, soluble fibre, insoluble fibre, vitamin E and folate/folic acid and added sugars in products (see also section 1.1.3) declared on the label. FDA estimated that manufacturers would incur 187,726 recordkeeping hours initially in order to implement the new rules, of which 31,283 would be attributable to the added sugars declaration. This would indicate that the added sugars declaration contributes approximately 16.5 percent to the total initial recordkeeping costs. The $21.4 million recordkeeping costs reported in Table 1 above also include 216 annually recurring hours not specific to the added sugars declaration.

Reformulation costs includes reformulating products to continue to make certain health and nutrient content claims or as a result of the requirement to display new information on the product label. The RIA states that *the labelling changes for added sugars would likely have a*

variety of effects on manufacturers regarding their decisions to reformulate voluntarily. In lieu of reliable data to precisely predict the extent of such reformulation, it was estimated that 7.5 to 9 percent of foods that significantly contribute added sugars to diets would be reformulated. The reformulation costs estimated for foods that significantly contribute added sugars to diets is $658 million of the total reformulation cost of $1,446 million reported in Table 1 above.

Labelling costs for future UPCs refers to new products in the future that would need to bear a Nutrition Facts label for which none was previously required. No costs were specifically attributed to the added sugars declaration for this segment of costs. The cost associated with a new dietary fibre definition does not directly relate to the added sugars declaration.

1.5 Implementation

1.5.1 Compliance date

In May 2016, the FDA finalised the Nutrition Facts Label and Serving Size rules and set the compliance date for 26 July 2018, with an additional year to comply for small businesses (those with annual food sales of less than $10 million). However, after considering feedback from industry and consumer groups on this issue, the FDA announced (on 13 June 2017) its intention to extend the compliance date to allow additional time for implementation (FDA 2017a).

On 29 September 2017, the FDA released a proposed rule to extend the compliance dates for the new rule from July 2018 to January 2020 for manufacturers with $10 million or more in annual food sales and from July 2019 until January 2021 for manufacturers with less than $10 million in annual food sales (FDA 2017a). This was in response to continued concern from the food industry regarding the time needed for implementation of the final rules and the need for FDA to provide further guidance. The FDA stated that extending the compliance dates is a means to provide a balance between giving industry more time and decreasing costs, and minimising the transition period during which consumers will see both the old and the new versions of the label in the marketplace. Comments on the proposed extension of the compliance dates are due by 1 November 2017.
In June 2017, the National Products Association (NPA) filed a formal petition to the FDA to shelve the new Nutrition Facts Label Rule (Prince 2017). The NPA provided arguments for its petition including, for example, that the rule overly burdens the food industry; is inconsistent with the Trump Administration's policy to reduce unnecessary regulations; FDA's consumer studies do not support the addition of the added sugars declaration; and inclusion of a % DV for added sugars in the final rule but not the proposed rule circumvented the public rule making process.

1.5.2 Guidance and education

The FDA released a draft guidance document regarding the requirements under the new Nutrition Facts Label Rule for public comment from 5 January – 6 March 2017 (FDA 2017b). The guidance includes detailed, technical information about determining the added sugars content, for example, how to calculate the amount of added sugars in a fruit juice blend containing the juices of multiple fruits that have not been reconstituted to full-strength. Around 1500 comments were received by the FDA in response to the draft guidance (FDA 2017c). A number of comments expressed concerns about the requirement to declare added sugars in the Nutrition Facts label for the sugars present in a jar of honey and bag of sugar, noting that sugar is not added to such products. The FDA have indicated that they plan to invite further comment on this matter in the near future (FDA 2017d).

With respect to consumer education, the FDA has stated that they intend to update existing educational materials and create new educational opportunities to explain how to use the label to help consumers make healthy dietary choices. They are not planning to focus educational activities on the added sugars declaration in isolation but will focus on a number of aspects of the new label to enhance its use and understanding by consumers (FDA 2016a).

1.6 Post-implementation evaluation

According to FDA staff[38], the United States National Health and Nutrition Examination Survey (NHANES) will most likely be used to undertake any evaluation of the new labelling rules as it considers both intake and labelling. The NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations.

2. Canada – Grouping Sugars-Based Ingredients and Percent Daily Value for Total Sugars

Snapshot

- A new rule requires *sugars-based ingredients* to be grouped in the ingredient list; and a percent daily value (% DV) for *total sugars* to be declared in the Nutrition Facts table in conjunction with a % DV footnote guide.
- The purpose is to provide information and educate consumers on the content of sugar and sugars-based ingredients, with the goal of supporting reduction in sugar intake.
- The new rule was based on stakeholder consultation and evidence that sugars intake may lead to overconsumption of calories and thus to obesity and associated chronic disease.
- Canada originally proposed to include *added sugars* in the Nutrition Facts label similar to USA.
- The *added sugars* approach was dropped following consultations. It was noted that % DV approach easier to understand and more useful; and little evidence to suggest that added sugars have health effects independent of total sugars.
- A Regulatory Impact Analysis was completed for combined amendments; not specific to sugar labelling changes.
- The effective date is December 2021 (giving 5 years from December 2016 to comply).

[38] R McKinnon Senior Advisor for Nutrition Policy, M Parett (Economist), K Kavanaugh and D Reese (International Section), FDA, personal communication March 2017

2.1 Overview of new labelling measures

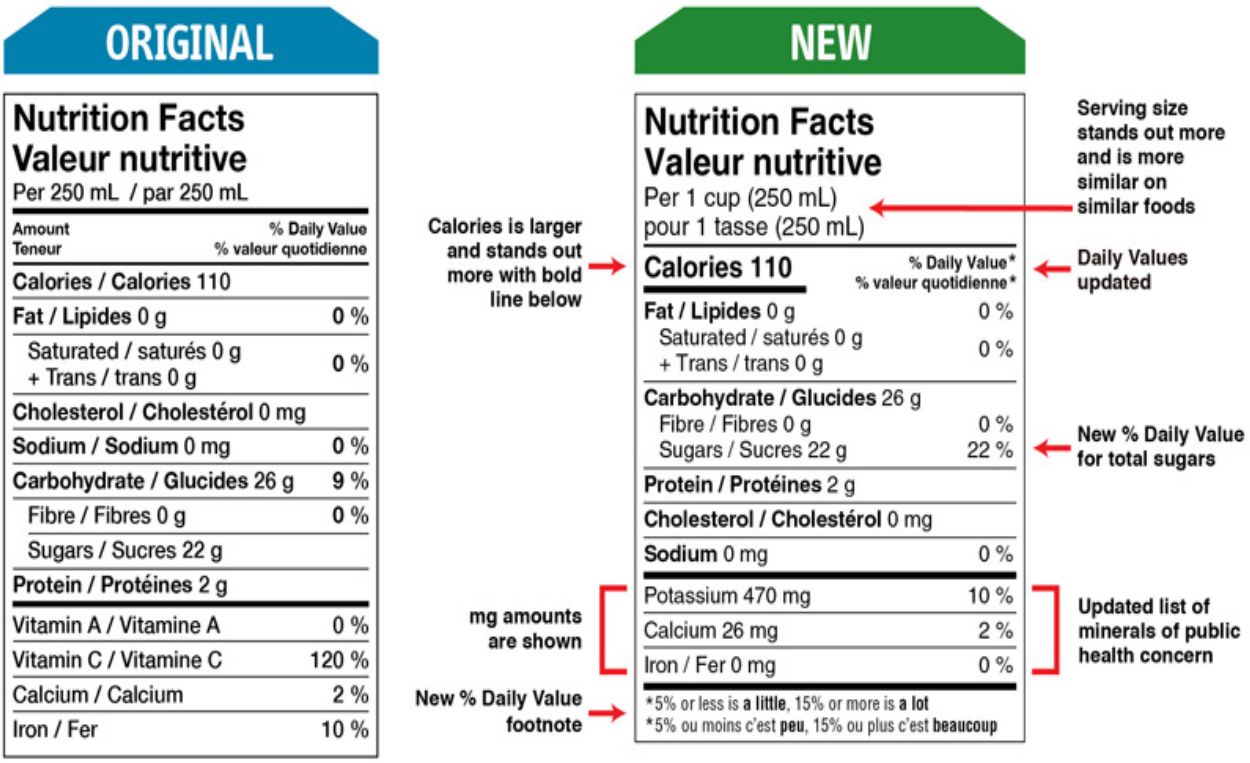
On 14 December 2016, Health Canada announced new requirements for the Nutrition Facts table and list of ingredients in the Food and Drug Regulations *(*Health Canada 2016a). Among other changes to the Nutrition Facts table and list of ingredients, the new regulations require that:

- all sugars-based ingredients must be grouped in the ingredient list under 'sugars'
- % DV for total sugars must be included in the Nutrition Facts table[39]
- a footnote about the % DV must be added to the bottom of the Nutrition Facts table to explain that 5% or less is a little and 15% or more is a lot.

Other changes to the Nutrition Facts table in the new regulations include amendments to the format, changes to the list of vitamins and minerals declared, and making the serving size more consistent and realistic. Other changes to the list of ingredients include listing food colours by their individual common names, and various amendments to the format.

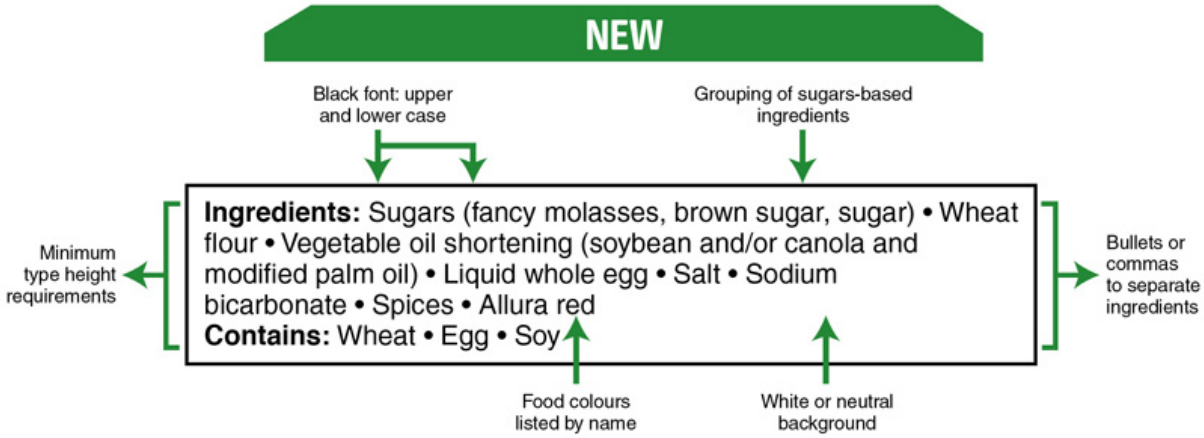
Illustrations of the changes to the Nutrition Facts table and the list of ingredients are provided in Figures 3 and 4 below.

Figure 3: Original and new Canadian Nutrition Facts table



[39] Based on a daily value for sugars of 100 g

Figure 4: New requirements for ingredient list in Canada



2.1.1 Requirements for sugar-based ingredients

The new regulation requires the term 'sugars' to be declared in the ingredient list in descending order of the proportion or percentage of all the sugars-based ingredients of the food. The sugars-based ingredients listed in brackets after the term 'sugars' are also required to be listed in descending order by weight. For example, in Figure 4 above, there is more fancy molasses by weight than brown sugar or sugar and more sugars in the food by weight than any other ingredient.

A definition of 'sugars-based ingredient'[40] is provided in the Food and Drug Regulations (FDR 2017). Health Canada has stated that sugars-based ingredients can include *white sugar, beet sugar, raw sugar, brown sugar, agave syrup, honey, maple syrup, barley malt extract or fancy molasses, fructose, glucose, glucose-fructose (also known as high fructose corn syrup), maltose, sucrose or dextrose, fruit juice concentrates and purée concentrates that are added to replace sugars in foods*.

Certain foods are exempt from this labelling requirement, for example, fruit or vegetable juice or purées or vegetable drink that do not contain any sweetening agent (as defined in the Food and Drug Regulations (FDR 2017)); and packaged products that contain only one sugars-based ingredient that has the word 'sugar' in its common name.

2.2 Purpose of new labelling measures

The Canadian government launched a *Healthy Eating Strategy* in October 2016 (Health Canada 2016b). It unites Health Canada's ongoing nutrition efforts with new, complementary initiatives to help create a food environment that makes healthier eating choices easier for Canadians. The strategy includes initiatives on:

- improving healthy eating
- protecting vulnerable populations

[40] sugars-based ingredient is defined as:
a) an ingredient that is a monosaccharide or disaccharide or a combination of these;
b) an ingredient that is a sweetening agent (also defined) other than one referred to in paragraph (a); and
c) any other ingredient that contains one or more sugars and that is added to the product as a functional substitute for a sweetening agent

- strengthening labelling and claims
- improving nutrition quality standards
- supporting increased access to and availability of nutritious foods.

In terms of strengthening labelling and claims, Health Canada has stated that the overall purpose of the new rules is to make labelling information more useful and easier to understand, to enable consumers to make informed food choices in order to maintain or improve their health (Canada Gazette 2016). In regard to sugar labelling, the provisions were aimed at providing information and educating consumers on the content of sugar and other sugars-based ingredients in foods, with the goal of supporting a reduction in sugar intake consistent with the recommendations of Canada's Food Guide (to limit foods high in sugar).

2.2.1 Purpose of % DV declaration

The declaration of % DV for total sugars in the Nutrition Facts table (in conjunction with the footnote which provides some interpretation of the % DV) has been included to help consumers compare the sugar content of different foods and to identify sugary foods that should be limited, i.e. those with 15% DV or more (Health Canada 2016a). Health Canada states that *consumers will be able to use the % DV to determine whether a food contains a lot or a little sugar (as indicated by the rule of thumb footnote), and as a result adjust or limit their sugars intake* (Canada Gazette 2016).

In addition, in Health Canada's 2014 consultation paper (Health Canada 2014) it was stated that the proposed % DV approach:

- could support an overall reduction in sugar intakes, which is consistent with Canada's Food Guide recommendation of limiting foods high in sugar
- would address consumers' interest to better understand the sugar content of food
- would be consistent with the approach for other nutrients of public health concern related to excessive intakes (e.g. fats, sodium).

It was also noted that the % DV approach would encourage consumers to make food choices consistent with the World Health Organization's (WHO) guideline on the intake of free sugars.

2.2.2 Purpose of grouping sugars-based ingredients

The sugars-based ingredients are grouped in brackets to help consumers to:

- identify that sugars have been added to the food
- quickly find the sources of sugars added
- understand how much sugars are added compared to other ingredients (Health Canada 2016a).

Additionally, Health Canada has stated that the new rules were intended to provide greater transparency regarding sugars added to food as ingredient names such as fancy molasses, malted barley, etc. may not be recognised by most Canadians as sugars-based ingredients (Canada Gazette 2016).

2.3 Pre-implementation evidence

In developing the new measures, Health Canada has stated that changes reflect the latest science and eating habits of Canadians (e.g. updates to the daily values based on recent dietary recommendations); and take into account feedback obtained from stakeholders throughout 2014 (Health Canada 2015a, Canada Gazette 2016).

Health Canada consulted with consumers early in 2014 on suggestions to improve nutrition information on food labels. Over 2400 stakeholder responses were received to the online questionnaire and the findings were published by Health Canada (Health Canada 2015a). Stakeholder views, along with a technical review to update various aspects of the food label, were used to develop a proposal for changing the ingredient and nutrition labelling. Health Canada outlined these proposed changes in consultation documents available for comment in July 2014 and June 2015 (Health Canada 2014, Health Canada 2015b).

With regards to the label changes relating to sugar, Health Canada has noted that excess sugars intake may lead to overconsumption of calories, and thus to obesity and associated chronic diseases (e.g. cardiovascular disease, type 2 diabetes, cancer). In their 2014 consultation paper (Health Canada 2014), they also stated that there is little evidence to suggest that added sugars have health effects independent of the effects of total sugars.

2.3.1 Original added sugars declaration proposal

Health Canada's 2014 consultation paper (Health Canada 2014) proposed to require added sugars to be declared in the Nutrition Facts table similar to the United States approach. Health Canada stated that foods providing the highest amounts of added sugars are often those with a low nutrient density (e.g. sugar-sweetened beverages, desserts). The added sugars declaration was being considered to help consumers identify and choose foods with less or no added sugars. It was also noted, however, that this approach may support the belief that added sugars are nutritionally different from naturally occurring sugars and would create enforcement challenges given then is no analytical method to distinguish between the two.

The added sugars declaration approach was later dropped as a result of the 2014 consultations. According to Health Canada, stakeholder feedback to the consultation revealed Canadians found the % DV approach, particularly in association with the % DV footnote, easier to understand and more useful than the added sugar approach. Information about carbohydrates and total sugars was found to be confusing when there was information on added sugars. However, Health Canada also noted that feedback was mixed, and that the added sugars approach was popular among consumers and health stakeholders. Industry stakeholders, however, questioned the scientific basis of requiring an added sugars declaration given the body metabolises naturally occurring and added sugars in the same way; and noted that the declaration would contribute to significant compliance and enforcement challenges, given the inability of analytical methods to distinguish between naturally occurring and added sugars. Further, industry stakeholders indicated that research undertaken in the USA concluded that consumers have a limited understanding of the *added sugar* declaration in the Nutrition Facts table (Canada Gazette 2016).

2.3.2 Stakeholder views on sugar labelling changes

Mixed views were reported by Health Canada in regard to the requirements to declare % DV for total sugars and the grouping of sugars-based ingredients (Canada Gazette 2016). Industry stakeholders raised concerns that the link with dietary recommendations relating to the declaration of % DV for total sugars was not clear. In relation to grouping sugars in the ingredient list, industry were concerned that this was inconsistent with other nutrients and

would disrupt the conventional practice of listing ingredients in decreasing order of weight. Consumers and health stakeholders were supportive of grouping sugars ingredients; however, a large proportion of the health sector submitters had concerns that the % DV approach might discourage consumption of healthy sources of sugars, such as plain dairy products, which in certain cases may exceed the 15% threshold.

2.4 Pre-implementation analysis of the cost and benefits

A Regulatory Impact Analysis Statement (RIAS) has been published by Health Canada considering the suite of regulatory amendments introduced to facilitate consumers making more informed food choices (Canada Gazette 2016). The RIAS considers the combined regulatory amendments to the Nutrition Facts table and list of ingredients. As such, the scope of the RIAS is broader than the changes made in relation to sugar labelling. The following is a summary of the analysis provided in the RIAS.

Costs and benefits included in this summary are the estimated total costs or benefits over a 10 year period displayed in 2016 Canadian dollars. As with all pre-implementation regulatory analysis, there is uncertainty in the quantification of costs and benefits. The RIAS includes sensitivity analysis to test the results given the uncertainty.

The estimated costs and benefits used to quantify the expected net benefit of implementing the suite of measures is outlined in Table 2 below.

Table 2: Quantified costs and benefits in the Regulatory Impact Analysis Statement for the suite of labelling amendments in Canada

Costs	Costs over 10 years[1]	Benefits	Benefits over 10 years[2]
Industry — one-time compliance	554.7 million	Indirect cost savings	184.2 million
		Direct cost savings: hospital and pharmaceutical costs	1,742 million
Total	**554.7 million**		**1,926 million**

[1]Costs are aggregated estimated costs over a 10 year period expressed in 2016 Canadian dollars.
[2]Benefits are aggregated estimated costs over a 10 year period expressed in 2016 Canadian dollars.

The figures provided in Table 2 above indicate an estimated net benefit (calculated from total benefits less total costs i.e. $13,713 million) of $1.371 billion over 10 years based on a five year implementation period.

The major benefit quantified for the suite of regulatory amendments, as displayed in Table 2 above, was an annual 1% reduction in direct and indirect health costs associated with five chronic diseases that were most linked to diet and nutrition. The benefit is based on the assertion that by enabling Canadians to compare products more easily and make more informed choices of the foods they consumed, their overall health would improve. The five diseases included in the RIAS are cardiovascular disease, malignant neoplasm, diabetes mellitus, musculoskeletal disease and nutritional deficiency. The benefit quantification is based on the economic burden of illness calculations by the Public Health Agency of Canada.

The RIAS notes that the changes may also lead to increased potential for product reformulation with improved nutrient profiles, reduced loss of productivity due to morbidity resulting from unhealthy eating patterns, trickle-down effects of healthy family eating habits into healthy adult eating habits and positive vital health indicators. However, these benefits were not quantified in the RIAS.

The major cost identified was for food manufacturers to undertake a one-off labelling update and associated other work, such as nutrient content analysis to meet new serving size requirements. Costs were calculated from a 2014 industry survey. Using a weighted average methodology, where greater weight is applied to reported costs closer to the average of all reported costs, costs were estimated to be $554.7 million.

These costs were estimated based on the inclusion of all regulatory elements that were presented during consultations. This meant, for example, that food manufacturers included costs associated with declaring added sugars in the Nutrition Facts table as per the United States approach. The decisions to use a daily value approach for total sugars instead of the added sugars approach (see section 2.3 above) may lower industry costs from those reported in the RIAS.

The RIAS reported that a number of industry groups identified reformulation as being a major cost implication. However, it was noted that the regulatory amendments do not require industry to reformulate its products, and choosing to do so would be a business decision.

The RIAS also notes that introducing the changes on a voluntary basis and a straight adoption of the new USA rules, as outlined in section 1, were considered in the development of the final suite of regulatory amendments. The voluntary approach was not further considered in the RIAS as it was believed it may lead to labelling inconsistency and thus not facilitate more informed consumer decisions. The USA approach of the added sugars declaration was also not further considered in the RIAS as consultation indicated Canadians found the % DV approach for total sugars easier to understand and more useful than the inclusion of added sugars per 100 g/100 mL.

2.5 Implementation

The food industry has a five year transition period from December 2016 to comply with the new regulations. Food businesses may comply with either the former regulations or the new regulations during this time (Health Canada 2017).

While Health Canada developed the new regulations, the Canadian Food Inspection Agency (CFIA) is responsible for enforcement of the regulations. Health Canada will respond to enquiries about the intent of the requirements, while the CFIA will address enquiries about compliance and enforcement. The CFIA intends to update its web guidance and tools during the transition period to reflect the new regulations. The CFIA also intends to deliver technical webinars for external stakeholders (CFIA 2016).

2.6 Post-implementation evaluation

In its final report (Canada Gazette 2016), Health Canada stated that it would implement program evaluation requirements with respect to labelling through the Food Safety and Nutrition Performance Measurement Strategy. During the five-year transition period, Health Canada intends to incorporate monitoring and data collection of the labelling amendments as part of this strategy.

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