Regulations Amending the Food and Drug Regulations (Nutrition Symbols, Other Labelling Provisions, Vitamin D and Hydrogenated Fats or Oils): SOR/2022-168

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FOOD AND DRUGS ACT

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, makes the annexed *Regulations Amending the Food and Drug Regulations (Nutrition Symbols, Other Labelling Provisions, Vitamin D and Hydrogenated Fats or Oils)* under subsection 30(1) [a] of the *Food and Drugs Act* [b].

Regulations Amending the Food and Drug Regulations (Nutrition Symbols, Other Labelling Provisions, Vitamin D and Hydrogenated Fats or Oils)

Amendments

1 Subsection B.01.001(1) of the *Food and Drug Regulations* [1] is amended by adding the following in alphabetical order:

Directory of Nutrition Symbol Specifications
means the document entitled *Nutrition Labelling — Directory of Nutrition Symbol Specifications*, published by the Government of Canada on its website, as amended from time to time; (*Répertoire des spécifications des symboles nutritionnels*)

fully hydrogenated,
in respect of a fat or oil, means a fat or oil that is hydrogenated and has an iodine value of 4 or less; (*entièrement hydrogénée*)

main dish
means a combination dish, as set out in the Table of Reference Amounts, that does not require the addition of ingredients, other than water, for its preparation and that contains food from at least two of the following categories:

(a) dairy products and their alternatives, except butter, cream, sour cream, ice cream, ice milk, sherbet and alternatives for those foods;

(b) meat products, poultry products, marine and fresh water animal products referred to in Division 21, and their alternatives such as eggs, tofu, legumes, nuts, seeds, nut or seed butters and spreads made from legumes;

(c) fruits and vegetables except pickles, relishes, olives and garnishes; and

(d) breads, breakfast cereals, rice and other grains, and alimentary pastes; (*plat principal*)

nutrition symbol
means a symbol that is carried on the principal display panel of a prepackaged product under subsection B.01.350(1); (*symbole nutritionnel*)

principal display surface,
in respect of a prepackaged product, means

(a) if the package has a surface that is displayed or visible under customary conditions of sale or use, the total area of that surface, excluding any surface that is the top of the package,

(b) if the package has a lid that is the part of the package that is displayed or visible under customary conditions of sale or use, the total area of the top surface of the lid,

(c) if the package does not have a particular surface that is displayed or visible under customary conditions of sale or use, 40% of the total surface area of the package, excluding any surface area that is its top and bottom, if it is possible for that proportion of the total surface area to be displayed or visible under customary conditions of sale or use,

(d) if the package is a bag with surfaces of equal dimensions, the total area of one of the surfaces,

(e) if the package is a bag with surfaces of different dimensions, the total area of one of the largest surfaces,

(f) despite paragraphs (a) to (e), if the package does not have a surface that is displayed or visible under customary conditions of sale or use to which a label can be applied, the total area of one side of a tag that is attached to the package,

(g) despite paragraphs (a) to (e), if the package contains wine that is exposed for sale, any part of the surface of the package, excluding its top and bottom, that can be seen without having to turn the package, and

(h) if the package is a wrapper or confining band that is so narrow in relation to the size of the food that it cannot reasonably be considered to

have any surface that is displayed or visible under customary conditions of sale or use, the total area of one side of a tag that is attached to the package; (*principale surface exposée*)

Table of Permitted Nutrient Content Statements and Claims
means the document entitled *Nutrition Labelling — Table of Permitted Nutrient Content Statements and Claims*, published by the Government of Canada on its website, as amended from time to time; (*Tableau des mentions et des allégations autorisées concernant la teneur nutritive*)

2 (1) The portion of subsection B.01.008.1(1) of the Regulations before paragraph (a) is replaced by the following:

B.01.008.1 (1) Information appearing on the label of a prepackaged product according to sections B.01.008.2 to B.01.010.4 and B.01.014 must be shown

(2) Paragraphs B.01.008.1(1)(d) and (e) of the Regulations are replaced by the following:

(d) in regular type, except as otherwise provided in those sections; and

(e) in type that is the same height that is not less than 1.1 mm with identical leading of not less than 2.5 mm, except as otherwise provided in this section or those sections.

(3) Subsections B.01.008.1(3) and (4) of the Regulations are replaced by the following:

(3) Except as otherwise provided in subsection (4) and sections B.01.008.2 to B.01.010.4, if a nutrition facts table appears on the label of a prepackaged product and the type size of the nutrients shown in the table is not less than 8 points, the information referred to in subsection (1) must be shown in type that is

(a) the same height as the type in which the nutrients are shown in the table; and

(b) of a height that is not less than 1.4 mm with identical leading of not less than 3.2 mm.

(4) A title that introduces a list of ingredients, a *food allergen source, gluten source and added sulphites statement* as defined in subsection B.01.010.1(1) or a declaration referred to in subsection B.01.010.4(1) may be shown in type that is of a greater height than the type used to show the information in the list, statement or declaration, as the case may be.

3 Paragraph B.01.008.2(2)(b) of the Regulations is replaced by the following:

(b) a background colour that creates a contrast between the background colour of the list and the background colour used on the adjacent surface of the label, other than the surface used to display

(i) a *food allergen source, gluten source and added sulphites statement* as defined in subsection B.01.010.1(1),

(ii) a declaration referred to in subsection B.01.010.4(1),

(iii) any statement referred to in subsection B.01.014(1), or

(iv) a nutrition facts table.

4 (1) Item 26 of the table to subsection B.01.009(1) of the Regulations is replaced by the following:

Item	Ingredient
26	vegetable or animal fats or oils for which a standard is prescribed in Division 9, and modified, interesterified or fully hydrogenated vegetable or animal fats or oils, if the total quantity of those fats and oils that are contained in a prepackaged product is less than 15 per cent of the prepackaged product

(2) Paragraph B.01.009(4)(b) of the Regulations is replaced by the following:

(b) fully hydrogenated peanut oil; and

5 Subsection B.01.010.1(1) of the Regulations is amended by adding the following in alphabetical order:

***height*,**
in respect of type, means the height of the lower case letter “x”. (*hauteur*)

6 Subsection B.01.010.2(1) of the Regulations is replaced by the following:

B.01.010.2 (1) In this section and in section B.01.010.3, ***sulphites*** means the food additives that are set out in the Common Names for Ingredients and Components Document and are present in a prepackaged product.

7 The portion of subsection B.01.010.3(1) of the Regulations before subparagraph (b)(ii) is replaced by the following:

B.01.010.3 (1) A food allergen source, gluten source and added sulphites statement must

a) be introduced by a title that

(i) consists of the terms

(A) "Contains", "Contains:" or "Contains :" in the English version of the statement, and

(B) "Contient", "Contient :" or "Contient:" in the French version of the statement,

(ii) is shown in bold type,

(iii) is shown without any intervening printed, written or graphic material appearing between it and the rest of the statement, and

(iv) if the statement is preceded by a statement referred to in subsection B.01.014(1) and begins on the line on which that statement ends, is shown in a type that is of a height that is at least 0.2 mm greater than the height of the type used in that statement;

(a.1) appear, in respect of each linguistic version, immediately after any statement referred to in subsection B.01.014(1) appearing in the same language or, if there is no such statement, immediately after the list of ingredients appearing in the same language and, in either case, without any intervening printed, written or graphic material;

(a.2) appear on the same continuous surface as the statement or list that immediately precedes it and be shown in the same manner as the list of ingredients is shown under subsection B.01.008.2(2);

(b) include all of the following information, even if all or part of that information is also shown in the list of ingredients:

(i) the source for each food allergen that is present in the prepackaged product,

8 (1) Paragraphs B.01.010.4(1)(a) to (d) of the Regulations are replaced by the following:

(a) the declaration must appear immediately after

(i) the food allergen source, gluten source and added sulphites statement, if there is one,

(ii) any statement referred to in subsection B.01.014(1), if no food allergen source, gluten source and added sulphites statement appears on the label, or

(iii) the list of ingredients, if neither of the statements referred to in subparagraph (ii) appears on the label;

(b) the declaration must appear in both English and French if the statement or list immediately preceding it appears in both languages;

(c) the declaration must appear on the same continuous surface as the statement or list that immediately precedes it and be shown in the same manner as the list of ingredients is shown under subsection B.01.008.2(2);

(d) the declaration must appear without any intervening printed, written or graphic material between it and the statement or list that immediately precedes it, except that a solid line may appear before the declaration if the declaration begins on a different line than the line on which the statement or list ends;

(e) the declaration must be shown in bold type if it begins on the line on which the statement or list that immediately precedes it ends and if it is not introduced by a title;

(f) any title that introduces the declaration must be shown in bold type if the declaration begins on the line on which the statement or list that immediately precedes it ends; and

(g) if the declaration is preceded by a statement referred to in subsection B.01.014(1) and begins on the line on which the statement ends, the title of the declaration — or the declaration itself, if no title appears — must be shown in a type that is of a height that is at least 0.2 mm greater than the height of the type used in the statement.

(2) Subsection B.01.010.4(2) of the Regulations is replaced by the following:

(2) If the English and French versions of the declaration appear on the same continuous surface of the label, the version that follows the other version must not begin on the line on which the other version ends unless the prepackaged product has an available display surface of less than 100 cm^2.

9 Sections B.01.014 to B.01.017 of the Regulations are replaced by the following:

B.01.014 (1) The label of a food that contains aspartame must carry a statement warning individuals with phenylketonuria that the food contains phenylalanine or a statement to the effect that aspartame contains phenylalanine.

(2) The statement must

(a) be shown in bold type;

(b) appear, in respect of each linguistic version, immediately after the list of ingredients appearing in the same language, either on the same line as the last ingredient in the list or on the following line, without any intervening printed, written or graphic material; and

(c) appear on the same continuous surface as the list of ingredients and be shown in the same manner as that list is shown under subsection B.01.008.2(2).

10 Sections B.01.019 and B.01.020 of the Regulations are repealed.

11 Sections B.01.022 and B.01.023 of the Regulations are replaced by the following:

B.01.023 The label of a food that is a table-top sweetener that contains aspartame, sucralose, acesulfame-potassium or neotame must carry a statement of the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness.

12 Paragraph B.01.305(3)(g) of the Regulations is replaced by the following:

(g) any statement referred to in subsection B.01.014(1);

13 The Regulations are amended by adding the following after section B.01.312:

Nutrition Symbols

Mandatory Information

B.01.350 (1) Except as otherwise provided in this section, the principal display panel of a prepackaged product must carry a symbol that is set out in Schedule K.1 if

(a) the product, as offered for sale, contains a nutrient that is set out in column 1 of the table to this section; and

(b) the amount of the nutrient, calculated as a percentage of the daily value, meets or exceeds the applicable threshold set out in columns 2 to 7 of that table.

(2) For the purposes of subsection (1), the percentage of the daily value for the nutrient is calculated on the basis of the amount of the nutrient, by weight, per serving of stated size or per reference amount, whichever is greater.

(3) Despite subsection (2), if the prepackaged product requires reconstitution with water or another liquid or the addition of any other ingredient for its preparation and the reference amount applicable to the product only refers to the food in its prepared form, the percentage of the daily value for the nutrient is calculated on the basis of the amount of the nutrient, by weight, per serving of stated size.

(4) In the case of a prepackaged product referred to in subsection (3), the applicable threshold set out in columns 2 to 7 of the table to this section is determined on the basis of the product's serving of stated size rather than its reference amount.

(5) Subsection (1) does not apply to the following:

(a) shipping containers, unless the containers and their contents are sold as a one unit prepackaged product to a consumer at the retail level;

(b) prepackaged products with an available display surface of less than 15 cm^2;

(c) prepackaged individual portions of food that are intended solely to be served by a restaurant or other commercial enterprise with meals or snacks;

(d) ready-to-serve multiple-serving prepackaged products that are intended solely to be served in a commercial or industrial enterprise or an institution;

(e) prepackaged products that are intended solely for use as an ingredient in the manufacture of other prepackaged products intended for sale to a consumer at the retail level or as an ingredient in the preparation of food by a commercial or industrial enterprise or an institution;

(f) milk, partly skimmed milk, skim milk, goat's milk, partly skimmed goat's milk, skimmed goat's milk, (naming the flavour) milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk or cream sold in a refillable glass container;

(g) sweetening agents, including maple sugar and maple syrup;

(h) salt for table or general household use, celery salt, garlic salt, onion salt and any other seasoning salt if "salt" forms part of the common name of the food;

(i) fats and oils referred to in Division 9, fish and other marine fats and oils, butter, ghee and margarine and other similar substitutes for butter; or

(j) individual rations intended for use by military personnel engaged in operations or exercises.

(6) Subsection (1) does not apply, in respect of a nutrient, to the following prepackaged products if the only ingredients containing the nutrient are, in the case of saturated fat or sodium, ingredients set out in subsection (7) or, in the case of sugars, ingredients set out in subsection (8):

(a) whole or cut fruits or vegetables, including frozen, canned or dried fruits or vegetables;

(b) milk obtained from any animal, in liquid or powdered form;

(c) whole eggs, including liquid, frozen or dried eggs, or whole egg mixes;

(d) nuts, seeds or nut or seed butters in which less than 30% of the total fat content consists of saturated fat;

(e) vegetable oils or marine oils in which less than 30% of the total fat content consists of saturated fat;

(f) marine and fresh water animal products referred to in Division 21 in which less than 30% of the total fat content consists of saturated fat; or

(g) any combination of the foods referred to in paragraphs (a) to (f).

(7) For the purposes of subsection (6) in relation to saturated fat and sodium, the ingredients are the following ingredients to which no saturated fat or sodium has been added:

(a) whole or cut fruits or vegetables, including frozen, canned or dried fruits or vegetables;

(b) milk obtained from any animal, in liquid or powdered form;

(c) whole eggs, including liquid, frozen or dried eggs, or whole egg mixes;

(d) nuts, seeds or nut or seed butters in which less than 30% of the total fat content consists of saturated fat;

(e) vegetable oils or marine oils in which less than 30% of the total fat content consists of saturated fat; and

(f) marine and fresh water animal products referred to in Division 21 in which less than 30% of the total fat content consists of saturated fat.

(8) For the purposes of subsection (6) in relation to sugars, the ingredients are the following ingredients to which no sugars have been added:

(a) the ingredients set out in paragraphs (7)(a), (b) and (d);

(b) dairy products other than those referred to in paragraph (7)(b);

(c) grains; and

(d) legumes.

(9) Subsection (1) does not apply, in respect of saturated fat and sugars, to prepackaged products that are cheese or yogurt – including drinkable yogurt – that are made from dairy products, kefir or buttermilk unless

(a) in the case of saturated fat, the product contains an ingredient, other than any of the following ingredients, that contains saturated fat:

(i) milk ingredients,

(ii) modified milk ingredients,

(iii) nuts or seeds in which less than 30% of the total fat content consists of saturated fat,

(iv) vegetable oils or marine oils in which less than 30% of the total fat content consists of saturated fat, or

(v) marine and fresh water animal products referred to in Division 21 in which less than 30% of the total fat content consists of saturated fat; and

(b) in the case of sugars, the product contains an ingredient, other than any of the following ingredients, that contains sugars or the product contains any of the following ingredients to which sugars have been added:

(i) whole or cut fruits or vegetables, including frozen, canned or dried fruits or vegetables,

(ii) dairy products,

(iii) grains,

(iv) legumes, or

(v) nuts or seeds.

(10) For the purposes of paragraphs (6)(a) and (7)(a), fruit does not include coconut.

(11) Subsection (1) does not apply, in respect of sodium, to prepackaged products that are cheese made from dairy products.

(12) For the application of subsections (9) and (11), the prepackaged products must

(a) have a reference amount of 30 g or 30 mL or less and contain 10% or more of the daily value for calcium per serving of stated size or per reference amount, whichever is greater; or

(b) have a reference amount greater than 30 g or 30 mL and contain 15% or more of the daily value for calcium per serving of stated size or per reference amount, whichever is greater.

(13) Subsection (1) does not apply to the following prepackaged products unless they are required to carry a nutrition facts table on their label:

(a) a beverage with an alcohol content of more than 0.5%;

(b) a raw single ingredient meat, meat by-product, poultry meat or poultry meat by-product that is not ground;

(c) a raw single ingredient marine or fresh water animal product;

(d) a product sold only in the retail establishment where it is prepared and processed from its ingredients, including from a pre-mix if an ingredient other than water is added to the pre-mix during the preparation and processing of the product;

(e) a product sold only at a road-side stand, craft show, flea market, fair, farmers' market or sugar bush by the individual who prepared and processed the product;

(f) an individual serving that is sold for immediate consumption and that has not been subjected to a process to extend its durable life, including special packaging;

(g) a product sold only in the retail establishment where it is packaged, if it is labelled by means of a sticker and has an available display surface of less than 200 cm^2; or

(h) a product with an available display surface of less than 100 cm^2.

(13.01) Subsection (1) does not apply to a prepackaged product that is a raw single ingredient meat, meat by-product, poultry meat or poultry meat by-product that is ground unless it meets any of the conditions that are set out in paragraph B.01.401(3)(a), (b), (c) or (e).

(14) If, as a result of the application of any provision in subsections (5) to (13.01), subsection (1) does not apply to a prepackaged product or does not apply to a prepackaged product in respect of a particular nutrient, that provision prevails over any other provision in subsections (5) to (13.01) that indicates otherwise.

(15) Despite any other provision in this section, the label of the following prepackaged products must not carry a symbol referred to in subsection (1):

(a) a prepackaged product intended solely for infants six months of age or older but less than one year of age;

(b) a human milk fortifier;

(c) a human milk substitute or a food represented as containing a human milk substitute;

(d) a *formulated liquid diet* as defined in section B.24.001;

(e) a meal replacement;

(f) a nutritional supplement;

(g) a food represented for protein-restricted diets;

(h) a food represented for low (naming the amino acid) diets; and

(i) a food represented for use in a *very low energy diet* as defined in section B.24.001.

TABLE

Thresholds Requiring a Nutrition Symbol

Item	Column 1 Nutrient	Column 2 Prepackaged product with a reference amount greater than 30 g or 30 mL, unless the product is described in column 4	Column 3 Prepackaged product with a reference amount of 30 g or 30 mL or less	Column 4 Prepackaged main dish with a reference amount of 200 g or more	Column 5 Prepackaged product with a reference amount greater than 30 g or 30 mL, unless the product is described in column 7	Column 6 Threshold for a prepackaged product other than one referred to in columns 5 to 7 Prepackaged product with a reference amount of 30 g or 30 mL or less	Column 7 Threshold for a prepackaged product intended solely for children one year of age or older, but less than four years of age Prepackaged main dish with a reference amount of 170 g or more
1	Saturated fat	15% of the daily value for the sum of saturated fatty acids and trans fatty acids set out in column 3 of Part 1 of the Table of Daily Values	10% of the daily value for the sum of saturated fatty acids and trans fatty acids set out in column 3 of Part 1 of the Table of Daily Values	30% of the daily value for the sum of saturated fatty acids and trans fatty acids set out in column 3 of Part 1 of the Table of Daily Values	15% of the daily value for the sum of saturated fatty acids and trans fatty acids set out in column 2 of Part 1 of the Table of Daily Values	10% of the daily value for the sum of saturated fatty acids and trans fatty acids set out in column 2 of Part 1 of the Table of Daily Values	30% of the daily value for the sum of saturated fatty acids and trans fatty acids set out in column 2 of Part 1 of the Table of Daily Values
2	Sugars	15% of the daily value for sugars set out in column 3 of Part 1 of the Table of Daily Values	10% of the daily value for sugars set out in column 3 of Part 1 of the Table of Daily Values	30% of the daily value for sugars set out in column 3 of Part 1 of the Table of Daily Values	15% of the daily value for sugars set out in column 2 of Part 1 of the Table of Daily Values	10% of the daily value for sugars set out in column 2 of Part 1 of the Table of Daily Values	30% of the daily value for sugars set out in column 2 of Part 1 of the Table of Daily Values
3	Sodium	15% of the daily value for sodium set out in column 3 of Part 1 of the Table of Daily Values	10% of the daily value for sodium set out in column 3 of Part 1 of the Table of Daily Values	30% of the daily value for sodium set out in column 3 of Part 1 of the Table of Daily Values	15% of the daily value for sodium set out in column 2 of Part 1 of the Table of Daily Values	10% of the daily value for sodium set out in column 2 of Part 1 of the Table of Daily Values	30% of the daily value for sodium set out in column 2 of Part 1 of the Table of Daily Values

Presentation of Nutrition Symbol

B.01.351 (1) A nutrition symbol must be displayed in black and white and must be in accordance with the applicable symbol set out in Schedule K.1.

(2) Subject to subsection (3), a nutrition symbol must be presented in one of the following formats:

(a) unilingual horizontal format, where two separate versions of the symbol are shown, one in English (EH) and one in French (FH); or

(b) bilingual horizontal format (BH), where the symbol is shown in both official languages.

(3) If the principal display surface is less than or equal to 450 cm^2 and the width of the nutrition symbol in either of the horizontal formats that could apply exceeds the width of the principal display panel, the symbol must be presented in one of the following formats:

(a) unilingual vertical format, where two separate versions of the symbol are shown, one in English (EV) and one in French (FV); or

(b) bilingual vertical format (BV), where the symbol is shown in both official languages.

(4) If, in accordance with subsection B.01.012(3) or (7), the information required by these Regulations may be shown on the label of a prepackaged product in English only or in French only and is shown in that language, the nutrition symbol may be displayed on the principal display panel of the product in that language only on a continuous surface of the available display surface.

(5) If a nutrition symbol is presented in a bilingual format, the order in which the languages appear may be reversed from the order shown in the applicable symbol set out in Schedule K.1.

B.01.352 (1) The version of the nutrition symbol that must be carried on a prepackaged product that has a principal display surface that is within a range set out in column 1 of the table to this section and that contains a nutrient set out in column 2 in an amount that meets or exceeds the applicable threshold referred to in subsection B.01.350(1) is the version that is referred to in column 3 or 5 of the table or, if applicable, column 4 or 6 of the table.

(2) Despite subsection (1), a prepackaged product that has a principal display surface that is greater than 250 cm^2 may carry the applicable version of the nutrition symbol that is referred to in item 4, column 2, of Table 1 or 3 in the Directory of Nutrition Symbol Specifications if the product is sold only in the retail establishment where it is packaged and is labelled by means of a sticker.

(3) A nutrition symbol must be displayed in accordance with the applicable specifications set out in the Directory of Nutrition Symbol Specifications.

(4) Despite subsection (3), a nutrition symbol may be displayed with larger dimensions than those set out in column 3 of the applicable table in the Directory of Nutrition Symbol Specifications if the symbol is enlarged in a proportional manner vertically and horizontally.

TABLE

Nutrition Symbols and Formats

Item	Column 1 Range of principal display surface	Column 2 Nutrients that meet or exceed threshold in subsection B.01.350(1)	Column 3 Nutrition symbol in unilingual horizontal format	Column 4 Nutrition symbol in unilingual vertical format	Column 5 Nutrition symbol in bilingual horizontal format	Column 6 Nutrition symbol in bilingual vertical format
1	> 30 cm^2	Saturated fat (Sat fat), sugars and sodium	1(EH) and 1(FH)	1(EV) and 1(FV)	1(BH)	1(BV)
		Saturated fat (Sat fat) and sugars	2(EH) and 2(FH)	2(EV) and 2(FV)	2(BH)	2(BV)
		Sugars and sodium	3(EH) and 3(FH)	3(EV) and 3(FV)	3(BH)	3(BV)
		Saturated fat (Sat fat) and sodium	4(EH) and 4(FH)	4(EV) and 4(FV)	4(BH)	4(BV)
		Saturated fat (Sat fat)	5(EH) and 5(FH)	5(EV) and 5(FV)	5(BH)	5(BV)
		Sugars	6(EH) and 6(FH)	6(EV) and 6(FV)	6(BH)	6(BV)
		Sodium	7(EH) and 7(FH)	7(EV) and 7(FV)	7(BH)	7(BV)
2	≤ 30 cm^2	Saturated fat (Sat fat), sugars and sodium	1(EH) and 1(FH)	1(EV) and 1(FV)	1(BH)	1(BV)
		Saturated fat (Sat fat) and sugars	8(EH) and 8(FH)	8(EV) and 8(FV)	8(BH)	8(BV)
		Sugars and sodium	9(EH) and 9(FH)	9(EV) and 9(FV)	9(BH)	9(BV)
		Saturated fat (Sat fat) and sodium	10(EH) and 10(FH)	10(EV) and 10(FV)	10(BH)	10(BV)

		Saturated fat (Sat fat)	11(EH) and 11(FH)	11(EV) and 11(FV)	11(BH)	11(BV)
		Sugars	12(EH) and 12(FH)	12(EV) and 12(FV)	12(BH)	12(BV)
		Sodium	13(EH) and 13(FH)	13(EV) and 13(FV)	13(BH)	13(BV)

B.01.353 (1) Subject to subsection (2), if a prepackaged product contains an assortment of foods and one or more of the foods requires a nutrition symbol, the nutrition symbols must be displayed in a manner that clearly indicates the applicable nutrients that are contained in each food.

(2) If a prepackaged product contains ingredients that are intended to be combined together or foods that are intended to be consumed together, the nutrition symbol must display the nutrients that are contained in the product as a whole.

B.01.354 The characters and other elements of a nutrition symbol must not touch each other.

Location of Nutrition Symbol

B.01.355 (1) A nutrition symbol must be displayed

(a) in the case of a prepackaged product with a principal display panel whose height is less than its width, on the right half of the panel; and

(b) in the case of any other prepackaged product, on the upper half of the principal display panel.

(2) The nutrition symbol must be surrounded by a buffer that

(a) has a width that is equal to or greater than that set out in column 4 of the applicable table in the Directory of Nutrition Symbol Specifications; and

(b) does not contain any text or other graphic material.

(3) If a prepackaged product is cylindrical in shape, the outer edge of the buffer must be a minimum distance of 10% of the width of the principal display surface from the edge of the left or right side of that surface.

(4) If it is impossible to comply with both paragraph (1)(a) and subsection (3), the nutrition symbol may be displayed partially in the left half of the principal display panel but only to the extent necessary to comply with that subsection.

B.01.356 A nutrition symbol must be oriented in the same manner as most of the other information that appears on the principal display panel unless the panel is displayed in the vertical plane and most of the other information is not displayed parallel with the base of the package, in which case the symbol must be oriented in such a manner that the words appearing in it are parallel with the base.

Prominence of Health-related Representations

B.01.357 (1) If both a nutrition symbol and a health-related representation appear on the principal display panel of a prepackaged product and the representation relates to a nutrient that is referred to in the nutrition symbol,

(a) the height of the upper case letters in the representation must not exceed the height of the upper case letters, excluding any accents, in the nutrition symbol, other than in the words “Health Canada” and “Santé Canada”; and

(b) the height of the tallest ascender of the lower case letters in the representation must not exceed the height of the tallest ascender of the lower case letters in the nutrition symbol, other than in the words “Health Canada” and “Santé Canada”.

(2) If both a nutrition symbol and a health-related representation appear on the principal display panel of a prepackaged product and the representation does not relate to a nutrient that is referred to in the nutrition symbol,

(a) the height of the upper case letters in the representation must not exceed two times the height of the upper case letters, excluding any accents, in the nutrition symbol, other than in the words “Health Canada” and “Santé Canada”; and

(b) the height of the tallest ascender of the lower case letters in the representation must not exceed two times the height of the tallest ascender of the lower case letters in the nutrition symbol, other than in the words “Health Canada” and “Santé Canada”.

(3) In this section, ***health-related representation*** means

(a) a declaration referred to in subsection B.01.301(1) or (2);

(b) a statement or claim referred to in subsection B.01.311(2) or (3);

(c) a representation referred to in any of sections B.01.503 to B.01.513;

(d) a statement or claim referred to in subsection B.01.601(1); or

(e) any other health-related statement, logo, symbol, seal of approval or mark, other than

(i) the brand name or product name of a prepackaged product, or

(ii) a statement or claim referred to in any of sections D.01.004 to D.01.007 and D.02.002 to D.02.005.

Prohibitions — Resemblance to Nutrition Symbol

B.01.358 It is prohibited to

(a) label a prepackaged product with any representation, including a word, phrase, illustration, sign, mark, symbol or design, that is likely to be mistaken for a nutrition symbol; or

(b) advertise or sell a prepackaged product that is labelled with a representation referred to in paragraph (a).

14 (1) Paragraph B.01.401(3)(c) of the Regulations is repealed.

(2) The portion of item 16 of the table to section B.01.401 of the French version of the Regulations in column 2 is replaced by the following:

Article	Colonne 2 Nomenclature
16	« *5 % ou moins c'est peu, 15 % ou plus c'est beaucoup »

15 (1) Paragraph B.01.467(2)(a) of the Regulations is replaced by the following:

(a) described in paragraph B.01.401(3)(a), (b) or (e); or

(2) The portion of subsection B.01.467(2.1) of the Regulations before paragraph (a) is replaced by the following:

(2.1) However, subsection (1) applies to a prepackaged product that is referred to in subparagraph B.01.401(3)(e)(ii) and that meets the conditions set out in item 37, column 2, of the Table of Permitted Nutrient Content Statements and Claims for the subject "Free of sugars" set out in column 1 if

(3) Paragraph B.01.467(2.1)(b) of the Regulations is replaced by the following:

(b) the energy value expressed in Calories per serving of stated size and the amount of sugar alcohols expressed in grams per serving of stated size are shown immediately after whichever of the following elements appears last on the label:

(i) the list of ingredients,

(ii) a *food allergen source, gluten source and added sulphites statement* as defined in subsection B.01.010.1(1),

(iii) a declaration referred to in subsection B.01.010.4(1), or

(iv) any statement referred to in subsection B.01.014(1); and

(4) The portion of paragraph B.01.467(2.1)(c) of the Regulations before subparagraph (i) is replaced by the following:

(c) any statement or claim that is set out in item 37, column 4, of the table for the subject "Free of sugars" set out in column 1 and that appears on the label is

16 (1) Paragraph B.01.502(2)(a) of the Regulations is replaced by the following:

(a) a representation otherwise provided for in these Regulations, including one that is in the form of a nutrition symbol;

(2) Paragraph B.01.502(2)(g) of the Regulations is replaced by the following:

(g) a representation that characterizes the amount of starch in a food, if the food is intended solely for infants six months of age or older but less than one year of age;

(3) Paragraph B.01.502(2)(j) of the Regulations is replaced by the following:

(j) a representation that characterizes the amount of alcohol in a beverage;

17 (1) Section B.01.503 of the Regulations is amended by adding the following after subsection (1):

(1.1) Despite subsection (1), no person shall, on the principal display panel of a prepackaged product, make a statement or claim that is set out in column 4 of the Table of Permitted Nutrient Content Statements and Claims and that relates to a nutrient that is referred to in a nutrition symbol that appears on the panel unless it is a statement or claim respecting one of the following subjects set out in column 1:

(a) "reduced in saturated fatty acids", set out in item 20;

(b) "reduced in sodium or salt", set out in item 33; or

(c) "reduced in sugars", set out in item 38.

(2) The portion of subsection B.01.503(2) of the Regulations before paragraph (a) is replaced by the following:

(2) Despite subsection (1), no person shall, on the label of or in any advertisement for a food that is intended solely for children under four years of age, make a statement or claim set out in column 4 of the Table of Permitted Nutrient Content Statements and Claims unless it is a statement or claim respecting one of the following subjects set out in column 1:

18 Section B.01.508 of the Regulations is renumbered as subsection B.01.508(1) and is amended by adding the following:

(2) Despite subsection (1), no person shall, on the principal display panel of a prepackaged product, make a representation, express or implied, that the product is for use in a sodium-restricted diet if a nutrition symbol referring to sodium appears on the panel.

19 Section B.01.509 of the Regulations is replaced by the following:

B.01.509 (1) A person may, on the label of or in any advertisement for a food, make the statement or claim that the food is "unsweetened" if

(a) the food meets the conditions set out in item 40, column 2, of the Table of Permitted Nutrient Content Statements and Claims for the subject "No added sugars" set out in column 1; and

(b) the food does not contain a sweetener referred to in section 2 of the *Marketing Authorization for Food Additives That May Be Used as Sweeteners*.

(2) Despite subsection (1), no person shall, on the principal display panel of a prepackaged product, make a statement or claim that the product is "unsweetened" if a nutrition symbol referring to sugars appears on the panel.

20 The table following section B.01.513 of the Regulations is repealed.

21 Subparagraph B.01.601(1)(c)(i) of the Regulations is replaced by the following:

(i) intended solely for children under four years of age, or

22 Paragraph B.08.003(b) of the Regulations is replaced by the following:

(b) shall contain 2 µg of vitamin D per 100 mL.

23 Paragraph B.08.004(c) of the Regulations is replaced by the following:

(c) shall contain 2 µg of vitamin D per 100 mL.

24 Paragraph B.08.005(c) of the Regulations is replaced by the following:

(c) shall contain 2 µg of vitamin D per 100 mL.

25 Paragraph B.08.007(d) of the Regulations is replaced by the following:

(d) shall contain 2 µg of vitamin D per 100 mL.

26 Paragraph B.08.010(d) of the Regulations is replaced by the following:

(d) shall contain 2 µg of vitamin D per 100 mL when reconstituted to its original volume; and

27 Paragraph B.08.011(e) of the Regulations is replaced by the following:

(e) shall contain 2 µg of vitamin D per 100 mL when reconstituted to its original volume; and

28 Paragraph B.08.012(f) of the Regulations is replaced by the following:

(f) shall contain 2 µg of vitamin D per 100 mL when reconstituted to its original volume; and

29 Paragraph B.08.013(c) of the Regulations is replaced by the following:

(c) shall contain 2 µg of vitamin D per 100 mL when reconstituted according to directions for use; and

30 Paragraph B.08.014(d) of the Regulations is replaced by the following:

(d) shall contain 2 µg of vitamin D per 100 mL when reconstituted according to directions for use; and

31 Paragraph B.08.016(c) of the Regulations is replaced by the following:

(c) shall contain 2 µg of vitamin D per 100 mL;

32 Paragraph B.08.017(d) of the Regulations is replaced by the following:

(d) shall contain 2 µg of vitamin D per 100 mL; and

33 Paragraph B.08.018(d) of the Regulations is replaced by the following:

(d) shall contain 2 µg of vitamin D per 100 mL;

34 Paragraph B.08.019(e) of the Regulations is replaced by the following:

(e) shall contain 2 µg of vitamin D per 100 mL.

35 Paragraph B.08.020(d) of the Regulations is replaced by the following:

(d) shall contain 2 µg of vitamin D per 100 mL.

36 Paragraph B.08.023(e) of the Regulations is replaced by the following:

(e) shall contain 2 µg of vitamin D per 100 mL; and

37 Paragraph B.08.026(e) of the Regulations is replaced by the following:

(e) shall contain 2 µg of vitamin D per 100 mL;

38 Section B.08.029 of the Regulations is replaced by the following:

B.08.029 (1) No person shall sell goat's milk or goat's milk powder to which vitamin D has been added unless 100 mL of that food, when ready-to-serve, contains 2 µg of vitamin D.

(2) No person shall sell skimmed or partly skimmed goat's milk or skimmed or partly skimmed goat's milk powder to which vitamin A or D has been added unless 100 mL of that food, when ready-to-serve, contains both vitamin A and D in the following amounts:

(a) not less than 140 I.U. and not more than 300 I.U. of vitamin A; and

(b) 2 µg of vitamin D.

(3) No person shall sell evaporated goat's milk to which any of the following vitamins have been added unless 100 mL of that food, when reconstituted to its original volume, contains each of the following vitamins in the following amounts:

(a) not less than 7 mg and not more than 9 mg of vitamin C;

(b) 2 µg of vitamin D; and

(c) not less than 10 µg and not more than 20 µg of folic acid.

(4) No person shall sell evaporated partly skimmed goat's milk or evaporated skimmed goat's milk to which any of the following vitamins have been added unless 100 mL of that food, when reconstituted to its original volume, contains each of the following vitamins in the following amounts:

(a) not less than 140 I.U. and not more than 300 I.U. of vitamin A;

(b) not less than 7 mg and not more than 9 mg of vitamin C;

(c) 2 µg of vitamin D; and

(d) not less than 10 µg and not more than 20 µg of folic acid.

39 The portion of section B.09.011 of the Regulations before paragraph (a) is replaced by the following:

B.09.011 [*S*]. Shortening, other than butter or lard, shall be the semi-solid food prepared from fats, oils or a combination of fats and oils, may be processed by full hydrogenation and may contain

40 Subparagraph B.09.013(c)(i) of the Regulations is replaced by the following:

(i) lard stearine or fully hydrogenated lard,

41 (1) Paragraphs B.09.016(a) and (b) of the Regulations are replaced by the following:

(a) shall be a plastic or fluid emulsion of water in fats, oil or fats and oil that are not derived from milk and may have been subjected to full hydrogenation;

(b) shall contain

(i) not less than 80% fat, oil or fat and oil calculated as fat,

(ii) not less than 3,300 I.U. of vitamin A per 100 g, and

(iii) 26 µg of vitamin D per 100 g; and

(2) Subparagraph B.09.016(c)(v) of the Regulations is replaced by the following:

(v) vitamin E, if added in such an amount that will result in the finished product containing not less than 0.6 I.U. of alpha-tocopherol per gram of linoleic acid present in the margarine,

42 Section B.14.006 of the Regulations is replaced by the following:

B.14.006 Powdered fully hydrogenated cottonseed oil may be applied as a release agent to the surface of meat, meat by-product, prepared meat, prepared meat by-product, extended meat product and simulated meat product in an amount not greater than 0.25% of the product.

43 Section B.21.009 of the Regulations is replaced by the following:

B.21.009 Powdered fully hydrogenated cottonseed oil may be applied as a release agent to the surface of marine and fresh water animal products in an amount not greater than 0.25% of the product.

44 Section B.22.010 of the Regulations is replaced by the following:

B.22.010 Powdered fully hydrogenated cottonseed oil may be applied as a release agent to the surface of poultry meat, poultry meat by-product, prepared poultry meat, prepared poultry meat by-product, extended poultry product and simulated poultry product in an amount not greater than 0.25% of the product.

45 The Regulations are amended by adding the following after section D.01.001.1:

D.01.001.2 If both a nutrition symbol, as defined in subsection B.01.001(1), and a statement or claim referred to in any of sections D.01.004 to D.01.007 and D.02.002 to D.02.005 appear on the principal display panel of a prepackaged product,

(a) the height of the upper case letters in the statement or claim must not exceed two times the height of the upper case letters, excluding any accents, in the nutrition symbol, other than in the words “Health Canada” and “Santé Canada”; and

(b) the height of the tallest ascender of the lower case letters in the statement or claim must not exceed two times the height of the tallest ascender of the lower case letters in the nutrition symbol, other than in the words “Health Canada” and “Santé Canada”.

46 The portion of section D.01.009 of the Regulations before paragraph (a) is replaced by the following:

D.01.009 Subject to section D.01.010, no person shall sell a food to which any of the following vitamins have been added unless a reasonable daily intake of that food by a person would result in the daily intake by such person of that vitamin in an amount not less than,

47 The portion of section D.01.010 of the Regulations before paragraph (a) is replaced by the following:

D.01.010 Where a food to which any of the following vitamins have been added is represented as being solely for use in the feeding of children under two years of age, no person shall sell such food unless a reasonable daily intake of that food by a child under two years of age would result in the daily intake by the child of that vitamin in an amount not less than,

48 The portion of section D.01.011 of the Regulations before paragraph (a) is replaced by the following:

D.01.011 No person shall sell a food to which any of the following vitamins have been added if a reasonable daily intake of that food by a person would result in the daily intake by such person of that vitamin in an amount more than,

49 The Regulations are amended by adding the following section after section D.01.011:

D.01.011.1 Sections D.01.009, D.01.010 and D.01.011 do not apply in respect of vitamin D in

(a) a food for which a standard is set out in Division 8 of Part B if the standard requires that the food contain vitamin D; or

(b) margarine or calorie-reduced margarine.

50 The portion of subsection D.02.009(1) of the Regulations before paragraph (a) is replaced by the following:

D.02.009 (1) No person shall sell a food to which any of the following mineral nutrients have been added unless a reasonable daily intake of that food by a person would result in the daily intake by such person of that mineral nutrient in an amount not less than,

51 The Regulations are amended by adding, after Schedule K, the Schedule K.1 set out in the schedule to these Regulations.

52 The Regulations are amended by replacing “table following section B.01.513” with “Table of Permitted Nutrient Content Statements and Claims” in the following provisions:

(a) subsection B.01.305(1) and paragraphs B.01.305(2)(a) and (3)(h);

(b) subparagraph B.01.401(3)(e)(ii) and the portion of subparagraphs 2(a)(i), 3(1)(a)(i), 4(a)(i) and 5(a)(i), the portion of paragraph 7(1)(a) and the portion of subparagraph 8(1)(a)(i) of the table to section B.01.401 in column 4;

(c) the portion of subsection B.01.500(1) before the definitions and subsection B.01.500(2);

(d) paragraphs B.01.502(2)(e) and (f);

(e) the portion of subsection B.01.503(1) before paragraph (a) and subsections B.01.503(2.01) to (3);

(f) the portion of section B.01.504 before paragraph (a);

(g) the portion of section B.01.505 before paragraph (a);

(h) the portion of subsection B.01.506(1) before paragraph (a), subsections B.01.506(2) and (3), the portion of subsection B.01.506(4) before paragraph (a) and the portion of subsection B.01.506(5) before paragraph (a);

(i) the portion of section B.01.507 before paragraph (a);

(j) the portion of subsection B.01.508(1) before paragraph (a);

(k) the portion of section B.01.510 before paragraph (a);

(l) subsections B.01.511(1) and (3);

(m) section B.01.512;

(n) the portion of paragraphs 1(a), (c), (e) and (f), 2(a) and 3(a), the portion of subparagraphs 3(e)(i) and (ii) and the portion of paragraphs 3(g) and (h) of the table following section B.01.603 in column 2;

(o) paragraphs B.08.033(1.1)(a) and (1.2)(a);

(p) paragraphs B.08.034(1.1)(a) and (1.2)(a); and

(q) the portion of subsection B.24.003(1.1) before paragraph (a) and the portion of subsection B.24.003(4) before paragraph (a).

Transitional Provisions

53 (1) The following definitions apply in this section.

former Regulations
means the *Food and Drug Regulations* as they read immediately before the day on which these Regulations come into force. (*ancien règlement*)

prepackaged product
has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*. (*produit préemballé*)

(2) A prepackaged product is not required to be labelled in accordance with the following provisions of the *Food and Drug Regulations* if the product is labelled in accordance with the former Regulations and no change has been made to the label of the product to bring the product into compliance with any of the following provisions:

(a) sections B.01.350 to B.01.358;

(b) subsection B.01.503(1.1);

(c) subsection B.01.508(2);

(d) subsection B.01.509(2); and

(e) section D.01.001.2.

(3) A prepackaged product is not required to be labelled in accordance with the following provisions of the *Food and Drug Regulations* if it is labelled in accordance with the former Regulations and no change has been made to the label of the product to bring the product into compliance with any of the following provisions:

(a) subsections B.01.008.1(1), (3) and (4);

(b) paragraph B.01.008.2(2)(b);

(c) subsection B.01.010.3(1);

(d) section B.01.010.4;

(e) section B.01.014;

(f) section B.01.023;

(g) paragraph B.01.305(3)(g); and

(h) section B.01.467.

(4) A prepackaged product is not required to be labelled in accordance with the following provisions of the *Food and Drug Regulations* if it is labelled in accordance with the former Regulations and no change has been made to the label of the product to bring the product into compliance with any of the following provisions:

(a) subsection B.01.305(1) and paragraphs B.01.305(2)(a) and (3)(h);

(b) subparagraph B.01.401(3)(e)(ii) and items 2 to 5, 7, 8 and 16 of the table to section B.01.401;

(c) section B.01.500;

(d) sections B.01.502 to B.01.507;

(e) subsection B.01.508(1);

(f) subsection B.01.509(1);

(g) sections B.01.510 to B.01.512;

(h) subparagraph B.01.601(1)(c)(i);

(i) items 1 to 3 of the table following section B.01.603;

(j) paragraphs B.08.033(1.1)(a) and (1.2)(a);

(k) paragraphs B.08.034(1.1)(a) and (1.2)(a); and

(l) subsections B.24.003(1.1) and (4).

(5) A food to which any of the following provisions of the *Food and Drug Regulations* applies is not required to contain an amount of vitamin D that complies with the requirement set out in the provision if the food contains an amount of vitamin D that complies with the requirement set out in the provision of the former Regulations:

(a) paragraph B.08.003(b);

(b) paragraph B.08.004(c);

(c) paragraph B.08.005(c);

(d) paragraph B.08.007(d);

(e) paragraph B.08.010(d);

(f) paragraph B.08.011(e);

(g) paragraph B.08.012(f);

(h) paragraph B.08.013(c);

(i) paragraph B.08.014(d);

(j) paragraph B.08.016(c);

(k) paragraph B.08.017(d);

(l) paragraph B.08.018(d);

(m) paragraph B.08.019(e);

(n) paragraph B.08.020(d);

(o) paragraph B.08.023(e);

(p) paragraph B.08.026(e); and

(q) subparagraph B.09.016(b)(iii), including as it applies to calorie-reduced margarine.

(6) For the purposes of the prohibitions set out in section B.08.029 of the *Food and Drug Regulations*, a food is not required to contain the amount of vitamin D set out in the applicable subsection of that section if the food contains an amount of vitamin D that falls within the range set out in the subsection of the former Regulations.

(7) This section ceases to have effect on December 31, 2025.

Coming into Force

54 These Regulations come into force on the day on which they are published in the *Canada Gazette*, Part II.

SCHEDULE

(Section 51)

SCHEDULE K.1

(Subsections B.01.350(1) and B.01.351(1) and (5))

Nutrition Symbols and Formats

Unilingual Horizontal Format

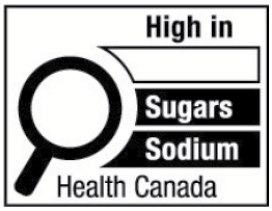
1(EH)

1(FH)

2(EH)

2(FH)

3(EH)



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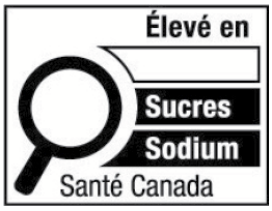

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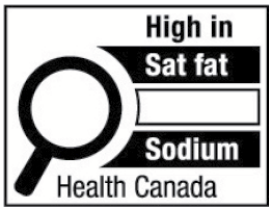
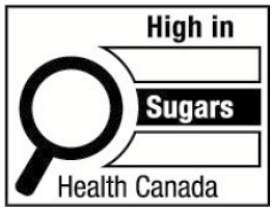


4(FH)

5(EH)

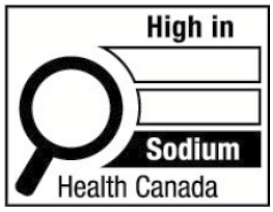
5(FH)

6(EH)

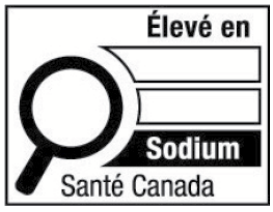


6(FH)

7(EH)



7(FH)



8(EH)

8(FH)

9(EH)

9(FH)

10(EH)

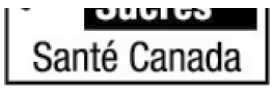
10(FH)

11(EH)

11(FH)

12(EH)

12(FH)



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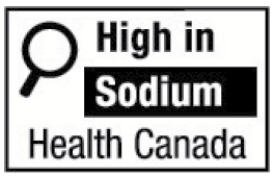


13(FH)

Unilingual Vertical Format

1(EV)

1(FV)

2(EV)

2(FV)

3(EV)

3(FV)

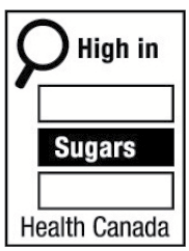
4(EV)

4(FV)

5(EV)

5(FV)

6(EV)



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7(FV)

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9(EV)

9(FV)

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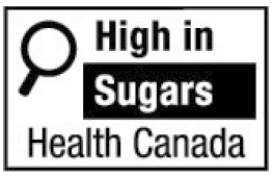
11(FV)

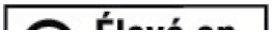
12(EV)



12(FV)

13(EV)

13(FV)



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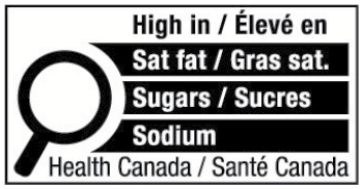
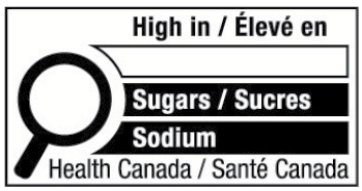
1(BH)



2(BH)

3(BH)



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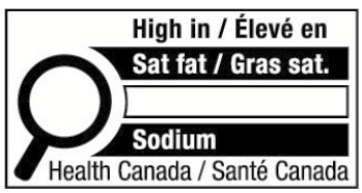

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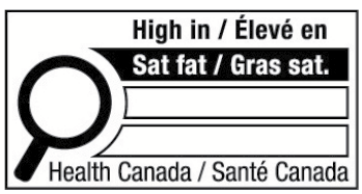

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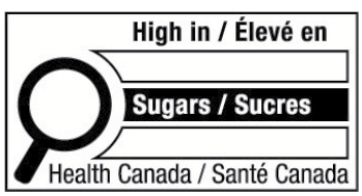

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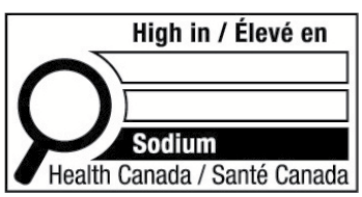

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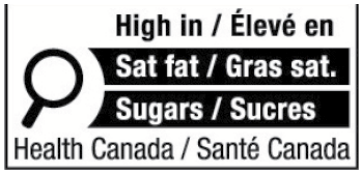

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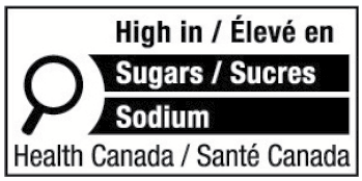

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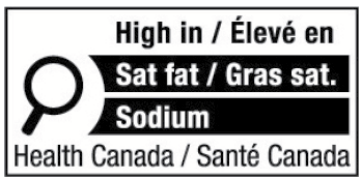

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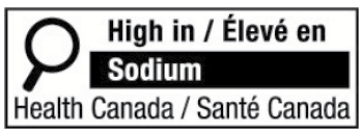

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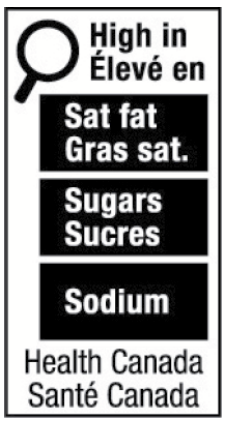

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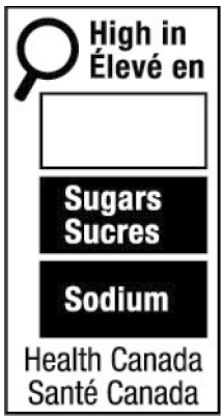

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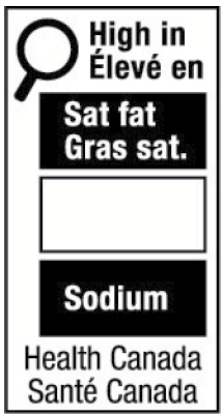

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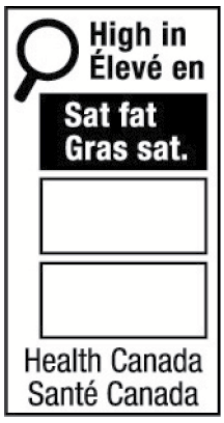

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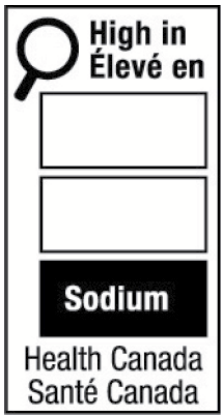

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REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Executive summary

Issues: Average intakes of saturated fat, sugars and sodium remain above recommended limits in the Canadian population. Unhealthy diets with high levels of these nutrients are risk factors for overweight and obesity, hypertension, and chronic noncommunicable diseases, such as cardiovascular disease (i.e., heart disease and stroke), some cancers and type 2 diabetes. While existing forms of nutrition information, such as the Nutrition Facts table (NFt) and voluntary nutrient content claims are helpful to consumers, further complementary labelling measures are needed to provide simple and interpretive front-of-package (FOP) information to help reduce the risks to the health of Canadians posed by excess consumption of these nutrients of concern.

In addition to the increasing rate of noncommunicable diseases, about 20% of Canadians are at risk of vitamin D inadequacy, while about 8% are at risk of deficiency. Health Canada recognizes that it is challenging for Canadians to consume the recommended amounts of vitamin D through the current food supply.

Amending nutrient content claims and/or their associated conditions of use currently requires regulatory amendments to the *Food and Drug Regulations* (FDR). Amendments are needed to the FDR to incorporate by reference the *Table of Permitted Nutrient Content Statements and Claims* to allow the Minister of Health to administratively update nutrient content claims in response to new scientific evidence and to align with the implementation of related nutrition labelling policies. FDR amendments are also required to remove references to partially hydrogenated oils (PHOs) as a result of Health Canada's decision to prohibit their use in foods through their addition to Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods*, which is incorporated by reference into the FDR.

Foods containing the high-intensity sweeteners aspartame, sucralose, acesulfame-potassium and neotame are currently subject to additional principal display panel (PDP) and quantitative declaration labelling requirements for which there is no health-based rationale. Moreover, these requirements are inconsistent with the labelling of foods containing other approved sweeteners and of foods containing other ingredients of concern (such as food allergens), none of which are subject to similar PDP and quantitative declaration labelling requirements.

Description: These regulations amend the FDR to require FOP labelling for most prepackaged products containing nutrients of public health concern (saturated fat, sugars and/or sodium) at or above specified thresholds to enable Canadians to more easily identify foods high in these nutrients and make healthier and more informed decisions that will help reduce their risks to health.

These amendments also repeal the table of nutrient content claims following section B.01.513 and incorporate it by reference into the FDR as a new *Table of Permitted Nutrient Content Statements and Claims*. Doing so enables the Minister of Health to amend such claims in response to evolving science.

These regulations amend the FDR to also help ensure that the use of such claims on the principal display panel does not hinder the effectiveness of the new FOP labelling requirements.

These amendments also increase the amount of vitamin D required in cow's milk and margarine and permitted in goat's milk to help bring the vitamin D intakes of Canadians closer to the 2011 recommendations of the National Academies of Sciences, Engineering, and Medicine.

Given the prohibition on the sale of foods containing PHOs, which came into effect on September 17, 2018 via the inclusion of PHOs on Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods*, [2] these regulations amend the FDR to ensure a coherent prohibition on the use of PHOs in foods.

Finally, to address the inconsistencies in the labelling of foods containing certain high-intensity sweeteners, these amendments repeal the additional PDP and quantitative declaration requirements for foods containing aspartame, sucralose, acesulfame-potassium and neotame. Amendments to the legibility and location requirements pertaining to the mandatory statement on foods containing aspartame (to the effect that aspartame contains the amino acid phenylalanine) are also made to improve its prominence on the label.

Rationale: Noncommunicable diseases remain a major public health concern in Canada and continue to place an increasing burden on Canadians, health systems, the economy and workplaces. Diet is a modifiable risk factor for noncommunicable diseases and an important component of Canadians' health and there is well-established scientific evidence that healthy diets both promote overall health and help protect against disease. The current food environment makes it increasingly difficult for Canadians to make healthy and informed food choices, however evidence also demonstrates nutrition labelling's effectiveness in improving decisions in food choice. FOP labelling complements the other nutrition and marketing information on the front of food packages offering consumers a simplified and visible indicator to help them make choices that support reductions in excessive intakes of nutrients of concern and, consequently helps reduce risks to their health. The selected approach is consistent with Health Canada's mandate to help protect the health and safety of Canadians. In addition, increasing the amount of vitamin D in milks and margarine will help bring the vitamin D intakes of Canadians closer to current intake recommendations, thereby improving their bone health.

The total direct benefits of introducing the regulations is estimated to be an annualized average of $255.66 million or $2.33 billion present value (PV) over a 15-year period, which is presented as the value that households place, in terms of willingness to pay (WTP), for the added information that FOP labelling provides. The total direct cost of the regulations is estimated to be an annualized average of $98.26 million or $894.93 million PV based on a one-time compliance cost to industry in order to conduct the necessary label changes and ongoing compliance and enforcement costs to the Government of Canada. A net PV benefit of $1.43 billion is anticipated over 15 years, based on a 7% discount rate.

Food labels on prepackaged products in Canada differ from those used in the United States due to Canada's bilingual labelling requirements and use of the metric system. Despite these differences, the health objective of providing consumers with nutrition information in both countries remains essentially the same. Furthermore, many elements of these amendments, which support the *Healthy Eating Strategy*, are aligned with or similar to requirements in the United States (e.g., high-intensity sweeteners).

With respect to mandatory FOP labelling, currently there is no equivalent requirement in the United States for foods containing nutrients of public health concern at or above a certain threshold. Other jurisdictions have adopted various systems of mandatory or voluntary FOP labelling. For example, Chile was the first country to implement a mandatory, "high-in" FOP labelling system. Since then, Israel, Peru, Mexico, Uruguay, Brazil and most recently Argentina have advanced FOP regulations targeting foods high in nutrients of concern. On the other hand, other countries, including the United Kingdom, France, Australia and New Zealand, have adopted voluntary FOP labelling systems, such as the traffic light, Nutriscore and Health Star Rating systems. The Codex Alimentarius Commission, the World Health Organization and the Food and Agriculture Organization of the United Nations support the need to assist consumers in making healthier choices through the use of simplified, science-based nutrition information on the front of food packages. The FOP nutrition symbol is in line with Canada's obligations under the World Trade Organization and free trade agreements, which allow countries to take appropriate measures to protect human health.

Issues

I. Lack of clear and consistent FOP information on key nutrients of concern

High sodium intake can lead to hypertension (high blood pressure), a risk factor for cardiovascular disease. The National Academies of Sciences, Engineering, and Medicine concluded that sodium intakes above 2,300 mg per day (equivalent to about one teaspoon of salt) increase the risk of cardiovascular disease associated with hypertension. [3] The daily average sodium consumption of Canadians is currently estimated to be 2,760 mg, well above the recommended limit. [4]

Excess sugars intake can lead to tooth decay and excess calorie consumption, the latter being a contributing factor to obesity. Obesity is a risk factor for hypertension, cardiovascular disease, type 2 diabetes and some forms of cancer. The World Health Organization recommends that individuals reduce their intake of free sugars [5] to less than 10% of total energy (calorie) intake, which is equivalent to about 50 g per day based

on a 2,000 calorie reference diet. [6] Analysis of the 2015 Canadian Community Health Survey data indicates that the average daily intake of free sugars among Canadians is estimated to be 12% of energy intake. [7] This means more than half of Canadians have free sugars intakes above the World Health Organization recommendation.

High intakes of saturated fat are correlated with increased risk of cardiovascular disease, primarily through their effect on total and low-density lipoprotein cholesterol. This is why the National Academies of Sciences, Engineering, and Medicine recommends that saturated fat intake be as low as possible while consuming a nutritionally adequate diet. In May 2018, the World Health Organization published draft guidelines recommending that individuals reduce their saturated fat intake to below 10% of total energy intake. [8] Analysis of the 2015 Canadian Community Health Survey data indicates that the average daily intake of saturated fat among Canadians is estimated to be 10.4% of energy intake. [9] This means more than half of Canadians have saturated fat intakes above this level.

Given the risks to Canadians' health due to continued excess consumption of saturated fat, sugars and sodium, additional measures are needed to help reduce the consumption of these nutrients of public health concern. Current regulated nutrition information, such as the NFt and nutrient content and health claims, provide valuable healthy eating information to consumers at point of purchase, such as the grocery store. The front of the package is often the first site of interaction between consumers and a food product; complementary, simplified and symbol-based nutrition information on this part of the label (FOP labelling) that flags high levels of sodium, saturated fat and/or sugars provides quick and easy guidance to assist consumers in making choices that help lower intakes of these nutrients and thus reduce risks to their health. FOP labelling also balances voluntary nutrition claims that highlight positive attributes of foods and helps consumers who may have difficulties understanding and using the NFt due to limited health literacy. According to *A Vision for a Health Literate Canada: Report of the Expert Panel on Health Literacy* (PDF), published in 2008, 55% of adult Canadians and 88% of seniors are estimated to have less than adequate health literacy skills.

Presenting key and relevant nutrition information on food labels in a way that all Canadians, in particular those with limited health literacy, can access, understand and use to make healthier food choices is of paramount importance to the health of all Canadians.

Interpretive FOP nutrition labelling is recognized as an effective policy measure among a suite of other interventions to help counteract rising rates of obesity and diet-related chronic disease. In the context of the *Healthy Eating Strategy*, it will complement existing labelling policies and other initiatives, such as the NFt and revised Canada's Food Guide, to help make the healthier choice easier for all Canadians.

II. Need for updates to nutrient content claims

The FDR prescribe 47 permitted nutrient content claims and set out the conditions that a food must meet in order to use these claims (e.g., "low in sodium," "no added sugars" and "free of *trans* fatty acids"). The conditions apply to nutrient content claims in advertisements and on food labels.

Amending nutrient content claims and/or their associated conditions of use currently requires regulatory amendments to the FDR. Regular and timely updates to permitted nutrient content claims and their conditions of use are needed to keep pace with evolving science, innovation by industry and the implementation of related policies. The use of modern regulatory instruments such as incorporation by reference will allow the Minister of Health to make administrative amendments to the regulations to respond to new and emerging science that will benefit Canadians and to consider the evolving innovation in the food sector.

In addition, FDR amendments are needed in order to restrict the use and size of nutrient content claims that can be made in relation to nutrients that appear in the nutrition symbol (e.g., reduced in saturated fat, low in sodium, less sugar).

The FDR also allow for various current market practices that reference nutrients, but that are not among the 47 permitted claims. Examples include representations about the amount of lactose in a food (e.g., "lactose-free" on a cheese) or the addition of sugars or salt to a food (e.g., "salted" nuts). Currently, representations characterizing the amount of alcohol in beverages containing more than 0.5% alcohol by volume may be made. However, representations about the absence or very low level of alcohol in beverages containing less than 0.5% alcohol by volume, such as de-alcoholized or non-alcoholic beverages, are not permitted. This does not reflect current market practices and the availability of a range of beverages with low levels of alcohol.

Finally, some specific provisions for nutrient content claims refer to "children under two years of age" as the age category for associated conditions. This age category is based on outdated dietary recommendations. Therefore, amendments to the FDR are required to reflect new age ranges associated with updated dietary recommendations. While these updates were made in provisions relevant to nutrition labelling as per the 2016 nutrition labelling regulations (e.g., age groupings for the new daily values (DVs)), provisions for nutrient content claims and other nutrition-related statements were not within the scope of those amendments and therefore were not updated at that time.

III. Inadequate amounts of vitamin D

Vitamin D is a nutrient that helps the body use calcium and phosphorus to maintain strong bones and teeth. It is obtained from food and supplements and can be made by the body after exposure to sunlight. Vitamin D deficiency can lead to rickets in children and osteomalacia (softening of the bones) in adults. Fortified foods, primarily milk, are the major dietary source of vitamin D for Canadians. The FDR set out the amount of vitamin D required or permitted in foods in Canada.

Health Canada recognizes that it is challenging for all Canadians to meet vitamin D intake recommendations through the current food supply. Approximately 20% of Canadians are at risk of vitamin D inadequacy (generally considered unsatisfactory for bone health), while about 8% are at risk of deficiency. Increasing the amount of vitamin D in the food supply helps mitigate these risks.

IV. Labelling requirement changes to align with prohibition of partially hydrogenated oils (PHOs)

Trans fats are a type of unsaturated fatty acid found naturally in foods from ruminant animals (e.g., milk and beef). They can also be industrially produced. The major source of industrially produced *trans* fats are PHOs, which are created through a process called partial hydrogenation. PHOs were historically used in the manufacture of foods such as margarines, shortenings and baked goods because they improve texture and increase shelf life.

The consumption of *trans* fats increases the risk of coronary heart disease, one of the leading causes of death in Canada. Large observational population studies [10] have shown that the risk of coronary heart disease is substantially increased with increasing intakes of *trans* fat. In light of the adverse health effects of *trans* fats, several authoritative health bodies, such as the National Academies of Sciences, Engineering, and Medicine and the World Health Organization, have recommended limiting their consumption.

In April 2017, Health Canada published the *Notice of Proposal: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods* (Ref. No. NOP/ADP-C-2017-3) signalling its intent to prohibit the use of PHOs by adding them to Part 1 of the *List of Contaminants and Other Adulterating Substances in Food*s that is incorporated by reference into the FDR. The adoption of this proposal was confirmed in the *Notice of Modification: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods* (Ref. No. NOM/ADM-C-2017-3) published by Health Canada on September 15, 2017. The ban officially came into effect on September 17, 2018. As a result, certain amendments to the FDR are required, including adding the definition of "fully hydrogenated" and ensuring the FDR reflects the new prohibition (e.g., by removing all references to "partially hydrogenated" and replacing "hydrogenated" with "fully hydrogenated").

V. Labelling requirement changes for certain high-intensity sweeteners to align with other sweeteners

Sweeteners, including high-intensity sweeteners, are regulated as food additives in Canada. To date, Health Canada has permitted a number of food additives for use as sweeteners, of which some are high-intensity sweeteners. [11]

As with all food additives, the presence of sweeteners in a food must be declared in the list of ingredients. In addition to this requirement, foods containing any of the four high-intensity sweeteners aspartame, sucralose, acesulfame-potassium and neotame were, prior to these regulatory amendments, also subject to the following mandatory labelling requirements:

- A statement on the principal display panel (PDP) that the food contains or is sweetened with the high-intensity sweetener (e.g., "contains aspartame");
- Where applicable, a statement on the PDP of any other sweeteners or sweetening agents used in conjunction with the high-intensity sweetener (e.g., "sweetened with aspartame and xylitol" or "sweetened with sucralose and xylitol");
- A quantitative declaration of the content of the high-intensity sweetener in the food (in milligrams per serving of stated size), grouped together with the list of ingredients; and
- In the case of aspartame only, a statement on any part of the label that aspartame contains phenylalanine.

These additional requirements do not apply to any other approved high-intensity sweeteners.

These additional labelling requirements were first introduced in 1981 when aspartame, the first high-intensity sweetener approved in Canada for use in non-dietetic foods, was approved. Aspartame contains the amino acid phenylalanine, which must be either limited or avoided by individuals with phenylketonuria. At the time of its approval, aspartame was a new and unfamiliar dietary source of phenylalanine. For this reason, the requirement to declare the presence of phenylalanine was put in place to alert consumers with phenylketonuria that aspartame is a source of this amino acid. The remaining additional labelling requirements (the PDP labelling and quantitative declaration) were put in place to give consumers information to assist them in using foods with this high-intensity sweetener in an informed manner. For consistency, these additional labelling requirements (with the exception of the phenylalanine statement) were subsequently applied to the high-intensity sweeteners sucralose (approved in 1991), acesulfame-potassium (approved in 1994) and neotame (approved in 2007).

While the additional labelling requirement to declare that aspartame contains phenylalanine is grounded in a health-based concern for a specific vulnerable population with phenylketonuria, there is no health-based rationale for the PDP labelling and quantitative declaration for aspartame, sucralose, acesulfame-potassium and neotame. Neither the PDP nor quantitative declarations are required for other approved high-intensity sweeteners (e.g., saccharin, steviol glycosides), and such labelling is not required for ingredients of concern, such as food allergens, sources of gluten, and sulphites. Therefore, there is a need to remove these unnecessary labelling requirements for aspartame, sucralose, acesulfame-potassium and neotame.

Background

Chronic diseases, also known as noncommunicable diseases, are an increasing global epidemic. Noncommunicable diseases kill 38 million people per year according to the World Health Organization and are the leading cause of premature death and disability globally. The major

chronic diseases — cardiovascular disease (i.e., heart disease and stroke), some cancers, type 2 diabetes and chronic respiratory disease — are the single greatest cause of preventable illnesses worldwide. The World Economic Forum has declared noncommunicable diseases a threat to global economic development. They reduce global and national economic output, strain health systems, and could drive individuals and households into poverty.

Some of the risk factors for these diseases are genetic or from other causes, but many are modifiable. Most premature deaths from noncommunicable diseases stem from four modifiable risk behaviours — tobacco use, harmful use of alcohol, physical inactivity and unhealthy diets. At the United Nations General Assembly High-level Meeting on the prevention and control of noncommunicable diseases in 2011, the Heads of State and government committed to a Political Declaration and Action Plan to develop multi-sectoral national policies and to adopt whole-of-government approaches to noncommunicable diseases. They recognized that prevention must be the cornerstone of a global response to noncommunicable diseases. In response, the global community has identified actions and set voluntary global targets to prevent and control noncommunicable diseases. This includes adopting policies, legislation and regulations to promote healthy diets by reducing sodium, eliminating *trans* fats, and limiting marketing of unhealthy food and beverages to children. The overarching global target is a 25% relative reduction in premature mortality by 2025. The 2030 Sustainable Development Agenda furthers the global target to one-third relative reduction in premature mortality by 2030.

Similarly, the World Health Organization Commission on Ending Childhood Obesity was established in 2014 to review, build upon and address gaps in existing mandates and strategies as a result of slow and inconsistent progress in tackling childhood obesity. The Commission's recommendations include (1) ensuring that appropriate and context-specific nutrition information and guidelines for both adults and children are developed and disseminated in a simple, understandable and accessible manner; (2) reducing the exposure of children and adolescents to, and the power of, the marketing of unhealthy foods; and (3) implementing easily understood front-of-package (FOP) labelling, supported by public education of both adults and children for nutrition literacy. It also calls on other sectors to contribute to ending childhood obesity. For example, it calls on the private sector to support the production of, and facilitate access to, foods and non-alcoholic beverages that contribute to a healthy diet.

In Canada, the Senate Committee on Social Affairs, Science and Technology released a comprehensive report in March 2016: *Obesity in Canada: A Whole-of-Society Approach for a Healthier Canada* (PDF). The Senate Committee's report offered a number of strategies including enacting more transparent and easier to understand food and beverage labelling and prohibiting the use of partially hydrogenated oils (PHOs). It estimated that the cost in health care spending and in lost productivity due to obesity alone is between $4.6 billion and $7.1 billion in Canada annually.

The Public Health Agency of Canada released its report *How Healthy are Canadians?* on April 11, 2017. While Canada has been actively working for decades to help prevent noncommunicable diseases and promote health through education, surveillance, monitoring and national and community-based programming, the prevalence of noncommunicable diseases continues to increase. In particular, the prevalence of cardiovascular disease, some cancers and especially type 2 diabetes is increasing. Diet is a primary risk factor for chronic disease burden in Canada.

Furthermore, the rates of obesity and hypertension - conditions that increase the risk of noncommunicable diseases - continue to be high in Canada. Obesity is a key driver of noncommunicable disease in Canada: one in three children and two in three adults are overweight or obese. Obesity has both immediate and long-term negative health outcomes and is strongly linked to various chronic conditions, including hypertension, type 2 diabetes, cardiovascular disease and certain cancers. The case for confronting noncommunicable diseases is urgent.

Evidence now shows that obesity and diet-related noncommunicable diseases place individuals at higher risk of severe complications or death from COVID-19. The relationship between poor diets, obesity and disease risk underscores the need for preventative public health measures such as those that support healthy eating. [12] For example, people with obesity and diet-related chronic diseases are more vulnerable to COVID-19. In a meta-analysis of 208 studies, obesity was associated with 73% higher odds of hospitalization and 23% higher odds of death. [13]

Health Canada, acting within its mandate to promote health and safety and to help reduce the risks to health, develops and promotes evidence-based, national food and healthy eating policies and standards to help ensure the safety and nutritional quality of food and enable Canadians to make informed decisions in relation to their health and safety.

In November 2015, the Prime Minister of Canada mandated the Minister of Health to implement a number of measures to promote public health. To help deliver on this mandate, the Minister of Health introduced the *Healthy Eating Strategy* in October 2016. This strategy is designed to tackle one of the key risk factors for chronic diseases in Canada: unhealthy diets. It includes revising Canada's Food Guide, restricting the advertising of certain foods to children, eliminating industrially produced *trans* fat and reducing sodium in the food supply, updating labelling requirements for the list of ingredients and the NFt, [14] and improving FOP nutrition information. The Strategy is one of the most comprehensive health promotion and illness prevention strategies undertaken in Canada since tobacco control strategies in the 1990s.

In October 2017, the Prime Minister confirmed these commitments, mandating the Minister of Health to work closely with the Minister of Agriculture and Agri-Food to align these regulatory initiatives with food policy. The *Healthy Eating Strategy* supports the *Food Policy for Canada* of the Minister of Agriculture and Agri-Food. The Policy seeks to promote healthy living and safe food with the aim of putting healthier, high-quality food, produced by Canadian ranchers and farmers, on the tables of families across the country. The *Healthy Eating Strategy* contributes to a whole-of-government approach as urged by the global community and continues to be rooted in high-quality scientific evidence and meaningful

consultation.

In February 2018, Health Canada pre-published its proposed regulations (*Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Nutrition Symbols, Other Labelling Provisions, Partially Hydrogenated Oils and Vitamin D)*) in the *Canada Gazette*, Part I, for a 75-day consultation period.

Recognizing that a healthy population is key to reducing vulnerability to future health events, the Minister of Health's mandate letter of December 2021 reconfirmed the Government's commitment to advancing the *Healthy Eating Strategy* by "finalizing the front-of-package labelling to promote healthy food choices…"

Objective

The objectives of the amendments to the FDR are to:

I. Help reduce risks to health by providing consumers with quick and easy-to-use information on foods high in saturated fat, sugars and/or sodium to help reduce consumption of these nutrients;

II. Enable the Minister of Health to administratively update nutrient content claims to consider the most up to date science and evolving innovations in the food sector;

III. Increase vitamin D in the food supply to help promote adequate bone health among Canadians without creating the risk of excessive intakes;

IV. Ensure that certain definitions, food standards and other regulatory provisions within the FDR are consistent with the new prohibition on the sale of foods that contain PHOs; and

V. Remove unnecessary labelling requirements for foods containing the high-intensity sweeteners aspartame, sucralose, acesulfame-potassium and neotame, while also improving the legibility of the mandatory phenylalanine statement for foods containing aspartame.

Description

I. FOP nutrition labelling

These regulations amend the FDR to add a new FOP labelling requirement for most prepackaged food products containing nutrients of public health concern (saturated fat, sugars and/or sodium) at or above specified thresholds to enable Canadians to more easily identify foods high in these nutrients when shopping for groceries and to help reduce health risks associated with excess consumption of these nutrients.

General rules

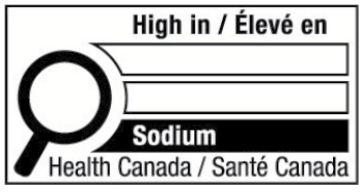
Nutrition symbol requirement: The label of a prepackaged product that meets or exceeds prescribed thresholds for saturated fat, sugars and/or sodium is required to carry a nutrition symbol on the PDP to indicate that the food is high in one or more of the nutrients. The size of the symbol is proportional to the size of the principal display surface (PDS), similar to the current requirement for the net quantity declaration.

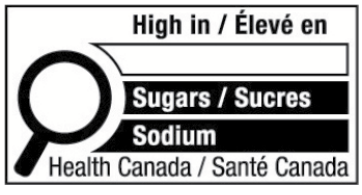
Nutrition symbol and its attributes: All unique nutrition symbol format designs are set out in the FDR in a new Schedule (Schedule K.1). The associated specifications, including the required dimensions, for each symbol are set out in the *Directory of Nutrition Symbol Specifications*, which is incorporated by reference into the FDR, according to a hierarchy that is based on the PDS of the prepackaged product. The regulations include a definition of the Directory.

The regulations stipulate which nutrition symbol format to use when the PDS is >30 cm^2 and which format to use when the PDS is ≤30 cm^2.

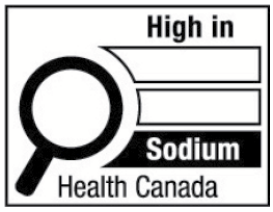
The regulations require, in most cases, that the nutrition symbol be presented in a bilingual horizontal format showing English and French information in the same symbol or a unilingual horizontal format showing English and French information in separate symbols. The following examples illustrate the nutrition symbol in a horizontal format, showing the information when one, two or all three of the nutrients must be shown.

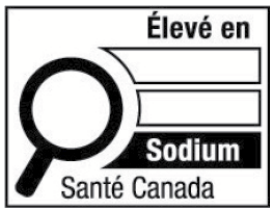
Bilingual Horizontal Format:

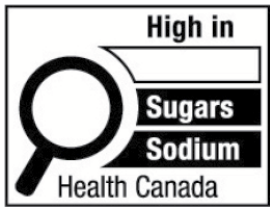


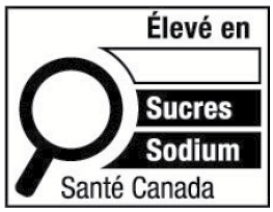


Unilingual Horizontal Format:



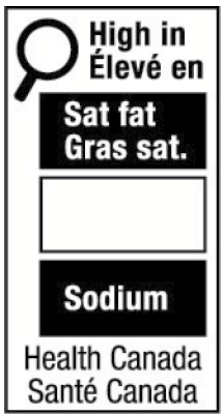


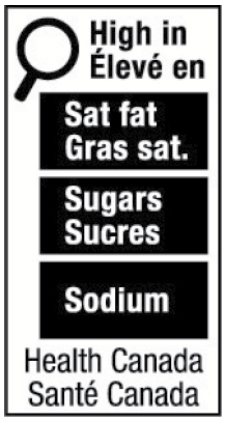




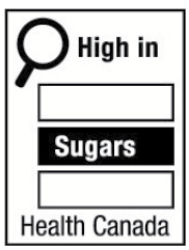
In cases where the PDS is ≤450 cm^2 and the horizontal format is wider than the PDP, a vertical format (available in both a bilingual and a unilingual version) as illustrated below, must be used.

Bilingual Vertical Format:



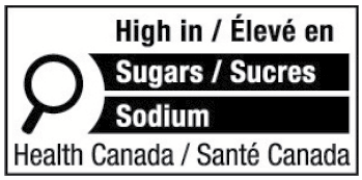


Unilingual Vertical Format:



When the PDS is ≤30 cm^2, there are no placeholder bars for those nutrients that are not required to be shown in the symbol, as illustrated below. This reduces the height of the nutrition symbol so that it takes up less space on smaller surfaces.

Bilingual Horizontal Format (PDS ≤30 cm^2):



Unilingual Horizontal Format (PDS ≤30 cm^2):

Bilingual Vertical Format (PDS ≤30 cm^2):

Unilingual Vertical Format (PDS ≤30 cm^2):

Further details about formatting and location requirements are described under “Format and location.”

Thresholds for prepackaged products for the general population: In most cases, the thresholds for prepackaged products are 15% of the DV for each nutrient of concern, based on the reference amount for the food [15] or the serving of stated size (also referred to as “serving size”) that appears in the NFt, whichever is greater. The 15% DV thresholds are based on analyses that took into account intake recommendations, dietary

survey data and food composition data.

In the case of foods that have a reference amount equal to or less than 30 g or 30 mL, the applicable thresholds are 10% of the DV of the nutrient of concern per reference amount or serving of stated size, whichever is greater. The use of 30 g or 30 mL as the reference amount at or below which a lower threshold is applied is consistent with the approach taken for certain nutrient content claims, such as "low in sodium." Analysis of the 2015 Canadian Community Health Survey data shows that consumption of foods that have a reference amount equal to or less than 30 g or 30 mL and that meet or exceed the 10% DV threshold can lead to excess intakes of saturated fat, sugars and sodium based on the types and amounts of foods Canadians consume.

The thresholds established for prepackaged main dishes that have a reference amount of 200 g or more are 30% of the DV for each nutrient of concern, based on the reference amount for the food or the serving of stated size that appears in the NFt, whichever is greater. These are combination dishes (as identified in the *Table of Reference Amounts* that is incorporated by reference into the FDR) that meet the definition of "main dish." This higher threshold is necessary because these products contribute more nutrients to the diet than do individual foods.

In determining whether a prepackaged product meets or exceeds the above-noted thresholds for the nutrients of concern in cases where the prepackaged product requires reconstitution with water or another liquid or requires the addition of another ingredient for its preparation and the reference amount applicable to the product as set out in the *Table of Reference Amounts* only refers to the food in its prepared form, the %DV is calculated on the basis of the amount of the nutrient, by weight, per serving of stated size since the nutrition symbol is based on the product as offered for sale.

Thresholds for prepackaged products intended solely for children one year of age or older but less than four years of age: To account for differences in the nutritional needs of young children, the established thresholds for foods intended solely for children one year of age or older but less than four years of age are 15% of the DV (for this age category) for each nutrient of concern, based on the reference amount for the food or the serving of stated size that appears in the NFt, whichever is greater.

Similarly, the thresholds for prepackaged products for this age category that have a reference amount of 30 g or 30 mL or less are 10% of the applicable DV per reference amount or serving of stated size, whichever is greater.

In the case of prepackaged main dishes intended solely for this age category, the thresholds are 30% of the DV, as in the case of prepackaged main dishes for the general population. This higher threshold applies to products with reference amounts of 170 g or more (i.e., those falling within category W.5 of the *Table of Reference Amounts* and that meet the definition of "main dish").

The approach of basing the %DV calculation on the serving of stated size for certain foods requiring preparation, as noted above in "Thresholds for prepackaged products for the general population," also applies to such foods that are intended solely for children one year of age or older but less than four years of age.

Exemptions

For technical, nutritional or practical reasons, the following food categories are exempt from the requirement to display a nutrition symbol. These exemptions maintain consistency with the NFt, support health protection for the general population or for vulnerable populations, mitigate unintended nutritional consequences, and recognize that a nutrition symbol would be redundant on some foods.

Conditional exemptions: In line with the exemptions from displaying an NFt, the following prepackaged products are **conditionally** exempt from the nutrition symbol requirements:

- Alcoholic beverages with more than 0.5% alcohol as these products are conditionally exempt from an NFt in order to avoid giving the impression that they may have positive nutritional value;
- Raw single ingredient meats, meat by-products, poultry meats or poultry meat by-products ("meats") that are not ground, or raw single ingredient marine and fresh water animal products are less standardized, which makes deriving accurate nutrient values challenging; and raw single-ingredient ground meats to level the playing field;
- Products prepared and processed from ingredients at retail, including from a pre-mix if an ingredient other than water is added to the pre-mix during preparation and processing, given the difficulties associated with labelling foods prepared with limited standardization and measures of control and to assist small businesses;
- Products sold only at a road-side stand, craft show, flea market, fair, farmers' market or sugar bush by the individual who prepared and processed the product, to alleviate the impact of the regulations on small businesses;
- Individual servings of food sold for immediate consumption and that have not been subjected to a process to extend the durable life, including special packaging, to alleviate the impact of the regulations on small businesses;
- Products sold only in the retail establishment where they are packaged, if labelled by means of a sticker and the available display surface is less than 200 cm^2, to account for space constraints and technical limitations of retail scale labels for printing, and to help alleviate the impact of the regulations on small businesses; and
- Products with an available display surface of less than 100 cm^2 due to space constraints.

Loss of conditional exemption: The products listed above lose their exemption from carrying a nutrition symbol if their label is required to carry an NFt. These products lose their exemption from carrying an NFt if any of the triggers listed in subsection B.01.401(3) or section B.01.467 of the FDR are present. For example, the exemption is lost if the label refers to calories or a specific nutrient, the food contains added vitamins or mineral nutrients, or the label of or advertisement for a food contains a nutrient content claim. Foods that are conditionally exempt from displaying an NFt but voluntarily do so are not required to display a nutrition symbol, as the requirement to display a nutrition symbol on these products could discourage manufacturers from voluntarily providing the NFt.

Full exemptions: The following prepackaged products are **fully** exempt from the nutrition symbol requirements:

- Products with an available display surface of less than 15 cm^2 since the packages are too small to fit a nutrition symbol that contains enough information to make it meaningful (symbol and text);
- Prepackaged individual portions of food that are intended solely to be served by a restaurant or other commercial enterprise with meals or snacks since the packages are generally too small to fit a nutrition symbol that contains enough information to make it meaningful (symbol and text);
- Refillable glass containers of whole, partly skimmed and skim cow's milk (unflavoured and flavoured) as well as cream and goat's milk, since the available labelling space is limited to the lid, and to help alleviate the impact of the regulations on small businesses;
- Sweetening agents, as defined in subsection B.01.001(1), which include maple sugar, maple syrup, and others listed in Division 18 such as sugar, honey and molasses, as these products are all or mostly all sugars and are used by consumers for sweetening purposes in different amounts depending on application, such as for coffee, tea, baked goods and toppings, and having a nutrition symbol for "high in sugars" on these products would be redundant;
- Salt for table use or general household use, celery salt, garlic salt, onion salt and other seasoning salt where "salt" forms part of the common name given that, similar to the situation for sweetening agents, it would be redundant to require a "high in sodium" nutrition symbol on such products;
- Butter and ghee, given that it would be redundant to require a "high in sat fat" nutrition symbol on fats from animal sources. Given that some vegetable oils and some fish and marine fats and oils are also high in saturated fat, the exemption is extended to all fats and oils listed in Division 9 of the FDR, fish and other marine fats and oils, as well as margarine and other similar substitutes for butter;
- Individual rations intended for use by military personnel engaged in operations or exercises since a nutrition symbol could discourage this population from consuming rations formulated to meet their specific needs;
- Foods intended solely for use in manufacturing other prepackaged products, as they are not sold directly to the consumer;
- Ready-to-serve multiple-serving prepackaged products that are intended solely to be served in a commercial or industrial enterprise or an institution, as they are not sold directly to the consumer; and
- Shipping containers, unless the containers and their contents are sold as a one unit prepackaged product to a consumer at the retail level.

Nutrient-specific conditional exemptions: The consumption of products exempted in this category should not be discouraged. These products either have recognized health protection benefits, such as fruits and vegetables, or are top contributors to shortfall nutrients such as calcium, that are not as readily available in other foods.

The following prepackaged products are conditionally exempt from the nutrition symbol requirement:

- Fresh, frozen, canned or dried vegetables and fruits (other than coconut) that are whole or cut since adequate consumption of fruits and vegetables is part of a healthy diet and may help reduce the risks of developing chronic disease, including cardiovascular disease;
- Foods that have a healthy fatty acid profile (less than 30% of total fat is saturated fat), regardless of the reference amount, are exempted from having to display the nutrition symbol for saturated fat. This includes foods such as seeds, nuts and their butters, vegetable oils, marine oils and marine and fresh water animals (e.g., fish);
- Whole eggs, in fresh, liquid, dried or frozen forms, and whole egg mixes, given that they have a healthy fatty acid profile, where the saturated fat content for most eggs is just slightly above 30% of the total fat content; and
- Milk, obtained from any animal, in liquid or powder form, including whole milk because it is recommended as the main milk source if an older infant is no longer breastfed, and 2% milk because it is consistent with Canadian dietary guidance. The saturated fat content of skim and 1% milk would not meet the threshold for a "high in sat fat" symbol.

When ingredients containing nutrients of concern are added to any of the listed conditionally exempted products, the product is no longer exempt from the nutrition symbol requirement for that particular nutrient, and total amount of that nutrient must then be assessed by the manufacturer to determine if it meets or exceeds the established threshold. However, whole or cut fresh, frozen, canned or dried fruits (other than coconut) and vegetables, liquid or powdered formats of milk obtained from any animal, fresh, liquid, dried or frozen forms of whole eggs and whole egg mixes, foods that have a healthy fatty acid profile (e.g., nuts and seeds and their butters, vegetable and marine oils and marine and fresh water animal products), that only contain naturally occurring saturated fat or sodium, are not considered to be ingredients containing

saturated fat or sodium for the purpose of triggering the loss of the exemption. Similarly, if whole or cut fresh, frozen, canned or dried fruits and vegetables, liquid or powdered formats of milk obtained from any animal, and any other dairy products, nuts and seeds and their butters in which less than 30% of the total fat content consists of saturated fat, grains and legumes only contain naturally present sugars, they are not considered to be ingredients containing sugars for the purpose of triggering the loss of the exemption.

The above-noted exemptions apply whether the food is sold alone or in combination with any one of the other named foods.

Finally, cheese and yogurt made from dairy products (including drinkable yogurt) as well as buttermilk and kefir are conditionally exempt from the requirement to display the “high in sat fat” or “high in sugars” nutrition symbol. When ingredients containing nutrients of concern are added to these conditionally exempt products, the product is no longer exempt from the nutrition symbol requirement for that particular nutrient and the total amount of that nutrient must then be assessed by the manufacturer to determine if it meets or exceeds the established thresholds. However, whole or cut fresh, frozen, canned or dried fruits or vegetables, dairy products, grains, legumes, nuts and seeds that only contain naturally present sugars are not considered to be ingredients containing sugars for the purpose of triggering the loss of the exemption. Similarly, milk ingredients, modified milk ingredients, foods that have a healthy fatty acid profile (e.g., nuts and seeds, vegetable and marine oils and marine and fresh water animal products) are not considered to be ingredients containing saturated fat for the purpose of triggering the loss of the exemption. In addition, when ingredients containing sodium are added to cheese made from dairy products, the exemption from the requirement for the “high in sodium” symbol is maintained, as sodium is required in the cheese-making process. For these products to benefit from any one of the nutrient-specific exemptions, they must contain a specific percentage of the DV for calcium: ≥ 10% DV per serving of stated size or per reference amount, whichever is greater, for products with a reference amount of 30 g or 30 mL or less and ≥ 15% DV per serving of stated size or per reference amount, whichever is greater, for products with a reference amount greater than 30 g or 30 mL.

These products are conditionally exempted because analysis shows that many dairy products including cheese and yogurt are important sources of calcium. Calcium is an essential nutrient of which Canadians do not get enough. Adequate calcium intakes are necessary for bone health, and consequently, reduce the risk of osteoporosis which is prevalent in Canada. The ongoing need for this exemption will be reassessed after 10 years to take account of possible changes in dietary intakes of calcium.

Foods prohibited from carrying a nutrition symbol: The nutrition symbol is prohibited on all categories of foods for special dietary use in Divisions 24 and 25 of the FDR, except gluten-free foods. Such foods are formulated liquid diets, foods represented for use in a very low energy diet, meal replacements, nutritional supplements, foods represented for protein-restricted diets and low amino acid diets, human milk fortifiers, human milk substitutes and foods represented as containing a human milk substitute. The composition and labelling of these products are regulated in the FDR in order to fulfil the nutritional needs of specific vulnerable groups. In most cases, these foods are the primary or sole source of nutrition for these groups. There is the potential for serious health consequences if the consumption of these foods is discouraged as a result of a nutrition symbol. Gluten-free foods, on the other hand, do not have specific compositional or labelling requirements aside from not containing any gluten protein and they are not only purchased by consumers with celiac disease but also by an increasing number of people from the general population.

Since there are no DVs for saturated fat, sugars and sodium applicable to infants six months of age or older but less than one year of age, foods targeted to this age group are also prohibited from carrying a nutrition symbol. This is consistent with the NFt for such foods, which is prohibited from carrying the %DV information for macronutrients including sugars and the sum of saturated and *trans* fatty acids, as well as sodium.

Format and location

Building on Health Canada’s experience with the NFt — where consultations with literacy experts revealed that consumers have difficulty finding and understanding information when different designs or formats are used — these amendments prescribe requirements to ensure that a standardized format for the nutrition symbol is used and that it is in a consistent location on the front of the package.

Format of the nutrition symbol: The following formatting requirements for the nutrition symbol are included to help ensure legibility:

- The size of the symbol is proportional to the PDS of the package, with symbol size decreasing as the PDS decreases. As described under “General rules,” the dimensions of the nutrition symbol are set out in a hierarchy in the *Directory of Nutrition Symbol Specifications* in a manner similar to the existing hierarchies for the NFt formats. However, a smaller symbol (the specifications for which are set out in columns 3 to 10 of item 4 of Table 1 or 3 of the Directory) is permitted when the PDS is greater than 250 cm^2 and the product is sold only in the retail establishment where it is packaged and is labelled by means of a sticker;
- A minimum buffer zone is specified for each symbol in the *Directory of Nutrition Symbol Specifications*, to ensure it is distinct from the background. The size of the minimum buffer zone is relative to the size of the symbol. While background in the label design may appear within the buffer zone, text or other graphics must not appear;
- The symbol is in the same orientation as most of the other information on the PDP, unless the PDP is displayed in a vertical plane and most of the other information is not parallel with the base of the package in which case the words in the symbol must be parallel with the base; and
- The outer edge of the buffer surrounding the symbol is a minimum distance from the edge of the PDS in the case of cylindrical containers.

Location of the nutrition symbol: The nutrition symbol is required to be placed anywhere within the upper 50% of the PDP on most packages, which provides flexibility for small or irregular shaped packages. Placing the nutrition symbol in a consistent location across products facilitates consumers' ability to quickly and easily notice and understand the symbol. This is consistent with feedback from consumers during consultation and consumer research. To accommodate differences in package and label designs, the nutrition symbol must be displayed on the right half of the PDP where the height of the PDP is less than its width. If the nutrition symbol appears on a cylindrical container, it can be located partially in the left half of the PDP only to the extent necessary to meet the minimum distance requirement from the edge of the PDS.

Use of other voluntary nutrition and health-related statements, claims or symbols on the PDP: When a product is required to carry a nutrition symbol, the height (of upper case letters and the tallest ascender of lower case letters) of any health-related representations as defined in subsection B.01.357(3) and any statements or claims described in sections D.01.004 to D.01.007 and D.02.002 to D.02.005 that are displayed on the PDP and are not related to a nutrient that appears in the symbol must not exceed twice the height of the text (i.e., upper case letters and tallest ascender of lower case letters) in the nutrition symbol other than the words "Health Canada" and "Santé Canada." This is because Health Canada's consumer research showed that consumers' ability to quickly and easily notice and understand the symbol was not compromised under these conditions. However, the height (of upper case letters and the tallest ascender of lower case letters) of any health-related representations as defined in subsection B.01.357(3) that are related to a nutrient that appears in the nutrition symbol (e.g., "reduced in sodium" on a product with a "high in sodium" nutrition symbol) must not exceed the height of upper case letters and the tallest ascender of lower case letters, as applicable, in the nutrition symbol, other than the words "Health Canada" and "Santé Canada." This is because such representations were shown to reduce the effectiveness of the nutrition symbol. [16] The height restrictions do not apply to the brand name or product name on the PDP.

Imitation symbols: The integrity of the nutrition symbol is protected by prohibiting the labelling of food packages with any representation, such as a word, phrase, illustration, sign, mark, symbol or design that is likely to be mistaken for a nutrition symbol.

II. Nutrient content claims and other nutrition-related statements

Prohibition of claims on the PDP when a nutrition symbol is displayed

The use of nutrient content claims related to saturated fat, sugars or sodium as set out in the incorporated by reference *Table of Permitted Nutrient Content Statements and Claims* is prohibited on the PDP when a food displays a nutrition symbol that identifies the food as being "high in" that particular nutrient. This is because such claims can reduce the effectiveness of the nutrition symbol by confusing consumers as to its meaning in the presence of an apparent contradictory claim about the same nutrient. Similarly, the use of the "unsweetened" claim is prohibited on the PDP of foods displaying a "high in sugars" nutrition symbol. However, this prohibition does not apply to "reduced in" nutrient content claims (items 20, 33 and 38 in the *Table of Permitted Nutrient Content Statements and Claims*). This is because such claims are used to distinguish products that have been processed, formulated, reformulated or otherwise modified to contain less of the nutrient than the similar reference food. Consumption of such foods, when chosen instead of the similar reference food, may help reduce intakes of nutrients of concern.

One further prohibition regarding sodium-related claims: a representation that a food is for use in a sodium-restricted diet is prohibited on the PDP of a food if the food is required to carry a nutrition symbol for "high in sodium."

Incorporation by Reference and Updating of the Table of Permitted Nutrient Content Statements and Claims

In order to enable the Minister of Health to make administrative updates to nutrient content claim requirements in response to new and emerging science, the table of nutrient content claims following section B.01.513 of the FDR is repealed and a new *Table of Permitted Nutrient Content Statements and Claims* is incorporated by reference into the FDR. This approach is consistent with the recent incorporation by reference of other tables as part of the 2016 nutrition labelling regulations (e.g., the *Table of Daily Values*, the *Directory of NFT Formats* and the *Table of Reference Amounts*).

This repeal requires consequential amendments to the FDR and to the *List of Permitted Food Additives with Other Accepted Uses* [17] in order to replace references to *"table following section B.01.513"* with *"Table of Permitted Nutrient Content Statements and Claims"* (the Table).

A number of changes are made to the Table that is incorporated by reference. These changes along with the Table are provided in the *Notice of Modification: Incorporating by Reference the "Nutrition Labelling - Table of Permitted Nutrient Content Statements and Claims"* (Ref. No. NOM/ADM-NCC-2022-1), which is available on the Government of Canada website. [18] These modifications were initiated by the publication of a Notice of Proposal, followed by a 75-day comment period for stakeholders.

Any future modification to the Table would follow Health Canada's established administrative process. A Notice of Proposal would be published and shared with stakeholders, followed by a consultation period to allow stakeholders to provide their comments. Once comments are received and analysed, a Notice of Modification would be published to inform stakeholders of modifications to the initial proposal, if any, the final changes made to the Table and when Health Canada intends to publish the modifications to the Table.

Other Amendments

These regulations amend the FDR to expand the scope of use of representations characterizing the amount of alcohol to allow beverages containing 0%–0.5% alcohol, such as non-alcoholic beers and wines and virgin cocktails (e.g., "mocktails"), to include representations as to their alcohol content. This provides factual information for consumers. Prior to this amendment, this information was not permitted on beverages

containing 0.5% alcohol or less by volume, which did not serve a public health and safety purpose. By permitting statements such as "alcohol-free" and "low in alcohol," there will be a level playing field for all alcoholic products, including those with 0.5% alcohol or less.

Furthermore, the references to food "intended solely for children under two years of age" are updated to reflect the new DV age categories, which have also been implemented under the 2016 nutrition labelling regulations.

III. Vitamin D fortification

These regulations amend the FDR to increase the amounts of vitamin D that are required in cow's milk and margarine and permitted in goat's milk. For consistency with the new DV for vitamin D set out in the 2016 nutrition labelling regulations, vitamin D quantities described in the FDR are based on micrograms (µg) rather than international units (I.U.). For clarity and ease of calculation, the amendments to the milk standards remove the current reference to "reasonable daily intake" and instead base the vitamin D content on a 100 mL quantity. Also, the minimum and maximum amounts of vitamin D, currently prescribed in the milk standards and goat's milk prohibitions, are replaced with a single level of 2 µg/100 mL (the range that will remain in effect until the end of the transition period is equivalent to ~0.9 to 1.2 µg/100 mL). For margarine, including calorie-reduced margarine, the FDR are amended to increase the amount of vitamin D to 26 µg/100 g (the FDR prescribed an amount equivalent to no less than 13.3 µg/100 g and no more than 17.5 µg/100 g, which will also remain in effect until the end of the transition period).

IV. FDR amendments related to the prohibition of PHOs

Given the existing prohibition on the use of PHOs in foods, by amending Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods* to include PHOs, these targeted amendments to the FDR are required in order to enhance clarity and define "fully hydrogenated." In addition, PHOs are currently referred to in certain provisions in Part B of the FDR, pertaining to common names, as well as in the standards for shortening, lard and margarine, and in the provisions relating to the use of powdered hydrogenated cottonseed oil as a release agent on meat, fish and poultry products. These provisions refer either to "oils that have been hydrogenated or partially hydrogenated" or simply to "hydrogenated X oil." This language is replaced with, for example, "oils that have been fully hydrogenated," "fully hydrogenated X oil," or "full hydrogenation" to eliminate all references to PHOs.

V. Labelling of foods containing certain high-intensity sweeteners

Health Canada is repealing the following labelling requirements from the FDR for foods containing the high-intensity sweeteners aspartame, sucralose, acesulfame-potassium and neotame:

- The statement on the PDP that the food contains or is sweetened with the high-intensity sweetener;
- Where applicable, the statement on the PDP of any other sweeteners or sweetening agents used in conjunction with the high-intensity sweetener; and
- The quantitative declaration of the content of the high-intensity sweetener in the food (in milligrams per serving of stated size), grouped together with the list of ingredients.

The mandatory requirement that the label of a food containing aspartame declare the presence of phenylalanine is being retained. However, to bring further prominence to this statement and to further align Canadian and the United States labelling requirements, changes have been made to how the statement may be expressed. The following format and placement specifications for this statement are also prescribed in the FDR:

- Products containing aspartame must either include a statement to the effect that aspartame contains phenylalanine or a statement warning individuals with phenylketonuria that the food contains phenylalanine. This would allow for the use of the statement in the United States "Phenylketonurics: contains phenylalanine" or other variations, such as "People with phenylketonuria: contains phenylalanine," "Persons with phenylketonuria: contains phenylalanine" and "Individuals with phenylketonuria: contains phenylalanine."
- The phenylalanine statement must follow the list of ingredients and may appear on the same line as the last ingredient in the list of ingredients or on a separate line (and before any food allergen related "contains" statement and/or precautionary declaration). This statement must be in bold and must have a font size consistent with the requirements for other text in the delineated list of ingredients area.
- The sequence of statements following the list of ingredients must be as follows: the phenylalanine statement; the "contains" statement for food allergens, gluten sources and added sulphites; and the precautionary declaration (e.g., "may contain"), which is used when there is a possibility that the food may be cross-contaminated with a food allergen or gluten source.
- Regardless of whether the phenylalanine statement starts on the same line as the last ingredient in the list of ingredients or on a separate line, any statement following it may also appear on the same continuous line provided that the introductory title "contains," "may contain" or the entire untitled precautionary declaration is in bold and in a type that is of a height that is at least 0.2 mm greater than the height of the type for the phenylalanine statement.

Finally, an amendment contained in these regulations provides a "conditional" small package exemption from having to display the nutrition symbol for food products with an available display surface of less than 100 cm^2 (due to space constraints). However, this conditional exemption is

lost if the product is required to carry an NFt.

The existing requirement for foods containing aspartame, sucralose, acesulfame-potassium or neotame to carry an NFt, despite their package size, is repealed. Foods containing these sweeteners therefore now have the conditional small package exemption from both the nutrition symbol and the NFt requirements available to them.

VI. Other technical amendments

Legibility requirements for voluntary precautionary declarations of potential food allergens or potential sources of gluten that could result from cross-contamination (e.g., "may contain" declarations) were included in the 2016 nutrition labelling regulations. While the intent was to prescribe the legibility and placement of a precautionary declaration only, the new amendments also required the use of prescriptive wording for the declaration, which was not the intent. The FDR are therefore amended to remove the requirement under subsection B.01.010.4(2) to use specific names for the source of the food allergen or gluten, thereby allowing the use of declarations that are currently used, e.g., "May contain tree nuts," and "May contain fish."

VII. Coming into force and transitional provisions

These regulations come into force upon publication in the *Canada Gazette*, Part II.

The amendments described herein related to FOP labelling, nutrient content claims, vitamin D fortification and the phenylalanine statement are subject to a transition period that ends December 31, 2025. This allows sufficient time for industry to change labels to comply with the new requirements and use existing label stock.

The transitional provisions for the different components of the package (e.g., FOP labelling, nutrient content claims, vitamin D and the phenylalanine statement) are independent of one another. This means that implementation of any labelling requirement within a component (e.g., FOP labelling) during the transitional period will trigger implementation of all labelling requirements within that component but will not trigger the application of requirements in other components of the package (e.g., phenylalanine statement). As such, manufacturers can choose to comply with the labelling requirements of one component before another, as long as they comply with all labelling requirements of the package by the end of the transition period, i.e., December 31, 2025. This measure gives manufacturers flexibility in managing their label changes.

As the 2016 nutrition labelling regulations are now in effect (as of December 14, 2021), the coming into force and transitional rules in these FOP labelling regulations do not need to be coordinated.

These regulations fall within the scope of the joint Health Canada and Canadian Food Inspection Agency Food Labelling Coordination policy. This policy was developed, in part, to provide greater predictability with respect to the compliance dates for changes to food labelling requirements. This policy establishes compliance date options for food labelling requirements at two-year intervals, beginning on January 1, 2026, which align with the intervals in the United States. Given that the amendments related to PHOs are needed in order for the FDR to align with the PHO ban, which is already in effect, such provisions come into force upon publication in the *Canada Gazette*, Part II, without any transition period.

Regulatory development

Consultation

To inform these regulations, Health Canada sought input from Canadians through broad consultations, stakeholder engagement activities as well as public opinion and consumer research.

On November 14, 2016, Health Canada launched pre-consultations on the following topics:

1. FOP labelling:

- proposed new FOP nutrition symbol for foods high in saturated fat, sugars or sodium;
- proposed changes to nutrient content claims and other nutrition-related statements; and
- proposed changes to the labelling of certain high-intensity sweeteners.

2. Prohibition of PHOs

The pre-consultations consisted of online consumer and technical questionnaires for each topic, each accompanied by a consultation document: *Toward Front-of-Package Nutrition Labels for Canadians* and *Toward the Prohibition of Partially Hydrogenated Oils in the Canadian Food Supply*. The consultations closed on January 13, 2017.

Approximately 2,155 comments were received (1,600 for the FOP pre-consultation and 555 for the PHO pre-consultation) from a range of stakeholders, including consumers, consumer advocacy groups, individual companies, industry associations, retailers, health professionals, health organizations, experts, researchers and Canadian provincial or territorial governments.

On February 10, 2018, Health Canada published its proposed regulations on FOP labelling in the *Canada Gazette*, Part I for a 75-day consultation period (ended on April 26, 2018). At the same time, it launched an online survey for consumers on four nutrition symbol design options and

undertook research on the nutrition symbol and related technical specifications. Close to 16,000 consumers participated in the online symbol consultation. Results of this consultation are available on the Government of Canada website. [19] Approximately 220 submissions were received from a range of stakeholders, including consumers, food industry, retailers, health organizations, health professionals, scientific experts, academics as well as provincial, territorial and international governments. Health Canada also received over 7,600 letters through letter writing campaigns.

In addition to these formal consultations, Health Canada held the following stakeholder engagement activities:

- **March 2015:** A proposal for a revised vitamin D fortification policy was discussed with experts at a Best Brains Exchange co-hosted by the Canadian Institutes of Health Research and Health Canada.
- **May 2016:** Health Canada launched a call for data to collect information on the current use of PHOs in the food supply. Data was submitted by seven manufacturers, two fats and oil processors, one restaurant, two industry associations and one academic.
- **October and November 2016:** Health Canada sought targeted feedback from key phenylketonuria groups and experts to obtain views on the current labelling requirements for foods containing aspartame. They included the Canadian PKU and Allied Disorders Inc. (CanPKU), the Garrod Association, the Toronto Hospital for Sick Children's Phenylketonuria program and dietitians involved in the care of individuals with phenylketonuria.
- **January and February 2017:** Health Canada met with academic experts and key health and industry stakeholders to provide further information on the FOP labelling proposal and to provide the rationale for the proposed FOP approach. This included the options analysis of the different FOP labelling systems that were considered.
- **February 2017:** Health Canada distributed a cost-benefit analysis survey to health and industry stakeholders relating to changes to FOP labelling and new vitamin D amounts in cow's milk, goat's milk and margarine.
- **March 2017:** Health Canada engaged with stakeholders on the FOP and PHO proposals at the annual Health Canada and Canadian Food Inspection Agency food supply chain meeting in Ottawa, Ontario.
- **March 2017:** Health Canada engaged with targeted industry and health stakeholders along with provincial and territorial government representatives to discuss proposed changes to its vitamin D fortification policy.
- **April 2017:** Health Canada published the *Notice of Proposal: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods* (Ref. No. NOP/ADP-C2017-3), signaling its intent to prohibit the use of PHOs by adding them to Part 1 of the incorporated by reference *List of Contaminants and Other Adulterating Substances in Foods*. The proposal was open for comments for a period of 75 days.
- **September 2017:** Health Canada hosted a day-long meeting with health and industry stakeholders and experts to discuss FOP labelling evidence and options for the nutrition symbol design.
- **November 2017:** Health Canada hosted a stakeholder engagement session and presented new nutrition symbol designs under consideration.
- **March 2018:** Health Canada held technical webinars with all interested stakeholders to provide an overview of the proposed regulations that were pre-published in the *Canada Gazette*, Part I on February 10, 2018. Health Canada also had bilateral meetings with stakeholders who requested further discussion about the regulatory proposal.
- **June 2018:** Health Canada hosted a design workshop with industry stakeholders and experts in graphic design, printing and packaging to discuss technical issues related to the nutrition symbol design and related technical specifications.

Health Canada also undertook public opinion and consumer research activities to support its proposal:

- **December 2016:** Health Canada conducted focus group testing on certain elements of the FOP proposal, namely nutrition symbol design, size and location, with 14 groups in six cities across Canada. The purpose was to assess how consumers understood and used the range of proposed nutrition symbols. A report on the results of the focus group testing is published on the Library and Archives Canada website. [20]
- **March and April 2018:** Health Canada conducted two consumer research projects. The first was a study in a grocery store setting aimed at assessing the effectiveness of the FOP symbols. Results of this research are published in the journal *Nutrients*. [21] The second was an online mock- package trial to test the size and location of the FOP nutrition symbol as well as restrictions on other health-related information on the package. A report on the results of the online trial is published on the Library and Archives Canada website. [22]

Pre-consultations as well as the other engagement activities undertaken between March 2015 and November 2017 allowed Health Canada to assess stakeholders' positions on the various proposed approaches, and served to inform the development of the regulatory proposal. The comments received during these pre-consultations, as well as Health Canada's responses, can be consulted in the Regulatory Impact Analysis Statement that was published alongside the proposed regulation in the *Canada Gazette*, Part I on February 10, 2018. [23]

Beyond the pre-publication consultation period, Health Canada undertook further consultations during the COVID-19 pandemic which also informed these regulations:

- **2020 – 2021:** Various bilateral meetings, including discussions about the 2016 nutrition labelling regulations.

- **December 2020, February – April 2021:** Health Canada and Canadian Food Inspection Agency consulted on a predictable labelling policy.
- **July 2021:** The public was notified of Health Canada's intent to publish a Marketing Authorization to enable increased vitamin D amounts in cow's milk, goat's milk and margarine.
- **March - April 2022:** Meetings with interested stakeholders to provide information on the policy changes between pre-publication in the *Canada Gazette*, Part I and final publication in the *Canada Gazette*, Part II.

In March 2022, Health Canada met with 17 major Canadian industry associations and four health organizations to provide information on the policy changes between pre-publication in the *Canada Gazette*, Part I, and final publication in the *Canada Gazette*, Part II. In addition, Health Canada provided explanations for certain requirements in the pre-publication proposal that were maintained or were removed.

During the meeting, stakeholders were provided with the opportunity to ask clarifying questions to ensure a common understanding. In particular, stakeholders were interested in the overall approach, exemptions, nutrition symbol design, thresholds, claims, implementation (education, monitoring and compliance), the cost-benefit analysis and transition period. Health Canada provided responses to address all of the questions that were asked, including speaking to the breadth of evidence in support of the updated policy. Stakeholders were provided four weeks to consult with their membership and to submit any written comments on the initiative.

A total number of 20 written responses were received. Some comments on the formatting of the nutrition symbol, thresholds, claims and the need for education and evaluation initiatives following implementation were previously received. New comments regarding exemptions for certain foods for technical purposes, the transition period and economic considerations including supply chain issues, the COVID-19 pandemic and rising food prices were considered by Health Canada and are addressed below.

Health Canada also received 13 new letters of support from 15 stakeholders, calling for the timely finalization of the FOP regulations.

As with any *Healthy Eating Strategy* initiative, all meeting summaries and correspondence on FOP labelling in which opinions and information are relayed to Health Canada with the intent to inform the development of policies, guidelines and regulations are available online.

Summary of comments on the *Canada Gazette*, Part I proposals and Health Canada's responses

Comments received on the proposals pre-published in the *Canada Gazette*, Part I, including those received through the *Canada Gazette*, Part I consultation process, the World Trade Organization Technical Barriers to Trade notification process, the COVID-19 pandemic, the Food Labelling Coordination policy consultation process, as well as those received through other engagement activities between February 2020 and April 2022 are summarized below. In response to comments and concerns raised by stakeholders, a number of adjustments to the proposed amendments have been made where supported by evidence.

I. FOP nutrition labelling

Comments on the proposed FOP approach

Consumers supported the proposed FOP approach, stating that it would help support informed decision-making. Health stakeholders were also supportive because it is consistent with international consensus on addressing noncommunicable diseases and it would support more consistent, comprehensive, and balanced messaging about nutrient content and facilitate healthier choices. Industry stakeholders did not support the proposed approach because they felt it was negative, simplistic, lacked nuance and could undermine public confidence in the food supply. Industry stakeholders reiterated their preference for facts-based or summary FOP systems that take into account the presence of positive and negative nutrients. A few more industry stakeholders recently expressed concerns that Health Canada did not explore or consult on alternative methods for the proposal, and did not indicate any planned reviews of the effectiveness of the proposed regulations.

Health Canada's response

In accordance with the *Cabinet Directive on Regulations*, Health Canada conducted an options analysis prior to selecting the proposed approach, as described in the "Regulatory and non-regulatory options considered" section and considered several alternatives to FOP labelling, ranging from consumer education, to digital tools, to mandatory limits on nutrients of concern. The chosen approach best complements the suite of existing healthy eating tools in order to help address nutrition-related chronic diseases and is consistent with Health Canada's mandate to help protect the health and safety of Canadians. Furthermore, it is a balanced approach that addresses Canadians' need for easy-to-use nutrition information, while limiting costs to industry. Furthermore, this FOP approach is a measure targeted at the public health purposes underlying the *Food and Drugs Act*.

Health Canada has welcomed input on the proposed approach, including alternatives, since it first started engaging with stakeholders on FOP labelling in 2016. The Regulatory Impact Analysis Statement pre-published in the *Canada Gazette*, Part I, in 2018 included a summary of regulatory and non-regulatory options considered. It also included a summary of stakeholder comments and Health Canada's responses on the approach received to that date. In addition, the stakeholder meeting on March 22, 2022, highlighted comments on the approach and the Departments' responses.

Further details about Health Canada's plans for monitoring and review of the regulations are provided below and in the "Implementation, Compliance and Enforcement" section. In addition, the *Cabinet Directive on Regulations* requires Departments to undertake a review of their

existing regulatory stock. This helps to ensure regulations continue to be appropriate and effective and that they achieve their intended policy objectives. Health Canada informs stakeholders of its intent to propose or finalize any regulatory changes within a two-year period through the Forward Regulatory Plan, which is published online. Health Canada will apply this review process to the FOP labelling regulations in the future, as required for all regulations.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on FOP labelling as a tool to achieve better nutrition

Industry stakeholders argued that characterizing foods as either healthy or unhealthy is ineffective in achieving better nutrition in the long run, and that it is both more accurate and more effective to educate people on the importance of variety, balance and moderation in their food intake.

Health Canada's response

The FOP nutrition symbol is not meant to categorize a food as healthy or unhealthy. Rather, it is meant to provide priority information about nutrients of public health concern in a way that consumers will find quick and easy to use when shopping for groceries. Regular or frequent consumption of foods high in nutrients of public health concern contributes to an unhealthy eating pattern that increases risks to health.

Excess intakes of the nutrients highlighted in the nutrition symbol are associated with increased risk of nutrition-related chronic diseases that are prevalent in Canada. FOP nutrition labelling is widely recognized among authoritative health organizations, such as the World Health Organization, as an important policy measure among a suite of labelling and other interventions to help counteract rising rates of obesity and diet-related chronic disease. Consumers can decide how to use the nutrition symbol to meet their specific goals. Health Canada's consumer research conducted in a grocery store setting showed that the majority of consumers used the FOP nutrition symbol to compare products within the same category or to choose a similar food that did not have the symbol. [21]

Education is an important intervention that helps Canadians understand and apply healthy eating guidance. In January 2019, Health Canada issued a revised Canada's Food Guide that provides Canadians with relevant and more user-friendly educational information and tools to facilitate healthy eating. Nutrition education, however, is only effective within a supportive food environment. This is why policy interventions, such as those that are part of the *Healthy Eating Strategy*, which target different aspects of the food environment, including food composition, labelling and advertising, are a necessary complement to education to help make the healthier choice the easier choice.

The concepts of balance and moderation are subjective terms and can mean different things depending on one's perspective. Consumer research completed in 2002 found that the term "moderation" was not well understood, and consumers did not seem to know how to apply the concept to their eating habits.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments related to concerns with unintended impacts of FOP labelling

Some stakeholders expressed concern that the proposed FOP labelling approach could encourage reformulation that does not improve the nutritional value of the product. For example, sugar can be replaced with artificial sweeteners or sodium can be replaced with preservatives. Industry also argued that when faced with the plethora of FOP labelled foods, consumers may give up on checking the NFt for more nuanced comparison shopping and simply ignore all the labels. A concern was also raised that consumers may deliberately choose FOP labelled foods over unlabelled foods if the latter taste inferior.

Health Canada's response

The concern that reformulation would not improve the nutritional value of the food arises any time attention focuses on specific nutrients or ingredients. Despite one or two examples where reformulation did not lead to improvements in the nutritional value of food, such as adding sugars to reduced fat products to increase palatability, there are examples of public health initiatives led by Health Canada that resulted in successful reformulation (e.g., *trans* fat labelling within the NFt).

The chosen FOP approach minimizes the risk of reformulation that does not improve the nutritional value of the food. By focusing on all three nutrients of greatest public health concern, this approach minimizes the risk that manufacturers would substitute one nutrient of public health concern for another.

Health Canada's recent consumer research in a grocery store setting showed that FOP labelling did not significantly affect the amount of time spent on the NFt. [21] Additionally, FOP labelling increased the use of nutrition information overall in food decision-making among consumers of varying health literacy levels, reinforcing that FOP labelling complements rather than replaces the NFt.

Consumer research at large, including that conducted by Health Canada, indicates that taste is a primary driver of food choices. However, Health Canada's research also showed that nutrition information was as important as taste in decision-making for consumers exposed to FOP labelling, suggesting that consumers are willing to make trade-offs for health benefits. This is consistent with the Consumer Goods Forum's 2018 Health and Wellness Progress Report, which shows that the food industry is moving towards creating and marketing healthier products in order to meet growing consumer demands.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on alignment with World Trade Organization obligations

Several industry stakeholders and governments have questioned whether the FOP regulatory proposal is in line with Article 2.2 of the World Trade Organization Technical Barriers to Trade Agreement. International industry associations felt that the FOP labelling regulations could hinder trade by making it significantly more difficult to export their products to Canada.

Health Canada's response

Canada's FOP labelling is consistent with Canada's obligations under the World Trade Organization Technical Barriers to Trade Agreement and equivalent chapters under Canada's free trade agreements. The World Trade Organization Technical Barriers to Trade Agreement allows countries to implement technical regulations that are appropriate to fulfil legitimate objectives such as the protection of human health based on scientific evidence. Two in five Canadians live with at least one of the 10 most common chronic diseases, including heart disease, stroke, type 2 diabetes and cancer. Poor diet, especially a diet high in saturated fat, sugars and sodium, is a primary risk factor for chronic disease. FOP labelling will help consumers easily identify foods that can contribute to excess intakes of these nutrients. In addition, the FOP labelling regulations do not discriminate between domestic and imported products.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on FOP labelling's potential impact on imported products

International food producers expressed concern that FOP labelling may damage brand image in markets outside of Canada and as such, they may choose not to import their products into Canada, thereby reducing consumer choice.

Health Canada's response

Health Canada acknowledges that some foreign manufacturers may decide not to sell their products in Canada and that this may reduce consumer choice to a certain extent. On the other hand, manufacturers may choose to reformulate or bring new products lower in nutrients of concern onto the Canadian market. This is consistent with the objective of the *Healthy Eating Strategy*, which aims to make the healthier choice the easier choice for Canadians. Furthermore, as noted earlier, the global food industry acknowledges that it must shift towards healthier foods to meet increasing consumer demands.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on alignment with Codex

Several industry stakeholders argued that the proposed FOP labelling approach did not appear to be in line with the international standards established by the Codex Alimentarius and urged Health Canada to wait for the Codex Committee on Food Labelling guidelines on FOP nutrition labelling to be final before moving forward with its final regulation. For instance, stakeholders noted that the Codex Committee on Food Labelling guidelines could recommend a voluntary FOP nutrition labelling approach rather than a mandatory approach.

Health Canada's response

In developing its FOP approach, Health Canada looked to Codex Alimentarius guidelines as its starting point. Canada's approach towards FOP labelling is consistent with the Codex Alimentarius Commission's Guidelines on Nutrition Labelling (CXG 2-1985). According to these guidelines, FOP labelling can be used to enhance consumers' understanding of the nutritional value of food and to assist in interpreting nutrient amount declarations, usually in small print on the back of packages. It specifically notes that there are a number of ways in which this information can be presented on food labels and the content of this information may vary from one country to another according to the educational policy of the country and the needs of the target groups.

At the 43rd Session (2016) of the Codex Committee on Food Labelling, the Committee agreed to undertake new work to develop guidance on the use of simplified nutrition information on the front of food packages. In the absence of Codex guidance on FOP labelling, the representative of the WHO and the Codex Secretariat emphasized that countries that have started or are planning to implement FOP labelling should still proceed with their work.

The Codex FOP project document notes that simplified nutrition information can play a role in facilitating greater understanding of the nutritional content of foods by consumers and may help guide consumers to healthier choices. It also states that simplified nutrition information, particularly on the front of packages, may also encourage food manufacturers to reformulate their food products to gain a more positive nutrient profile, thus improving the nutritional quality of the food supply available to consumers. Improved nutrition via either a healthier food supply or consciously made healthier choices would improve the risk profile for a number of noncommunicable diseases globally.

At the 46th session (2021) of the Codex Committee on Food Labelling, proposed draft guidelines on FOP nutrition labelling were put forward for adoption by the Codex Alimentarius Commission. They were adopted and are included as an Annex to the Guidelines on Nutrition Labelling (CXG 2-1985).

It is important to note that these guidelines set out principles for the establishment of FOP nutrition labelling systems, rather than a specific

system for use by national authorities. Canada's FOP labelling approach aligns with the guidelines.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on Canada's FOP requirements contradicting those pursued in other jurisdictions

Industry commented that Canada's FOP approach contradicts previous positions Canada has taken regarding FOP requirements pursued in other jurisdictions, such as Chile.

Health Canada's response

When Chile notified member countries of the World Trade Organization of their proposed FOP nutritional labelling requirements for food products high in saturated fat, sugars, sodium and/or calories, Canada voiced some concerns on some of the technicalities of the regulations. However, Canada did not challenge Chile's labelling approach and recognized Chile's legitimate goal to decrease their growing obesity rates.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on the need for education and evaluation

Health, industry and government stakeholders emphasized the importance of a public education campaign and educational resources to introduce the FOP nutrition symbol, facilitate consumer understanding/use of the FOP nutrition symbol in making informed choices, and decrease risk of misinterpretation-related unintended consequences. Health and government stakeholders suggested that education campaigns/resources be pilot tested and include a variety of tools targeting different groups, including children and vulnerable populations. Research, health, government and industry stakeholders highlighted the need for ongoing evaluation, monitoring and reporting following FOP policy implementation.

Health Canada's response

Public awareness and education efforts will accompany the implementation of the FOP labelling policy to introduce the nutrition symbol and help consumers understand how to use the nutrition symbol in making informed food choices. Health Canada recognizes that the development of educational resources on the FOP nutrition symbol will need to follow best practices, including the targeting and testing of messages. While educational efforts will be applicable to all Canadians, vulnerable populations will be a priority target audience. Health Canada supports a multi-stakeholder approach to public education, as it falls within the mandate of various groups.

Health Canada is committed to monitoring changes in Canadians' nutrient intakes and reporting on the quality of the food supply. Health Canada's approach to performance measurement and evaluation is further outlined in the "Implementation, enforcement and service standards" section.

Comments on the proposed nutrients of concern

Many stakeholders supported the inclusion of saturated fat, sugars and sodium as priority nutrients of public health concern that should be highlighted in the nutrition symbol.

Saturated fat was the most contested among the three nutrients. Several researchers, health and industry groups commented that the evidence does not support an association between reducing saturated fat and heart disease risk reduction. Some industry groups and some researchers commented that all saturated fats are not equal and that they should not be treated the same. Several industry groups commented that the source of saturated fat should be taken into consideration stating that saturated fat from dairy products do not have negative health impacts.

Several consumers and health stakeholders commented that free sugars or added sugars should be identified in the nutrition symbol, rather than total sugars, since total sugars includes sugars naturally present in fruits, vegetables and dairy products.

Some health and industry stakeholders commented that the scientific evidence does not support the upper limits set for sodium by scientific organizations such as the World Health Organization and the National Academies of Sciences, Engineering, and Medicine.

Others felt that calories should be included because calories are of most concern from a public health perspective for obesity.

Health Canada's response

Health Canada selected saturated fat, sugars and sodium for inclusion in the nutrition symbol because there is strong evidence linking excess consumption of these three nutrients to increased risk of obesity (in the case of sugars) and chronic disease (in the case of all three nutrients). Dietary intake data from the 2015 Canadian Community Health Survey indicates that Canadians consume these nutrients in excess of recommended limits.

Health Canada's 2015 Evidence Review for Dietary Guidance found that there is convincing evidence that lowering saturated fat and replacing it with unsaturated fat reduces low-density lipoprotein cholesterol and lowers cardiovascular disease risk. Following a review of the totality of the scientific evidence, in May 2018, the World Health Organization published draft guidelines that recommend:

- reducing saturated fat intake when it is greater than 10% of total energy intake;
- using polyunsaturated fat as a source of replacement energy when reducing saturated fat intake; and

- not increasing saturated fat when intake is less than 10% of total energy intake.

The inclusion of saturated fat in the nutrition symbol aligns with other national and international policies, including labelling policies, which also identify it as a priority nutrient of public health concern. The totality of the evidence does not support distinguishing between saturated fat from dairy products and from other sources. This is why all of the saturated fat in a food product, regardless of whether it comes from a dairy source or another source, is included in the calculation to determine whether the amount meets or exceeds the threshold for saturated fat.

To ensure consistency with the declaration of sugars in the NFt, which is for total sugars and not added sugars, total sugars were selected for the FOP approach. Most foods that would meet or exceed the nutrition symbol thresholds are foods which contain sugars that should be limited (i.e., sugars added by the manufacturer, cook or consumer and those naturally present in syrups, honey, fruit juice and fruit juice concentrates) rather than sugars naturally present in fruits, vegetables and unsweetened dairy products.

The threshold for sodium is based on the DV for sodium, which corresponds to the current upper tolerable level of intake established by the National Academies of Sciences, Engineering, and Medicine. Health Canada will continue to monitor recommendations made by authoritative organizations.

Calories are not included in the FOP approach because there is no DV for calories on which to base the “high in” threshold. Moreover, caloric needs are highly individualized and dependent on a number of factors.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on 15% DV thresholds

Many stakeholders, including industry, supported the 15% DV threshold because it aligns with existing policies and is consistent with a healthy eating pattern. A few health stakeholders and researchers felt the threshold for total sugars was too high when compared to the limits set by other authoritative organizations, such as the World Health Organization. Other stakeholders, particularly from the dairy and meat sectors, felt the thresholds were too stringent. For sugars, the dairy industry commented that the threshold does not provide considerations for lactose that is naturally present in milk, as it is not considered a free sugar by the World Health Organization. The processed meat industry was also concerned that the sodium threshold does not consider the safety aspects of sodium used in their products. A few researchers commented that the dietary recommendations used as the basis for the thresholds were developed to describe properties of the total diet and not individual food items. They also highlighted that consumption patterns and research to support the chronic disease risk associated with consumption of foods high in saturated fat, sugars and sodium would not yield the same threshold value for all three nutrients.

Health Canada’s response

While Health Canada recognizes that lactose is not considered among the sugars that should be limited according to the World Health Organization definition, it would not be appropriate to exclude the lactose in dairy products since the DV for sugars was set for total sugars, which takes the sugars naturally present in dairy into account. However, in the nutrient-specific conditional exemptions, special consideration is given to the lactose that is naturally present in dairy products. Specifically, the addition of ingredients containing sugars, which triggers the loss of the exemption if the threshold is met or exceeded, does not include those sugars naturally present in dairy products (i.e., lactose).

With respect to sodium, Health Canada acknowledges that certain processed meats, for example, are not able to be reformulated to avoid the nutrition symbol. However, the thresholds are based on the potential of foods to contribute to excess intake of nutrients of concern rather than on the potential for reformulation.

Health Canada agrees that single foods, when their significance in the total daily diet is considered, do not generally increase disease risk. Rather, it is an unhealthy dietary pattern that increases disease risk. However, a dietary pattern is made up of single foods. Health Canada took this into consideration and proposed threshold levels that will allow consumers to use the nutrition symbol to choose foods that contribute to a total diet that helps reduce the risk of disease.

The DVs for sodium, saturated fat and sugars reflect either upper limits or intakes as low as possible that are consistent with an achievable, health-promoting diet. The thresholds reflect current established scientific evidence related to overall nutrient intake and risk of diet-related diseases as well as consumption data.

Specifically, the 2015 Canadian Community Health Survey data were used to calculate the number of portions of foods (equivalent to the reference amounts) consumed each day that contain a meaningful amount of each nutrient of concern (i.e., 1% or more of the DV for the nutrient). Next, the %DV threshold per portion that would lead to an intake above each DV was calculated. Results indicated that Canadians consumed 14, 11 and 10 portions per day containing a meaningful amount of sodium, sugars and saturated fat, respectively. Based on these estimates, %DV thresholds of 8%, 10% and 11% would contribute to intakes that exceed 100% of the DV for sodium, sugars and saturated fat. The differences in the thresholds, while relatively small, are due to how prevalent each nutrient is in the food supply. Sodium is the most ubiquitous, followed by sugars, mostly because these two nutrients are added during processing for a variety of reasons, including taste and other functional properties such as texture and preservation. On the other hand, saturated fat is mostly present in foods from animal sources, such as dairy and meat.

Health Canada considered it appropriate to set one threshold for the three nutrients of concern to make them easier to understand and apply.

The rounded up average of the thresholds that would contribute to intakes that exceed 100% of the DV is 10% DV. However, food composition analysis using an indicator food database indicated that 10% applied to all foods would trigger the symbol on too many foods. This in turn could desensitize the consumer to the nutrition symbol, making it less effective. A threshold of 15% DV on most foods is consistent with a recommended overall healthy eating pattern. Foods to choose more often are not required to display a nutrition symbol, whereas many foods whose consumption should be limited, such as cookies, ice cream, sausages and sugar-sweetened beverages, will likely be required to display the nutrition symbol. The 15% DV threshold is aligned with well-established Canadian food and nutrition policies, including Canada's Food Guide, nutrition labelling and the conditions for making "high in" claims for positive nutrients, such as calcium, which are set out in the FDR as well as in guidance. Health Canada has therefore retained the 15% DV threshold for foods that do not have small reference amounts or that are not considered main dishes.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on the proposed approach for foods with small reference amounts

Consumers, researchers and health stakeholders strongly supported the proposal to adjust the threshold basis for foods with small reference amounts. They commented that the FOP nutrition symbol should provide consumers with guidance about foods which, despite their small reference amounts, can contribute to excess intakes of nutrients of concern.

Industry stakeholders strongly opposed the requirement for small reference amount foods to base the 15% DV threshold on 50 g of the food, instead of using the serving size or reference amount. They felt that this approach misrepresented the nutrient content of these foods and was overly restrictive, particularly for foods with very small reference amounts, such as sauces and condiments. Some noted that the proposed approach could require complex calculations and this would increase the burden to industry. Industry and a few health stakeholders also expressed concern about the inconsistency between the 50 g cut-point used to define small reference amount foods for the purposes of FOP nutrition labelling and the ≤30 g or 30 mL cut-point being used currently for the assessment of foods for their ability to carry certain nutrient content claims. To address industry concerns, some health stakeholders suggested using a lower threshold for foods with small reference amounts rather than adjusting the basis for the threshold.

Health Canada's response

To address stakeholder concerns, Health Canada identified the following options for defining and assessing foods with small reference amounts:

- 8% DV threshold applied to foods <50 g or 50 mL;
- 8% DV threshold applied to foods ≤30 g or 30 mL;
- 10% DV threshold applied to foods <50 g or 50 mL; and
- 10% DV threshold applied to foods ≤30 g or 30 mL.

The 8% options are the lowest threshold from the analysis of the 2015 Canadian Community Health Survey data used to support the 15% threshold, whereas the 10% is a rounded up average of the nutrient specific thresholds (8%, 10% and 11% for sodium, sugars and saturated fat, respectively). The two cut-off values to define foods with small reference amounts represent the *Canada Gazette*, Part I proposal (<50 g or 50 mL), and the value used in the nutrient content claims regulations (≤30 g or 30 mL). The analysis found that applying a 10% DV threshold to the largest of the serving size or reference amount for foods with reference amounts of ≤30 g or 30 mL creates nuance within many categories of foods, while still targeting foods that can contribute to excess intakes of nutrients of concerns; therefore, this option was chosen.

Outcome: Health Canada has revised the approach for foods with small reference amounts to define these foods as foods with a reference amount of ≤30 g or 30 mL and applying a 10% DV threshold to the largest of the serving size or reference amount.

Comments on alignment with NFt footnote messaging

Health and industry stakeholders noted that the threshold for foods with small reference amounts could create a disconnect between the requirement to display the nutrition symbol on the front of the package and the educational messaging displayed in the footnote of the NFt, which includes the statement "15% or more is a lot." They expressed concern that this could lead to confusion among consumers.

Health Canada response

Alignment between the information in the NFt and the requirement to display the FOP nutrition symbol is impacted not only by lower thresholds for foods with small reference amounts, but by other adjustments made to nuance the 15% threshold, such as exemptions for certain foods and higher thresholds for prepackaged main dishes. These adjustments ensure that the foods contributing to excess intakes of nutrients of concern are required to display a nutrition symbol. To help mitigate consumer confusion, Health Canada is committed to implementing a coordinated multi-stakeholder public awareness and education campaign on nutrition and FOP labelling following the implementation of the FOP labelling regulations.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on 30% DV thresholds for main dishes

Many industry stakeholders supported the 30% DV threshold for prepackaged main dishes because these products make larger contributions to total daily energy (calorie) intake than individual foods. However, several health stakeholders expressed concerns that the amount of sugars in prepackaged main dishes would never exceed the 30% DV threshold and could result in the unintended consequence of having more sugars added when sodium or saturated fat is reduced during reformulation.

Health Canada response

The concern that the sugars threshold of 30% for prepackaged main dishes is too high has merit, as there are very few prepackaged main dishes that contain this level of sugars. However, since these products make a larger contribution to total daily intake than individual foods, these products can contain more nutrients of concern, including sugars, before they lead to a level of intake that increases the risk of adverse health outcomes associated with these nutrients; hence the main dish threshold for sugars is set at 30% (vs. 15%) of the DV.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on the definitions for “prepackaged meal” and “main dish”

Industry stakeholders commented that the proposed revised definition of “prepackaged meal” and the proposed new definition of “main dish” in the *Canada Gazette*, Part I, do not capture all of the foods they were intended to capture. They indicated that requiring a full reference amount of food from at least two different categories would exclude many products, causing them to be subject to the 15% DV thresholds, while comparable products (in terms of weight and nutrient composition) qualify for the 30% DV thresholds. It was also highlighted that many prepackaged meals for use in weight maintenance and reduction diets, as regulated under Division 24 of the FDR, would no longer qualify as prepackaged meals under the proposed definition. Furthermore, industry stakeholders commented that the proposed “serving of stated size of 200 g or more” criterion in the table of thresholds would prevent many products that have serving sizes less than 200 g but reference amounts of 200 g or more from being able to apply the 30% DV thresholds. In addition, one industry stakeholder requested to remove the need for portion-controlled products bearing a lean claim to meet the “prepackaged meal” definition.

Health Canada’s response

Based on the comments received, Health Canada concluded that proposed revisions to the prepackaged meal definition could have unintended implications for foods for special dietary uses regulated under Division 24 of the FDR. Because the new definition for main dish, as revised following comments received in response to *Canada Gazette*, Part I, meets the intent of the FOP policy, the proposed revisions to the prepackaged meal definition are not needed for the purpose of the FOP policy. Related to claims required to meet this definition, such as “lean” on portion controlled products, this would be considered as part of a review of Division 24.

Health Canada agrees that the definition of main dish proposed in *Canada Gazette*, Part I, would not have captured all intended foods due to the requirement that the amount of food from each category be equal to or greater than one reference amount. Health Canada also agrees that the reference amount requirement and the use of serving of stated size as the basis for the 200 g weight-based criterion would have been unnecessarily restrictive. Analysis determined that the scope of the definition should be broadened to include foods that do not require the addition of ingredients (other than water) rather than only foods that require no preparation other than heating.

Outcomes: Health Canada has removed the proposed revision to the definition of prepackaged meal.

Health Canada has revised the main dish definition to: remove the reference amount requirement for foods coming from at least two different categories; apply to combination dishes (as set out in the *Table of Reference Amounts* which is incorporated by reference into the FDR); apply to products with a reference amount of 200 g or more (or 170 g or more in the case of products intended solely for children one year of age or older but less than four years of age); and apply to foods that do not require the addition of ingredients (other than water) for their preparation. Health Canada has also revised the criterion for main dishes in the table to section B.01.350 of the FDR entitled “Thresholds Requiring a Nutrition Symbol.”

Comments on serving size and reference amount basis for the threshold calculation

Most industry stakeholders did not support basing the %DV calculation for the requirement for the FOP nutrition symbol on the largest of the serving size or the reference amount. They commented that the calculation to determine if the product meets or exceeds the threshold should be based solely on the amount of nutrient in the serving size of the food. In addition, they expressed concerns that for products where the serving size is smaller than the reference amount, basing the FOP requirement on the reference amount could undermine persons who use portion control to achieve a healthier diet. One industry stakeholder provided a report that ranked portion control as the top intervention to address obesity in terms of cost effectiveness and impact if it was applied at a national level. [24]

Health Canada’s response

The amendments to the nutrition labelling regulations in 2016 introduced new requirements to make serving sizes on multiple-serving prepackaged products (e.g., yogurt tubs, boxes of crackers or cereal) consistent and as close as possible to the regulated reference amounts (i.e., the amount that is typically consumed in one sitting). In addition, when the package contains less than 200% of the reference amount for the food, the product is considered a single-serving prepackaged product and the nutrition information must be presented for the whole package (e.g., yogurt cup, granola bar, 473 mL carton of milk).

The regulated reference amounts, which are included in the incorporated by reference *Table of Reference Amounts*, serve as the basis for determining the serving size for both single-serving prepackaged products and multiple-serving prepackaged products. The establishment of reference amounts is informed by consumption and/or market data. The reference amounts were last updated in 2016 as part of the amendments to the nutrition labelling regulations following extensive consultation. The ambulatory nature of the *Table of Reference Amounts* allows for updates to the reference amounts, if data analysis indicates the need to do so. During the consultation, Health Canada received comments indicating that current market practices would necessitate a change to the reference amount for yogurt. Analysis of the 2015 Canadian Community Health Survey data confirmed that the reference amount for yogurt needs to be amended to reflect current amounts typically consumed in one sitting.

The requirement to base the %DV calculation for assessing against the thresholds on the larger of the serving size or reference amount impacts single-serving prepackaged products that have a serving size smaller than the reference amount. Health Canada acknowledges that this could discourage manufacturers from reducing the portion size to avoid an FOP nutrition symbol without reformulation. For example, the same beverage containing 23 g of sugars per reference amount of 250 mL will have 14 g of sugars per serving size of 150 mL. While there is considerable evidence showing that larger serving sizes increase caloric intake, evidence is uncertain that reducing portions at the smaller end of the size range is as effective in reducing food consumption as reductions at the larger end of the range. A recent study examined consumers' experience consuming a cola beverage from smaller compared with larger bottles. When given the smallest bottles, participants described an increased frequency of drinking occasions and likelihood of drinking numerous bottles in succession. Factors described as facilitating their consumption included perceived insufficient quantity per bottle and positive attitudes (i.e., related to perceptions of the superior taste of beverages in smallest bottles or perceived bottle attractiveness). [25] Consumers may still choose to purchase portion-controlled products (with or without the FOP nutrition symbol) to help reduce their overall calorie intake. The FOP symbol on portion-controlled products will help them make an informed choice with respect to saturated fat, sugars, and sodium.

Given that the reference amount is the amount typically consumed at a single eating occasion, there would need to be new consumption and/or market data to show that people are eating less in order to support decreasing the reference amount for these types of foods.

Outcomes: On June 24, 2021, Health Canada published a *Notice of Proposal to update the nutrition labelling: Table of reference amounts for food* (Ref. No. NOP/ADP-QRAC-2021-1) to amend the Table of Reference Amounts, which includes the proposed change to the reference amount for yogurt from 175 g to 115 g. The Notice of Proposal was open for comment for a 75-day period. Health Canada will keep stakeholders advised of other potential changes to reference amounts through the notification process.

The *Canada Gazette*, Part I, proposal to use the larger of the serving size or reference amount as the basis for assessing against the threshold is maintained.

Comments on use of most up-to-date consumption data

A few industry stakeholders were concerned that Health Canada has not accounted for the latest consumption data in the development of this policy.

Health Canada's Response

While Health Canada mostly relied on data from the 2004 Canadian Community Health Survey in the development of the proposed regulations that were pre-published in the *Canada Gazette*, Part I, subsequent analyses of the 2015 Canadian Community Health Survey data indicated that most Canadians continue to consume saturated fat, sugars and sodium in excess of recommended limits. Furthermore, Health Canada used the 2015 Canadian Community Health Survey data to assess and adjust thresholds that will trigger the requirement for the FOP nutrition symbol, as described above in the responses to comments on the specific threshold levels.

Comments on the design of the nutrition symbol

Results from Health Canada's online consumer consultation indicated that the exclamation point and red text-only designs were felt to be the most useful for making food choices because they were attention grabbing and intuitive. The magnifying glass and black and white text-only designs were felt to be the least useful. These results did not differ according to level of consumer vulnerability, which was assessed based on education, income and unemployment mapped against the postal codes of respondents. Researchers and health stakeholders strongly supported the exclamation point because it is easy to understand, draws attention and implies an alert that is consistent with the objective of the FOP initiative.

Industry stakeholders had concerns that the red text-only and exclamation point designs were too alarming and could undermine public trust in the food supply. Industry and some health stakeholders preferred the magnifying glass design because they liked its neutral tone and felt it would encourage consumers to refer to the NFt and the list of ingredients.

Consumers, researchers and health stakeholders supported the use of the Health Canada attribution to provide credibility to the nutrition symbol. Industry commented that the attribution unnecessarily increased the size of the nutrition symbol, and one industry stakeholder wanted the attribution removed noting some consumers may misunderstand it to mean an endorsement by Health Canada.

One stakeholder commented that "Gras sat" may not be well understood and, if used, should include a period at the end of "Gras sat." to follow

French grammar rules.

Health Canada's response

The results of the online consumer consultation showed that, when exposed to all four proposed nutrition symbols, respondents preferred the red text-only symbol and the exclamation point symbol. However, Health Canada's consumer research conducted in a grocery store setting showed that all nutrition symbols were equally effective at helping consumers make more informed choices compared to having no FOP nutrition symbol. [21] A total of 625 participants of varying health literacy levels (60% marginal/40% adequate) including individuals from Indigenous communities and vulnerable groups, such as youth and seniors, were randomized to one of four nutrition symbol design groups or a control group with no nutrition symbol. Participants performed a number of tasks involving multiple food product categories with a diverse range of current food products on the market and the effectiveness of the nutrition symbol was measured. Eye-tracking technology was used to obtain insight into participants' interactions with the nutrition symbol and other label information. The results of this study clearly showed that the presence of an FOP nutrition symbol, regardless of the design, is more effective than current labelling at helping consumers of varying health literacy levels quickly and easily identify foods high in nutrients of concern and choose products lower in these nutrients. Given that each participant in the consumer research study was exposed to only one of the four nutrition symbols, the results remove any impact of personal preference.

The choice of the magnifying glass symbol takes into consideration the outcomes of Health Canada's consumer research and stakeholder comments received during the consultation.

Health Canada agrees that attribution to Health Canada is needed to provide credibility to the symbol and that a period should be included at the end of "Gras sat." to align with French grammar rules.

Outcome: Health Canada has chosen the magnifying glass symbol design.

Comments on the location, look and size of the nutrition symbol

Consumers, health stakeholders and researchers strongly supported the proposal for size and location of the nutrition symbol. They indicated that large size and consistent location are important for consumer awareness, understanding and use. One stakeholder suggested that the nutrition symbol size should be even larger to ensure that it is as accessible as possible for people with disabilities.

Most industry stakeholders disagreed with the proposed size and location requirements as pre-published in the *Canada Gazette*, Part I. Many felt that the dimensions of the nutrition symbol should be based on the PDP rather than the PDS. They indicated that there are a number of products with irregular surfaces to which labelling cannot be affixed, and thus have a PDP area that is considerably smaller than the PDS. Some also commented that the size of the nutrition symbol should be proportional to the number of nutrients being declared.

Industry stakeholders also commented that the proposed location as pre-published in the *Canada Gazette*, Part I did not provide enough flexibility. It would require label redesigns and affect the location of important branding information. Some also noted that the proposed location was not practical for small and irregular shaped packages and that the nutrition symbol could end up in "no print zones" such as re-sealable zippers or cut-outs. Industry stakeholders who participated in Health Canada's technical design workshop suggested that the regulations should allow an option for vertical stacking of the nutrition symbol as a way to provide more flexibility for narrow labels. Those from the retail sector noted the limitations of retail scale labelling, specifically that they are a fixed width regardless of package size.

Following the March-April 2022 consultation, the retail sector requested a full exemption from the nutrition symbol requirements for labels printed on retail scales. If an exemption is not possible they asked for additional flexibility such as being allowed to use a text-based symbol. They noted that the option to use stickers was not ideal because it requires training staff. Other challenges noted from this sector included equipment and space limitations, as well as delays in implementation for prepackaged foods prepared from multiple vendor-sourced ingredients.

Some commented that the new labelling requirements should not drive increases in packaging size and should provide design flexibility that enables packaging innovation while ensuring policy objectives are met.

In addition, some industry stakeholders requested the use of a simplified format for all package sizes, as would be permitted for packages with an available display surface of 100 cm^2 or less, and some felt the criteria for a vertical symbol was too restrictive.

Two industry stakeholders felt the placeholder nutrient bars for nutrients that are not "high in" would be distracting and confusing to consumers, specifically noting the "high in sodium" symbol resembled a barometer or thermometer. One health stakeholder supported the use of placeholders.

Health Canada's response

Health Canada agrees that a large and legible nutrition symbol and a consistent location are important principles for information processing. Results from the online consumer research commissioned by Health Canada showed that the proposed nutrition symbol size (compared to a smaller symbol) and a consistent location (compared to a variable location) facilitated and quickened consumer understanding. Other evidence indicates that warning labels that are relatively larger than their surrounding space are more likely to be noticed and are therefore more effective.

In terms of location, research has found that nutrient information located at the top of a label is viewed more frequently. However, to address industry stakeholders' concern, Health Canada has provided additional flexibility with respect to the design and location of the nutrition symbol.

Health Canada does not agree with the view that the "high in sodium" symbol resembles a barometer or thermometer as this does not apply to the "high in saturated fat" or "high in sugars" symbols. Health Canada did not receive any comments in this regard in its consumer research. Consumers also did not raise any concerns about placeholder nutrient bars being confusing. Placeholder nutrient bars ensure nutrients appear in a consistent location within the symbol, allowing consumers to quickly and easily tell at a glance which nutrient the food is high in. They also ensure a consistent symbol footprint on packages with similar sizes.

Health Canada notes the three and a half year transition period allows industry significant time to comply with the new regulations, mitigating the need for packaging to be wasted. The amendments consider the nutrition symbol to be sized based on the PDS of the package and provide design flexibility that would still enable packaging innovation. No significant environmental impacts are expected as a result.

Outcomes: *Canada Gazette*, Part I proposal maintained for size of the symbol. However, Health Canada has revised the requirements for packages with a PDS ≤30 cm^2 by removing the placeholder bars for those nutrients that are not required to be shown in the symbol. This is to reduce the amount of space required for the symbol on small and irregular shaped packages.

Health Canada is introducing for a vertical format for packages with a PDS of 450 cm^2 or less where the width of each applicable version of the nutrition symbol in a horizontal format exceeds the width of the PDP. With respect to location, Health Canada is requiring that the nutrition symbol appear within the top half of the PDP, or the right half of the PDP in the case of horizontal packages, compared to the top 25% (or the right-most 25%) of the PDP as proposed in the *Canada Gazette*, Part I.

On June 12th, 2018, Health Canada hosted a FOP nutrition labelling technical design workshop to discuss the design and implementation of the FOP proposal, including retail scale labels. Key stakeholders in attendance included graphic designers and industry experts representing packaging design, printing, retail and regulatory compliance. It was confirmed that the FOP nutrition symbol can be printed using retail label printers, although there would be cost implications. The use of a separate sticker label was suggested.

FOP nutrition symbols will be required on products with labels printed using retail scales to ensure consistent application of the FOP policy. Keeping the design of the FOP symbol consistent on most packages will allow consumers to tell quickly and easily at a glance what the food is "high in." However, to address the challenges associated with this type of labelling, Health Canada is allowing for a smaller and standardized version of the nutrition symbol to be used on these labels, regardless of package size. If this is not possible, Health Canada is allowing for the application of a separate FOP nutrition symbol sticker on these labels.

Comments on the restrictions on placement and size of other health-related names, symbols, claims and statements on the PDP

Consumers, health stakeholders, researchers and other governments strongly supported restrictions on the location and size of other health-related information on the front of the package, such as nutrient content claims, health claims and other FOP systems. They felt that restrictions would help minimize confusion due to conflicting messages and distraction from the nutrition symbol.

Most industry stakeholders did not support the proposed restrictions. A few associations supported the proposal in principle but felt that it was more restrictive than necessary. They commented that the restrictions would require expensive label redesigns and affect the location of important marketing messages. Industry stakeholders also argued that the restrictions would impair their ability to communicate important nutrition information and thus potentially impact the health of Canadians. A few industry stakeholders requested an exemption for implied health-related claims used as brand names, such as the use of the word "fibre" or "probiotics."

Health Canada's response

Results from the online consumer research commissioned by Health Canada found that restrictions on the location of other health-related information unrelated to the nutrients of concern did not quicken or improve consumer awareness or understanding of the nutrition symbol. Therefore, Health Canada agrees with industry stakeholders that the location restriction is not justified. Proposed size restrictions on other health-related information are important to ensure that consumers are able to notice the nutrition symbol amongst other health-related information on the front of packages. This is supported by findings in the consumer research commissioned by Health Canada, which showed that the size of the nutrition symbol was important. Other evidence shows that the presence of a claim related to a nutrient of concern in the nutrition symbol, such as "reduced in sodium" on a product displaying a "high in sodium" symbol, compromised the effectiveness of the nutrition symbol regardless of size or location of the claim relative to the symbol. However, given that a "reduced in" claim is sometimes used to distinguish a product from its similar reference food, Health Canada is providing for this practice, but is further restricting the prominence of these claims on the PDP to no more than the height of the text within the nutrition symbol. With respect to statements or claims that are not in relation to a nutrient that appears in the nutrition symbol (such as "source of fibre"), Health Canada will maintain the proposed size restriction to twice the size of the text within the symbol. Health Canada agrees with industry comments that the size of health-related information that is a part of a brand name should not be restricted on the PDP and has adjusted the regulations accordingly.

Outcome: Health Canada has removed the restriction on the location of other health-related names, symbols, claims and statements and added a more stringent restriction on size when the claim is related to a nutrient in the symbol. Health Canada has also removed the restriction on the size of brand names and product names that could be considered health-related names on the PDP.

Comments on exemptions for foods currently exempt from the requirement to display the NFt

Most health stakeholders were opposed to the FOP exemption for certain foods exempted from the requirement to display the NFt (e.g., prepared dishes from the deli counter, home meal replacements and in-house bakery products) arguing that it would lead to consumer confusion and create an uneven playing field. Industry support for this category of exemptions was mixed. A few industry stakeholders asked that this category of exemptions be expanded to include: products voluntarily carrying an NFt in order not to discourage its display; raw single ingredient ground meat to level the playing field with whole cuts of meat; and products destined for food services, enterprises or institutions, as they are not sold directly to consumers. Following the March-April 2022 consultation, the meat sector reiterated their belief that ground meat should be exempted, for several reasons including a level playing field with whole cuts.

Health Canada's response

Health Canada acknowledges that certain foods exempted from the NFt requirement can be high in nutrients of concern. The ideal solution would be to review the conditional NFt exemptions and, if appropriate, require the NFt and nutrition symbol on all foods made and sold in the retail establishment where standardized nutrition information is available. Unfortunately, it was not possible to complete this work within the scope of this initiative.

Certain types of meat (e.g., pork and beef) are generally high in saturated fat and therefore contribute to excess intakes, whereas others (e.g., chicken and turkey) are not. However, Health Canada agrees that the FOP symbol on ground meat could give the impression that ground meat is nutritionally inferior to whole cuts. Therefore, ground meats will be given a conditional exemption to level the playing field with raw, single ingredient whole meats. The conditions that trigger the NFt requirement, and therefore FOP nutrition labelling, for raw whole single ingredient meat, other than when the meat is ground, will be the same conditions that trigger FOP nutrition labelling on raw single ingredient ground meat. To help ensure Canadians have the information they need to make healthier choices, a public awareness and education campaign will be developed that links to Canada's Food Guide, which gives advice on choosing foods lower in saturated fat, sodium and sugars.

Health Canada agrees that requiring a nutrition symbol on products voluntarily displaying an NFt could discourage manufacturers from providing the NFt.

A nutrition symbol on foods for use in manufacturing other foods and foods destined for use in an enterprise or institution will not be required given that consumers do not interface with these foods. The exemption will also be extended to shipping containers as long as the containers and their contents are not sold as a one unit prepackaged product to a consumer at the retail level.

Outcome: Health Canada has adjusted the regulations so that ground meats will be granted the same conditional exemption as whole cuts of meat. Health Canada has also adjusted the regulations so that the voluntary declaration of an NFt will not trigger the requirement to display a nutrition symbol. Health Canada has allowed an exemption for nonconsumer prepackaged products (e.g., shipping containers, foods intended solely for use in manufacturing other foods and foods destined for use in an enterprise or institution).

Comments on exemptions for foods for which there is evidence to support protective health effects

Consumers, health and industry stakeholders supported the exemptions for foods that have a protective effect on health. Industry stakeholders asked that the exemption for fruits and vegetables be expanded to include dried forms, juices and purées, and to allow for the addition of spices and herbs to any form. Industry stakeholders argued that dried fruits, 100% fruit juices and purées contribute many of the same positive nutrients as whole fruits and vegetables. They also noted that purées play an important role in the diet of toddlers and young children, and fruit and vegetable juices are an important source of nutrients for Canadians in communities that do not have easy access to fresh fruits and vegetables. Health stakeholders strongly supported the "high in sugars" nutrition symbol on fruit juices. The cranberry industry requested that sweetened cranberry products also be exempt from FOP labelling claiming that cranberries have unique health benefits, such as preventing recurrent urinary tract infections in women. Many health and industry stakeholders argued that the exemption provided for milk should be extended to other nutritious dairy products such as plain yogurt and cheese. Reasons included their role in reducing the risk of chronic disease and providing shortfall nutrients such as calcium. One industry stakeholder commented on the scope of cheese that would benefit from the exemption should one be provided. Industry stakeholders also requested exemptions for bread and ground meat because they are good sources of folic acid and iron, respectively.

Industry stakeholders commented that nuts and seeds packaged as snacks, which have a reference amount of 50 g, should also be exempted because they have a cardio-protective fatty acid profile of less than 30% total fat as saturated fat.

One industry association requested that canned fish and seafood be exempt from the requirement to display an FOP nutrition symbol because they have a healthy nutrient profile and there is evidence that eating a variety of seafood lowers the risk of heart disease.

One also asked that the exemption for whole eggs be expanded to include cooked forms.

Health Canada's response

Health Canada agrees that fruits and vegetables with added spices or herbs should maintain their exemption, since the nutrients of concern are not impacted. With respect to dried fruits, Health Canada recognizes that the World Health Organization excludes sugars naturally present in dried fruits from their definition of sugars to limit. Therefore, Health Canada extended the exemption for fruits and vegetables to include dried

fruits and vegetables and to allow for the addition of ingredients that do not contain nutrients of concern. The addition of sugars to tart fruits, such as cranberries or rhubarb, triggers the requirement to display the nutrition symbol, if the sugars threshold is met or exceeded, to align with the World Health Organization guidance and Health Canada's goal to help Canadians reduce sugars consumption.

Health Canada does not agree that the exemption should be expanded to include juices and purées. The sugars in juices and purées are included in the World Health Organization definition of sugars to limit. Furthermore, the positive nutrients in juices and purées, such as vitamins and mineral nutrients, are available in whole and cut fruits and vegetables which are eligible for the exemption so as to encourage their consumption among all Canadians, including children. The totality of the evidence to support juices and chronic disease risk reduction is not sufficiently strong to rationalize an exemption. In terms of purées, these are not necessary foods for toddlers and young children. According to *Nutrition for Healthy Term Infants, A joint statement of Health Canada, Canadian Paediatric Society, Dietitians of Canada, and Breastfeeding Committee for Canada*, the feeding guidelines for 6-24 months are to ensure that lumpy textures are offered no later than 9 months. Delaying the introduction of lumpy textures beyond this age is associated with feeding difficulties in older children and a lower intake of nutritious foods such as vegetables and fruits.

In terms of extending the exemption for milk to include other dairy products, Health Canada notes that according to the 2015 Canadian Community Health Survey data, dairy products are the main source of saturated fat in the diet. There is convincing evidence that lowering saturated fat and replacing it with unsaturated fat reduces low-density lipoprotein cholesterol and lowers risk of cardiovascular disease. There is no convincing evidence that dairy sources of saturated fat are healthier than other sources of saturated fat. However, analysis shows that many dairy products including cheese and yogurt are important sources of calcium, which is a shortfall nutrient due to inadequate intakes among Canadians. Adequate calcium intakes are necessary for promoting and maintaining bone health, and consequently, helping to reduce the risk of osteoporosis which is prevalent in Canada. To help ensure Canadians have the information they need to make healthier choices, a public awareness and education campaign will be developed that links to Canada's Food Guide, which gives advice on choosing foods lower in saturated fat, sodium and sugars.

Health Canada does not agree that an exemption should be extended to pantry breads. Exemptions from requiring a nutrition symbol are provided for food categories that have a recognized health protection benefit, for redundancy purposes or for categories that are top contributors to intakes of shortfall nutrients that are not readily available in other foods. The latter is intended to avoid discouraging consumers from choosing foods in this category. Health Canada estimated 51% of breads to be high in a nutrient of concern, resulting in Canadians having many bread options without an FOP nutrition symbol.

Ground meats do not qualify for a health exemption because they are not a top contributor to a shortfall nutrient of public health concern, such as iron. Most Canadians get their iron from grain products and there are readily available alternatives not high in saturated fat. However, ground meats will be given a technical exemption from the requirement to carry the nutrition symbol to level the playing field with raw, single ingredient whole meats.

Health Canada acknowledges that fish and seafood are part of a healthy eating pattern because they contain a range of nutrients, including omega-3 fatty acids, protein and vitamin D, and are low in saturated fat.

With respect to whole eggs, Health Canada agrees that the exemption should include the cooked form as the same health rationale applies regardless of whether the whole eggs are liquid, dried, frozen or boiled.

Outcomes:

Health Canada has extended the exemption for fruits and vegetables to include unsweetened dried fruits and vegetables. The *Canada Gazette*, Part I, proposal is maintained for juice and purées.

In order to mitigate risks of negative impacts on calcium intakes, Health Canada has exempted cheese and yogurt made from dairy products (including drinkable yogurts) as well as kefir and buttermilk from the requirement to display the "high in sat fat" or "high in sugars" nutrition symbol. For the same reason, Health Canada has exempted cheese made from dairy products from the requirement to display the "high in sodium" nutrition symbol as sodium is required in the cheese-making process. To benefit from the exemption, the products must contain a specific percentage of the DV for calcium: ≥10% DV per serving or reference amount, whichever is greater, for products with a reference amount of 30 g or 30 mL or less and ≥15% DV per serving or reference amount, whichever is greater, for products with a larger reference amount.

Health Canada agrees with the comments made by industry stakeholders in relation to the exemption for nuts and seeds. For this reason, Health Canada has extended the exemption from the requirement to display a "high in sat fat" nutrition symbol to nuts and seeds in which less than 30% of the total fat content consists of saturated fat, regardless of their reference amount. Furthermore, the exemption will apply to nut and seed butters, marine and fresh water animal products (e.g., fish) as well as vegetable and marine oils given that these foods have a cardio-protective fatty acid profile of less than 30% of total fat as saturated fat.

Except for cheese and sodium, all of these exemptions are conditional and will be lost when certain ingredients containing nutrients of concern are added as outlined in the "Description" section.

Comments on exemptions for foods where the FOP nutrition symbol would be redundant

There was little support from health and industry stakeholders for the proposal to exempt sweetening agents and salts; they felt that the nutrition symbol would not be redundant, especially on certain sweetening agents or salts believed by consumers to be healthy, such as honey or sea salt. Some stakeholders suggested that, if retained, the salt exemption should be extended to other seasoned/seasoning salt not listed in Division 7 of the FDR. Some stakeholders commented that butter, like sweetening agents and table salt, should be exempt from having a "high in sat fat" nutrition symbol because it is redundant.

Health Canada's response

Health Canada acknowledges that this exemption appears not to be consistent with the policy intent. However, Health Canada continues to believe that a "high in sodium" symbol on packaged salt and a "high in sugars" nutrition symbol on packaged sugar is redundant. To ensure a level playing field between packaged sugar and other sweetening agents, the whole category is exempted. Sweetening agents, which are composed mainly of sugars, are defined in subsection B.01.001(1) of the FDR and include those listed in Division 18. Similarly, salts listed in Division 7 of the FDR, i.e., celery salt, garlic salt and onion salt, as well as any other seasoning salt if "salt" forms part of the common name of the food, are also exempted.

Health Canada also acknowledges that consumers may view some sweetening agents and salts as being more or less healthy than others and believe that education can help address these misconceptions. Health Canada is committed to implementing a coordinated multi-stakeholder public awareness and education campaign on nutrition and FOP labelling following the implementation of the FOP labelling regulations.

Outcome: *Canada Gazette*, Part I proposal maintained for sweetening agents. Health Canada has extended the exemption for salt to include other seasoning salts that contain the word "salt" in their common name. Health Canada has also exempted butter and ghee on the basis of redundancy, similar to that granted for salt and sweetening agents. Given that some vegetable oils and some fish and marine fats and oils are also high in saturated fat, the exemption is extended to all fats and oils listed in Division 9, fish and other marine fats and oils, as well as margarine and other similar substitutes for butter to level the playing field.

Comments on prohibition for foods for special dietary use

Stakeholders supported the nutrition symbol prohibitions for infant formulas, foods represented as containing infant formula, and foods intended solely for infants six months of age or older but less than one year of age. Most also supported the prohibitions for certain Division 24 products (i.e., formulated liquid diets, foods for very low energy diets). Some commented that the prohibitions should be extended to include all Division 24 products.

Health Canada's response

The proposed regulations would have required the nutrition symbol on some but not all Division 24 foods, including meal replacements, nutritional supplements, gluten-free foods, and foods for protein-restricted diets and low amino acid diets. Health Canada agrees that the prohibition should be extended to include all Division 24 foods, except gluten-free foods (see below). While some of these products are used as "regular foods," many are primary or sole source products and have specific compositional or labelling requirements. FOP nutrition symbols on these products could discourage their consumption among vulnerable groups who need them to meet their nutritional requirements.

Health Canada did not include gluten-free foods in the prohibition for foods for special dietary uses because it is the only category of Division 24 foods sold at retail that does not have specific compositional or labelling requirements (aside from not containing any gluten protein) and that is required to carry the NFt. Gluten-free foods are not only purchased by consumers with celiac disease but also by an increasing number of people from the general population.

The issue of nutrients of public health concern in foods for special dietary uses would be better addressed in a comprehensive manner through the modernization of Division 24, Part B of the FDR.

Outcome: Health Canada has extended the prohibition to include all categories of foods for special dietary use in Divisions 24 and 25, Part B of the FDR, except gluten-free foods.

II. Nutrient content claims and other nutrition-related statements

Comments on nutrient content claims about the same nutrient appearing in the nutrition symbol

Health stakeholders expressed concerns about nutrient content claims for saturated fat, sugars and/or sodium appearing on foods high in the same nutrient(s). Research submitted during consultations showed that claims about the same nutrient appearing in the nutrition symbol could confuse consumers and diminish the understanding and effectiveness of the nutrition symbol. Some called for the prohibition of all claims related to a nutrient of concern on foods high in that nutrient. Some industry stakeholders commented that claims such as "no added sugars" made on foods that meet the conditions of use are factually based and therefore should be allowed. Industry noted consumers' interest in identifying "natural" versus added sources of sugars in foods.

Health Canada's response

The "no added sugars" claim on a product required to display the "high in sugars" symbol, such as fruit juice, would give the consumer a contradictory message. It potentially misleads consumers to believe that the sugars in the product are healthier because they are not added. This

is not supported by the World Health Organization's 2015 guideline on sugars intake. The World Health Organization guideline recommends limiting the intake of free sugars, which include sugars in fruit juice. Moreover, research commissioned by Health Canada showed that a "no added sugars" claim was the key piece of information used to make the product choice when a "high in sugars" nutrition symbol was present, indicating that the presence of the claim reduced the effectiveness of FOP labelling. This, combined with the evidence from consumer research submitted during consultations, indicates that the presence of any claim related to a nutrient of concern can decrease the effectiveness of the nutrition symbol when the food is high in that nutrient.

Outcome: Health Canada considers it necessary to prohibit the use of nutrient content claims, on the PDP, related to the nutrients of concern when the food carries a nutrition symbol for that nutrient. However, this prohibition will not apply to "reduced in" claims (items 20, 33 and 38 in the incorporated by reference *Table of Permitted Nutrient Content Statements and Claims*) because they are used to distinguish products that have been processed, formulated, reformulated or otherwise modified to contain less of the nutrient than the similar reference food. Such foods, when chosen instead of the similar reference foods, may lead to reduced intakes of nutrients of concern. Nevertheless, their size will be restricted to mitigate decreased effectiveness of the nutrition symbol.

Comments on various nutrient content claims and Health Canada's responses

A number of comments were received on the proposed changes to nutrient content claims. A summary of the comments received and Health Canada's responses are provided in the *Notice of Modification: Incorporating by Reference the "Nutrition Labelling – Table of Permitted Nutrient Content Statements and Claims,"* which is available on the Government of Canada website. [26]

Comments on nutrition-related statements in the FDR

Health Canada received comments on the following proposed amendments pertaining to nutrition-related statements: expanding the scope of the use of representations characterizing the amount of alcohol; updating the references to food intended solely for children under two years of age; and prohibiting the representation that a food is for use in a sodium-restricted diet if the food carries a nutrition symbol for "high in sodium." Most stakeholders supported these amendments.

Industry stakeholders were not supportive of the proposal to move the "unsweetened" claim to the *Table of Permitted Nutrient Content Statements and Claims* being incorporated by reference into the FDR. They noted that this claim is a sensory claim (e.g., for taste) because it is intended to communicate to consumers that the product carrying the claim has no added ingredients that impart additional sweetness, a property that is not related only to the absence of sugars. Therefore, they felt it should not be included in the *Table of Permitted Nutrient Content Statements and Claims*. One stakeholder further requested that the term "unsweetened" be completely decoupled from the conditions of use for the "no added sugars" claim.

Health Canada's response

Health Canada agrees that the "unsweetened" claim is partly a sensory claim.

Outcome: Health Canada has retained the provision regarding the "unsweetened" claim in the FDR. However, conditions of use applicable to the "no added sugars" nutrient content claim will continue to apply to the "unsweetened" claim and its use will be prohibited on the PDP of foods carrying a "high in sugars" nutrition symbol.

III. Vitamin D fortification

Comments on vitamin D fortification of milk and margarine

A majority of stakeholders were supportive of the proposal. A few stakeholders raised concerns over the approach to increase vitamin D only in milk and margarine and not in other products. In particular, one industry stakeholder noted that data shows that Canadians' intakes of these products have decreased in recent years and that some ethnic groups do not consume cow's milk. One health professional organization questioned the overall effectiveness of the approach in helping Canadians increase vitamin D intake. They expressed concerns over the importance of increasing vitamin D in margarine at this time in relation to the overall public health strategy. They proposed that Health Canada explore modifying dietary guidance to improve vitamin D intake instead.

Health Canada's response

Milk and margarine are the major contributors to vitamin D in Canadians' diets. However, in order to expand the dietary sources of vitamin D available to Canadians, Health Canada has included additional foods in its vitamin D fortification strategy. In fact, on May 4, 2022, Health Canada enabled increased vitamin D amounts in fortified plant-based beverages to align with the new amount in milk. This was achieved by updating the interim policy that allows their sale. The final planned step in the strategy is to permit the vitamin D fortification of yogurt. In the fall of 2022, Health Canada plans to hold a technical consultation with industry to discuss this proposal. Health Canada will continue to monitor the vitamin D status of Canadians as part of the Canadian Health Measures Survey. If necessary, Health Canada will consider allowing the addition of vitamin D to more foods in the future. Health Canada released the updated Canada's Food Guide in January 2019, which continues to include foods that provide vitamin D.

Outcome: *Canada Gazette*, Part I proposal maintained.

IV. Comments on proposed FDR amendments related to the prohibition of PHOs

The majority of respondents supported the proposed consequential amendments to the FDR, including the definition "fully hydrogenated." One industry representative pointed out that the proposed PHO definition is specific to fats and oils as ingredients, stating that it does not lend itself to assurance for importers that a mixed-ingredient product is PHO-free. To this end, the respondent requested that a finished product-testing standard based on a *trans* fat threshold be provided to industry.

Health Canada's response

Health Canada has shared this comment with the Canadian Food Inspection Agency, which is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to food. Under the *Safe Food for Canadians Regulations*, importers will be required to demonstrate that the food they import meets Canadian requirements. With any new policy or regulatory initiative, such as the introduction of the PHO prohibition, the Canadian Food Inspection Agency reviews and updates its guidance as needed.

Health Canada also notes that the proposed definition of "partially hydrogenated" consulted on in the *Canada Gazette,* Part I, will instead be added to the *List of Contaminants and Other Adulterating Substances* since the term will no longer be used in the FDR.

Outcome: *Canada Gazette*, Part I proposal maintained.

V. Labelling of foods containing certain high-intensity sweeteners

Comments on the proposed repeal of the PDP declaration and quantitative declaration requirements for foods containing aspartame, sucralose, acesulfame-potassium and/or neotame

Industry stakeholders overwhelmingly supported the proposed repeal of the additional PDP and quantitative labelling requirements that currently apply to foods containing the sweeteners aspartame, sucralose, acesulfame-potassium and neotame.

Government respondents and health stakeholders were divided in their support for the proposal. Those who opposed the repeal of these labelling requirements expressed the same concerns raised during the November 2016 pre-consultation, which are summarized below along with Health Canada's responses.

Concerns about the legibility of the list of ingredients

A key concern raised by those who opposed the proposal to repeal the PDP requirements commented that the list of ingredients is difficult to navigate or read and suggested that this prevents many consumers from consulting it. They reiterated that the declaration on the PDP should therefore be maintained as it provides an easily identifiable and upfront indication that a food contains one or more of these sweeteners.

Health Canada's response

New formatting specifications for the list of ingredients were brought into force as part of the 2016 nutrition labelling regulations that will make it easier to locate, read and understand the information provided in the list of ingredients on prepackaged products. The new legibility and placement requirements for the mandatory phenylalanine statement will also make it easier for those with phenylketonuria to identify foods containing aspartame.

Outcome: *Canada Gazette*, Part I proposal maintained.

Comments on the mandatory phenylalanine statement for products that contain aspartame

Regarding the optional use of the statement used in the United States "Phenylketonurics: contains phenylalanine," some stakeholders commented the wording of this statement should be plainer, "people-first" language.

Health Canada's response & Outcome: In response to these concerns, Health Canada has amended the language of subsection B.01.014(1) to be more general such that a regulated party could use the statement used in the United States "Phenylketonurics: contains phenylalanine" or a "people-first" statement, such as "People with phenylketonuria: contains phenylalanine" or "Those with phenylketonuria: contains phenylalanine." Existing industry guidance on aspartame labelling will be revised to provide further direction on acceptable permutations of this statement. Regulated parties will also retain the option of using a statement to the effect that aspartame contains phenylalanine.

Comments on the loss of small package exemption from the nutrition symbol requirement due to the presence of the four sweeteners in question

Two stakeholders commented that the proposed regulations should be revised to ensure that the presence of aspartame, sucralose, acesulfame-potassium and/or neotame does not automatically revoke a product's eligibility for the small package exemption from the nutrition symbol.

Health Canada's response

Health Canada agrees that the presence of these sweeteners should not revoke the small package exemption. Amendments to achieve this should have been included in the proposed regulations pre-published in the *Canada Gazette*, Part I.

Outcome: Health Canada has repealed paragraph B.01.401(3)(c) and amended section B.01.467 to ensure that foods otherwise exempted from an NFt do not lose their NFt exemption, and subsequently their exemption from the FOP nutrition symbol, when they contain aspartame, sucralose, acesulfame-potassium or neotame.

Despite these amendments, it should be noted that foods containing these sweeteners would still lose their NFt exemption if they meet any of the other conditions for loss of exemption, for example, if a nutrient content claim is made on the label or if the product contains an added vitamin or mineral nutrient.

Concerns about the use of sweeteners by food manufacturers

Consumers and health stakeholders commented that there could be an increase in the use of these high-intensity sweeteners by manufacturers, either due to the removal of the PDP requirement or the new requirement to display a "high in sugars" nutrition symbol if the food meets or exceeds the FOP threshold for sugars.

Health Canada's response

Health Canada acknowledges the possibility that some food manufacturers may choose to substitute sugars with sweeteners in order to avoid the "high in sugars" nutrition symbol. The possibility of using sweeteners to reduce the amount of added sugars has been an option available to food manufacturers for many years, provided that the sweetener: is approved for use in Canada; is only used in those foods where it is permitted; and does not exceed the maximum level of use prescribed by Health Canada. Therefore, even if there were to be increased use of sweeteners, the strict controls that are in place to help ensure that dietary exposure to sweeteners remains within safe levels.

With respect to the concern that the removal of the PDP requirement will further encourage the replacement of sugars with sweeteners, the requirement to declare sweeteners on the PDP only applied to the four high-intensity sweeteners in question. There are other high-intensity sweeteners (some artificial and some derived from natural sources) as well as a number of polyol sweeteners that are approved for use in Canada that are not required to appear on the PDP. There is no evidence that the absence of a PDP declaration for these other approved sweeteners has influenced whether manufacturers choose to use sweeteners in place of added sugars.

Outcome: *Canada Gazette*, Part I proposal maintained.

Concerns about the safety of sweeteners

Some respondents indicated their belief that sweeteners have negative health effects and mentioned research suggesting a correlation between the consumption of foods containing sweeteners and obesity and type 2 diabetes. Some respondents not only recommended retaining the additional labelling requirements for the four sweeteners in question but also extending such labelling to all sweeteners.

Health Canada's response

All food additives, including sweeteners, are thoroughly assessed prior to their approval to ensure that they are safe for use in foods. Health Canada regularly monitors emerging scientific evidence to ascertain whether its food additive provisions need to be updated. To date, the body of available scientific evidence continues to support the safety of the sweeteners approved by Health Canada for use as food additives. Evidence on the association between foods containing sweeteners and possible negative health outcomes remains limited and inconclusive. Given this, there is no health rationale for requiring PDP labelling of foods containing the four high-intensity sweeteners in question or for expanding the PDP labelling requirement to foods containing any approved sweeteners.

The additional labelling requirements for these sweeteners were not put in place to help mitigate a particular safety concern with these ingredients. The requirement to declare the presence of these sweeteners on the PDP as well as their quantity grouped together with the list of ingredients was first introduced in 1981, with the approval of aspartame, as a means of supporting the informed use by the general public of what at the time was a new high-intensity sweetener for use in non-dietetic foods. These additional labelling requirements were subsequently applied, for reasons of consistency, to sucralose, acesulfame-potassium and neotame when they were approved for use. Such additional labelling is unnecessary from a health and safety perspective and, since the approval of neotame in 2007, Health Canada has ceased to require additional PDP and quantitative labelling for foods containing other high-intensity sweeteners.

Outcome: *Canada Gazette*, Part I proposal maintained.

VI. Transitional provisions

Comments on implementation timelines

Health stakeholders commented that the proposed transition period of approximately four years in the *Canada Gazette*, Part I, pre-consultation ending in December 2022 was too long whereas industry stakeholders supported it. Some industry stakeholders suggested a minimum five-year implementation period once the last regulatory amendment for major label changes has been finalized, including Canadian Food Inspection Agency's former Food Labelling Modernization amendments, now proceeding under the name "Food Product Innovation."

Following the March-April 2022 consultation, a few industry stakeholders did not support the transition period of three and a half years as they noted it was not reasonable and did not align with the approximately four-year period considered in the *Canada Gazette*, Part I, pre-consultation. In particular, comments shared were related to modifications to nutrition labels, which involve nutrient analysis, labour and change processes as well as branding changes and related intellectual property implications. Some stakeholders requested that Health Canada coordinate the finalization and compliance of all regulations impacting food labels, and some recommended that Health Canada extend implementation to the next compliance date under the Food Labelling Coordination policy, i.e., January 1, 2028. Two health stakeholders reiterated that the transition

period was too long, with one indicating manufacturers have shorter implementation periods in other jurisdictions and the other that it was important not to further delay benefits to Canadians. One health stakeholder also noted that compliance measures should be sufficiently rigorous to ensure full adherence to the regulations.

Health Canada's response

Regulated parties are given a transition period for all components of these amendments, except for those relating to PHOs, ending on January 1, 2026. This will allow sufficient time for regulated parties to make the necessary changes to their labels and ensure that the benefits of the initiative are not delayed unnecessarily.

These regulations fall within the scope of the joint Health Canada and Canadian Food Inspection Agency Food Labelling Coordination policy. This policy was developed, in part, to provide greater predictability with respect to the compliance dates for changes to food labelling requirements and establishes compliance date options for food labelling requirements at a two-year interval, beginning on January 1, 2026. The policy does not restrict industry stakeholders from making changes to align with the new FOP labelling regulations, or any other nutrition labelling regulations (e.g., NFt or list of ingredients as per the 2016 nutrition labelling regulations), before the end of the transition period, as this remains a business decision. More information about the Food Labelling Coordination policy consultation, which health and industry stakeholders were involved in, included below.

Health Canada recognizes the resources that go into preparing new labels and bringing new products to market and is of the view that trademarks and trade dress are not disrupted by these regulations.

Following the March-April 2022 consultation, Health Canada received comments from industry stakeholders with respect to recent supply chain and inflationary challenges (increased costs for printing, operating costs, etc.). Data from Statistics Canada (2021) indicate the food industry has shown adaptability and resilience despite recent challenges and that manufacturers are operating at near pre-pandemic levels. However, Health Canada has increased its estimated cost per stock keeping unit (SKU) in the CBA to account for these challenges and maintains its decision to keep the first compliance date of January 1, 2026 in the Food Labelling Coordination policy.

With respect to alignment with the Canadian Food Inspection Agency regulatory changes, the Food Product Innovation initiative does not contain any mandatory label changes so there are no implementation dates to align.

Outcome: *Canada Gazette*, Part I proposal maintained. The three and a half year transition period allows time for industry stakeholders to exhaust their existing product and label stocks in order to eliminate waste, while updating their labels to include the appropriate labelling requirements.

VII. Cost-benefit analysis (CBA)

Comments about costs to industry

Industry stakeholders disagreed with the cost estimate because they believed it underestimated the implementation costs and the number of SKUs that would be impacted. Industry stakeholders also disagreed with not including impacts such as the need to shift funds and resources from innovation and capital investment to regulatory compliance or indirect costs such as reformulation and lost market share.

Following the March-April 2022 consultation, industry stakeholders raised additional concerns on the resulting costs of the proposal, including concerns regarding its potential to contribute to food inflation, beyond those raised over supply chain pressures and increased manufacturing costs (i.e., labour costs, packaging material costs, and availability of raw materials). One industry stakeholder raised the issue of costs to replace scale label printers. One industry stakeholder also raised concerns on potential reformulation costs, stating that these costs could rise as a result of ingredient shortages and global demand.

With respect to costs to the Government of Canada, a few industry stakeholders suggested that the costs for implementation have not been fully accounted for.

Health Canada's response

The cost estimate was based on industry survey data and only direct costs and benefits can be included in the CBA statement. The opportunity cost lost from resources having to be used in order to comply with the regulations as well as indirect costs, including loss of market share and reformulation costs are described but not quantified in the CBA statement.

The number of SKUs that would be impacted by the proposal was based on information provided by the Food Processing Industry Roundtable report in combination with information provided by stakeholders and the Department's own estimates. For *Canada Gazette*, Part I, it was estimated that 47% of products with an NFt would be required to include an FOP nutrition symbol. Additional analysis conducted using Health Canada's own estimates, led to an increase in the number of prepackaged products anticipated to be impacted. However, this value was later revised to approximately 57.5% following policy changes relating to the expansion of certain exemptions.

Health Canada recognizes the current economic conditions that industry is facing (i.e., the COVID-19 pandemic), and has made the necessary adjustments in response to those concerns. Since cost estimates were provided in 2017, Health Canada has adjusted the range of costs per SKU to account for inflation to 2021 constant dollars and the transition period of three and a half years, increasing the range of costs for a black and

white nutrition symbol from $10,784-$18,525 (2017 CAD) to $13,473-$23,146 (2021 CAD). In addition, the CBA now assumes the higher-bound cost estimate provided by industry of $23,146/SKU. In the current context, moving away from applying a weighted-average approach best represents the current volatility of the food and beverage industry in Canada. The list of cost considerations included in the CBA recognizes the steps involved with creating new labels. Although it does not quantify the cost of upgrading retail scales per store with respect to FOP labelling, the CBA incorporates costs of designing and producing the physical label in the total quantified costs. In response to comments received on reformulation costs, Health Canada considers the primary quantified cost of the regulations to be the one-time compliance cost to conduct labelling changes to incorporate the FOP nutrition symbol. Reformulation is treated as an indirect cost because it is one possible adjustment that manufacturers may make in response to the regulations; however, the regulations do not require manufacturers to reformulate.

Health Canada now includes more information regarding the incremental costs to the Government of Canada including the direct cost of implementation as well as ongoing compliance and enforcement activities.

Comments about benefits to Canadians

Industry stakeholders disagreed with the methodology used to measure the direct benefits of the proposal pre-published in the *Canada Gazette*, Part I, which included an assessment of the reduced burden on health care costs. It was indicated by these stakeholders that there were too many factors that impact the CBAs assumptions (e.g., environmental factors and genetic makeup), and health care savings should not be directly linked to food labelling.

Following the March-April 2022 consultation, a few industry stakeholders questioned the validity of applying the WTP model in estimating the benefits to consumers, claiming that it is not valid in the context of food and does not meet Treasury Board Secretariat requirements. Industry also raised that the cost of conducting a label change may be passed on to consumers.

Health Canada's response

The CBA now assesses reductions in disease due to improved nutrition as indirect benefits and any downstream health care spending savings qualitatively. The direct benefit of these regulations is now presented as the value that households place, in terms of WTP, for the added information that FOP labelling provides. According to Treasury Board Secretariat *Canadian Cost-Benefit Analysis Guide*, the WTP model is one way to measure the value of a particular attribute of the total economic value of a good, and applies to both non-market outcomes and market goods, which includes food and beverage products. This approach mirrors the United States Food and Drug Administration's Impact Analysis in support of its Nutrition Labelling Final Rule of 2016, which in turn is based on Jason Abaluck's paper titled *What Would We Eat if We Knew More: The Implications of a Large-Scale Change in Nutrition Labeling*.

With respect to potentially increasing prices for Canadians, implementing FOP labelling is not expected to increase prices for consumers. Following the implementation of FOP labelling in Chile, data indicated that consumer prices were not affected by the cost of FOP labelling requirements. [27, 28] This analysis is outlined in more detail below, under the Regulatory Analysis section.

VIII. Comments regarding amendments to the 2016 nutrition labelling regulations

In the *Canada Gazette*, Part I, the FOP labelling regulations proposed an amendment to the transition period of the 2016 nutrition labelling regulations, which was set to end on December 14, 2021, to align the two packages. Due to challenges caused by the COVID-19 pandemic the food industry asked for more time to meet the new requirements set out in the latter regulations.

Health Canada's response

Stakeholders were notified in February 2021 that while the end of the transition period for the 2016 nutrition labelling regulations will remain December 14, 2021, flexibility would be provided to support the food industry. In the first year (until December 14, 2022), the Canadian Food Inspection Agency will focus its efforts on education and compliance promotion. As of December 15, 2022, the Canadian Food Inspection Agency will verify compliance and apply enforcement discretion in cases of non-compliance when regulated parties have a detailed plan that shows how they intend to comply at the earliest possible time, and no later than December 14, 2023. The Canadian Food Inspection Agency guidance will provide further information.

Outcome: *Canada Gazette*, Part I proposal amended. Health Canada has removed the amendments to the transition period of the 2016 nutrition labelling regulations from the FOP labelling regulations, as these are now in force.

IX. Comments related to the Food Labelling Coordination policy

As part of the Government of Canada's commitment in the *Agri-food and Aquaculture Regulatory Review Roadmap* (June 2019), Health Canada and CFIA conducted a 60-day consultation on a joint policy statement that proposed an interdepartmental process to establish fixed compliance dates for food labelling requirements at a two-year interval, beginning on January 1, 2026. The policy would apply to regulatory amendments enacted under the *Food and Drugs Act* or the *Safe Food for Canadians Act* that mandate a food label change.

A total of 32 stakeholders provided comments on the draft policy with respect to the overall approach, enforcement, exceptions, ease of knowing future labelling changes, intervals between compliance dates, transition periods for labelling regulations and scope. A summary of responses was published online.

Health Canada's response

During industry stakeholder meetings in December 2020 and July 2021, the Department and Canadian Food Inspection Agency communicated that the FOP labelling regulations would align with the predictable compliance dates.

Outcome: *Canada Gazette*, Part I proposal amended. The Food Labelling Coordination policy came into effect on August 5, 2021, and the transition period of the FOP labelling regulations was amended to align with the first proposed compliance date of January 1, 2026.

X. Comments related to interim measures for vitamin D

The 2016 nutrition labelling regulations provided for an increase in the DV for vitamin D to account for updated dietary intake recommendations. Industry must use the higher DV as of December 2021, but this would result in a change to the "% DV" declared on the NFt and impact the ability of some milks to maintain the "excellent source" claim. [29]

In the spirit of bringing flexibility to industry stakeholders and aligning with the 2016 nutrition labelling regulations, on July 22, 2021, a Notice of Intent was published online indicating the Minister of Health's intention to publish a Marketing Authorization to permit increased vitamin D amounts in cow's milk, goat's milk and margarine. The Marketing Authorization would allow manufacturers who had not already updated their product labels to transition to the new vitamin D amounts and the new DV simultaneously, avoiding multiple label changes and minimizing costs. The notice was disseminated via email to over 5,300 industry and health stakeholders, none of whom provided feedback.

Health Canada's response

In order to permit manufacturers to voluntarily increase vitamin D levels in cow's milk, goat's milk and margarine, the *Marketing Authorization for Vitamin D in Milk, Goat's Milk and Margarine* [30] came into force on December 29, 2021 and was published in the *Canada Gazette*, Part II on January 19, 2022.

This is an interim measure until the vitamin D amendments are made to the FDR as part of this package.

Outcome: The *Canada Gazette*, Part I proposal for vitamin D retained. The Marketing Authorization will be repealed after the vitamin D requirements in these regulations come into force.

Modern treaty obligations and Indigenous engagement and consultation

The FOP labelling regulations are for all Canadians. Problems related to poor diet quality are particularly prevalent among Canadians including Indigenous peoples and racialized communities, and those experiencing social and economic disadvantage (as determined by income and education levels). The Public Health Agency of Canada report *Key Health Inequities in Canada* indicates this is due to complex socio-economic and food environment factors, such as food insecurity, poor access and availability of healthy food options and more culturally-appropriate food choices (e.g., in remote and Northern areas), as well as lower prices/heavy promotion of highly processed foods. This has resulted in an unequal burden of ill health among those sub-populations. In addition, the prevalence of diabetes is higher for First Nations adults living off reserve and for Métis adults compared to non-Indigenous peoples, and Indigenous women suffer from type-2 diabetes at a higher rate than that of the non-Indigenous Canadians. [31] With increased access to packaged foods in remote and Northern areas, FOP labelling will allow Indigenous Peoples to quickly and easily identify foods that are high in nutrients of concern enabling them to make more informed food choices.

During pre-consultation, some vitamin D experts expressed that margarine is a useful vehicle for reaching certain subpopulations, such as Indigenous peoples, who are particularly vulnerable to vitamin D deficiency and inadequacy.

It is anticipated that these amendments will not have an impact on the Government's modern treaty obligations.

Instrument choice

I. FOP nutrition labelling

FOP nutrition labelling refers to the use of symbols and nutrient thresholds to indicate on the front of food packaging that a food has certain nutritional characteristics. Several systems exist: some simply indicate the number of calories or the amount of one or more nutrients in a food, while others provide cues that a food is high or low in a nutrient or that a food has a certain rating based on its nutrient profile. Some systems are voluntary whereas others are mandatory.

Option 1: Status quo (voluntary)

Many Canadians use the existing nutrition information on food packages to make informed choices when selecting foods at point of purchase, either to maintain good health or to help manage diet-related chronic diseases. Proprietary (i.e., manufacturer or non-profit owned) FOP labelling systems, using different criteria and symbols, are widespread in the Canadian marketplace. One study found FOP systems on 20% of packaged foods between March 2010 and April 2011. [32] Common examples of systems used on food packages include Walmart's Great for You icon and the Heart and Stroke Foundation's Health Check program (now discontinued). Shelf-tag systems can also be considered FOP nutrition labelling systems; Smiles in Metro stores and Guiding Stars previously in Loblaws stores are examples of shelf-tag systems.

Studies indicate that many people still find the information too complex or they are too limited either in time or motivation to consult the information. Canadians would not have as much information if the status quo were maintained, nor would information be as accessible to them

to inform choices about their consumption of saturated fat, sugars and sodium.

Stakeholder feedback received during consultations also indicated that the status quo is not sufficient to provide Canadians with the information they need to help them make more informed food choices in order to help reduce risks to their health. During Health Canada's 2014 consultations on improving nutrition information on food labels, consumers and health stakeholders asked for simple, consistent and credible information on the front of packages. Some health stakeholders called for the Government of Canada to implement one national system to reduce the number of competing FOP systems in Canada or, at a minimum, to develop a common set of criteria for all systems. Additionally, between October 2014 and June 2015, the Standing Senate Committee on Social Affairs, Science and Technology heard testimonies from a broad range of stakeholders on the increasing incidence of obesity in Canada. In its final report, *Obesity in Canada: A Whole-of-Society Approach for a Healthier Canada*, the Senate Committee recommended that the Government of Canada undertake a regulatory approach to mandate the use of FOP labelling on prepackaged products displaying an NFt. Feedback on the proposed updates to nutrition labelling requirements, pre-published in the *Canada Gazette,* Part I, in June 2015, indicated a strong interest from health stakeholders and consumers for an FOP system for food labels.

Option 2: Regulatory approach (chosen option)

At the international level, the National Academies of Sciences, Engineering, and Medicine, which was commissioned in 2011 by the United States Congress to develop guidance on FOP labelling, supports the use of such labelling [33] and recommends the use of a single, mandatory, standardized FOP system that can be easily understood by most consumers to simplify and clarify nutrition information. Similarly, the World Health Organization and the Pan American Health Organization recommends interpretive FOP labelling as part of a comprehensive approach to promote healthy diets and reduce obesity and diet-related chronic diseases. [34], [35], [12]

The joint World Health Organization and Food and Agriculture Organization international food standard setting body, the Codex Alimentarius, through its Codex Committee on Food Labelling, supports the need to assist consumers in making healthier choices through the use of simplified, science-based nutrition information on the front of food packages. At its 43rd annual meeting in May 2016, the Codex Committee on Food Labelling unanimously endorsed a proposal [36] to consider the role of Codex in providing guidance on FOP nutrition labelling to governments and industry. The Committee further encouraged member countries that were planning to develop and implement FOP labelling systems to proceed with their work. [37] At the 46th session of Committee, guidelines on front-of-package nutrition labelling were adopted by Codex Alimentarius Commission and are included as an Annex to the Guidelines on Nutrition Labelling (CXG 2-1985). [38], [39]

In Canada, considerable interest in FOP nutrition labelling was expressed by a broad range of stakeholders (consumers, parents, health-focused organizations, etc.) during Health Canada's consultations on nutrition labelling and hearings of the Standing Senate Committee on Social Affairs, Science and Technology in 2014 and 2015.

Mandatory FOP labelling that highlights when a food is high in nutrients of public health concern (saturated fat, sugars and sodium) is the most appropriate enhancement to current food labels to help Canadians make more informed food choices to help reduce their risk of chronic diseases. A national, consistent and credible system would increase consumers' trust and confidence in FOP information and provide them with reliable, quick and easy guidance that they can rely on to make informed decisions about foods in relation to nutrients of concern. Moreover, a national system would maintain a level playing field for prepackaged products, whether domestically produced or imported. Additionally, this FOP approach is a measure targeted at the public health purposes underlying the *Food and Drugs Act*.

There are many FOP systems in Canada and around the world. The Department conducted an options analysis prior to selecting a mandatory approach. The following five approaches were assessed: the fact-based approach, the traffic light approach, the National Academies of Sciences, Engineering, and Medicine's approach, the summary approach, and the "high in" approach. Health Canada reviewed each option based on the policy objectives, available scientific evidence and consistency with international guidance and recommendations.

(a) Fact-based approach

Fact-based systems such as the voluntary 'Facts Up Front' in the United States or Guideline Daily Amounts in the European Union are typically developed and used by the food industry. These systems use basic icons or "thumbnails" that provide numeric amounts and %DV, where applicable, from the NFt on calories and on a number of nutrients, as set out for the particular system, usually a combination of negative and positive nutrients. This FOP approach is generally well-received by consumers, especially those who understand the NFt, because it makes familiar nutrition information more accessible by displaying it on the front of the package. Research consistently shows that among all of the options, fact-based approaches are the most difficult for consumers to understand and are less effective than other systems in helping consumers identify and make healthier choices, particularly when comparing multiple products, as in a grocery store. Therefore, a fact-based approach does not reduce the cognitive burden of interpreting nutrition information compared to the NFt, and does not align with recommendations from authoritative health organizations, as they are neither simple nor interpretive. As such, the approach does not meet the stated objective of these regulations because it merely repeats information already present in the NFt without providing any interpretive value related to the nutrients of public health concern, and therefore this option was not chosen.

In addition, a 'Facts Up Front' approach would be costly to implement, as it would be required on all prepackaged food products that are required to carry an NFt on their labels, not just limited to products with higher level of nutrients of concern. It is estimated that requiring all SKUs with an NFt to incorporate a black and white 'Facts Up Front' FOP labelling would cost industry more than $1.8 billion to implement.

(b) Traffic light approach

A traffic light approach provides a colour-coded rating for high (red), medium (yellow/amber) or low (green). Multiple traffic lights that provide a rating for each nutrient of concern are the most common and studied form of this approach. Often, the Guideline Daily Amounts are included in the ratings to provide quantitative information about the nutrients. Public opinion research commissioned by industry stakeholders in 2017 showed that this hybrid approach was favoured by a representative sample of the Canadian population. However, this research had several limitations; for example, the symbols were not shown on mock food packages, and participants were not asked to perform any task to assess understanding and use, and therefore, potential effectiveness. Experimental research shows that traffic light systems are easier to understand and use than fact-based approaches alone because they add interpretive value through the use of colours. However, research also shows that consumers find it difficult to use traffic light labels and compare products when there is a combination of different colour ratings; to alleviate the cognitive burden, consumers focus on avoiding foods with red, or "high in," ratings. Furthermore, research that assessed the impact of multiple traffic lights FOP approach on consumer purchasing behaviour suggest limited efficacy. This could be due in part to the "health halo" effect created by the presence of the green colour on foods that are not consistent with dietary guidance. For example, a sugary drink could display two green ratings (saturated fat and sodium) and one red rating (sugars).

In light of the evidence, Health Canada concluded that such an approach would not align well with the stated objective of the regulations, and therefore this option was not chosen.

A traffic light approach would be the most costly for industry to implement as it both includes colours and would impact all prepackaged products carrying an NFt on their label. According to industry estimates, the costs to include multiple colours on a label increases the cost per SKU. Requiring all SKUs with an NFt to incorporate traffic light FOP labelling would cost industry more than $2.3 billion to implement.

(c) National Academies of Sciences, Engineering, and Medicine's approach

The United States Government funded the National Academies of Sciences, Engineering, and Medicine to provide recommendations on an FOP system. The approach, published in 2012, emerged following an extensive review of the literature on food labelling, packaging, marketing and visual design. It involves indicating the number of calories along with stars or checkmarks on foods that meet acceptable (e.g., "low in") criteria for nutrients of public health concern (in this case, saturated and *trans* fats, sodium and added sugars). Nutrients of concern are not specified in the symbol, which could make it difficult for consumers to interpret whether the stars / checkmarks represent specific nutrients or a global assessment of the relative healthfulness of a product. A limitation of this approach is that it has not been implemented anywhere, so it is unclear how it would perform under real conditions. In addition, due to the use of stars or checkmarks, the National Academies of Sciences, Engineering, and Medicine symbol could be perceived as a government endorsement of foods that meet one or more nutrient criteria, which is not the objective of these regulations. For these reasons, this option was not chosen.

As all 80,000 prepackaged food products that are required to carry an NFt on their labels would be required to include information regarding calorie count and an indicator (i.e., stars or checkmarks) on the healthfulness of the product, implementing the National Academies of Sciences, Engineering, and Medicine approach would be as costly as the 'Facts up Front' approach if printing in black and white. The National Academies of Sciences, Engineering, and Medicine approach would cost industry more than $1.8 billion to implement.

(d) Summary approach

Summary approaches include both nutrients to limit and nutrients to encourage, and often use complex algorithms to rate the overall nutritional value of a food. Examples of summary systems include Australia and New Zealand's Health Star Rating, France's Nutriscore, and Nordic countries' Keyhole. Many of the existing summary approaches currently used in Canada are based on proprietary algorithms from the private sector that extend to characteristics beyond the nutrient profile of the food. Like other interpretive FOP labelling systems, summary approaches improve consumers' understanding and use of nutrition information. In studies of foods labelled green, yellow or red, sales of foods with red (unhealthy) labels decreased, whereas sales of foods with green (healthy) labels increased. Summary approaches were not chosen because they do not explicitly provide interpretive information in relation to levels of saturated fat, sugars or sodium that contribute to excess intake. In addition, some summary approaches classify foods as healthy or unhealthy, which is not the intent of these regulations.

The summary approach is more costly than a "high-in approach," as it would also be required on all prepackaged food products that are required to carry an NFt on their labels, not just products with higher level of nutrients of concern. If printed in black and white, this would cost industry more than $1.8 billion to implement and more than $2.3 billion if required in colour.

(e) "High in" approach (chosen approach)

A "high in" approach is a nutrient-specific FOP system that is triggered only when foods meet or exceed predetermined thresholds for nutrients deemed to be of public health concern. In comparative research that included the "high in" approach, most studies show that it is more effective than other FOP systems in helping consumers quickly and easily identify foods to limit in relation to their content of nutrients of concern, which is the first critical step to influence consumer choice. [40, 41, 42] Findings from Health Canada's consumer research study in a grocery store setting found that a "high in" nutrition symbol helped consumers with varying levels of health literacy make healthier food choices and identify foods high in nutrients of public health concern. [21] When asked to choose a food for their household, 50% more participants selected a healthier product when exposed to "high in" symbols, as compared to current labelling. Participants exposed to FOP labelling consistently selected

healthier products across a variety of shopping tasks.

Data obtained from the evaluation of the *Law of Food Labelling and Advertising* in Chile provide further evidence that the "high in" approach is effective. Six months after the implementation of the law, of the 44% of consumers who reported using the symbols, 92% reported that the presence of FOP symbols influenced their purchasing decision and 26% indicated that they stopped consuming certain products. Purchase of sugary breakfast cereals dropped by 14%. In terms of reformulation, one year after implementation, the proportion of prepackaged products "high in" sugars, saturated fats or sodium decreased from 51% to 44%. [43] The proportion of beverages, milks and milk-based drinks, breakfast cereals, sweet baked products, and sweet and savoury spreads with a "high in sugars" symbol decreased from 80% to 60%. The proportion of savory spreads, cheeses, ready-to-eat meals, soups, and sausages with a "high in sodium" symbol decreased from 74% to 27%. The combination of reformulation and labelling decreased consumption of sugar-sweetened beverages by 24% [44], while breakfast cereals experienced a reduction of 26% in a similar period. [45]

The "high in" FOP labelling approach only impacts those prepackaged food and beverage products that meet or exceed predetermined thresholds for nutrients deemed to be of public health concern. Using this approach, only a percentage of SKUs with an NFt would be subject to FOP labelling. As presented in the Regulatory Analysis below, this is the least costly in comparison to all other labelling approaches considered. These findings support Health Canada's decision to select a "high in" FOP labelling approach to achieve the stated objective of these regulations. As an important part of a comprehensive suite of policies, the "high in" approach complements existing labelling measures to enable Canadians to make choices that help them reduce their intakes of nutrients of public health concern associated with increased risks of chronic disease.

Option 3: Voluntary government-led approach

Voluntary implementation of a government-led approach would not achieve the objectives of these regulations. With a voluntary approach, manufacturers may choose not to display a symbol, particularly on foods with an unfavourable nutrient profile. An evaluation of the Health Star Rating system in Australia indicated that adoption was slow and poor with only 28% of eligible products on the market displaying the symbol in 2017, three years after implementation. Industry may implement a voluntary system if there is a benefit to their products, brand or company; however, when there is no such benefit there is little incentive to carry the costs associated with a label change. In Australia, most products that display the symbol have higher ratings; very few display low ratings. [46] If an FOP approach is not applied to all foods, consumers have no way of knowing if a product does not display the FOP nutrition symbol because the manufacturer is not participating in the program or because the symbol makes the food look like a poor choice. Therefore, voluntary implementation would not consistently provide quick and easy guidance to support informed choices. It would also not encourage the availability of foods that are lower in saturated fat, sugars and sodium.

II. Nutrient content claims and other nutrition-related statements

Option 1: Status quo

The status quo is not viewed as a viable option as it would not prohibit the use of certain nutrient content claims that are in relation to a nutrient that appears in the nutrition symbol – a situation that could reduce the effectiveness of the nutrition symbol. In addition, the size of "reduced in" claims would not be restricted under the status quo option. "Reduced in" claims are used by industry to indicate to the consumer that a product has been processed, formulated, reformulated or otherwise modified to contain less of the nutrient compared to the regular version of the food (i.e., the similar reference food). If these claims are too large, they could reduce the effectiveness of the nutrition symbol. Furthermore, the status quo would not allow for changes to the criteria for making certain nutrient content claims (e.g., "no added sugars") and other nutrition-related statements (e.g., representations that the food is for use in a sodium-restricted diet) that are necessary for consistency with the nutrition symbol requirements. Also, under the status quo option, amendments to permitted nutrient claims set out in the table following section B.01.513 of the FDR could only be made through the Governor in Council process.

Option 2: Regulatory approach (chosen option)

Currently, manufacturers may voluntarily choose to use nutrient content claims on their food labels. The conditions of use for nutrient content claims and other nutrition-related statements are prescribed in the FDR. Given that the use of such claims for a nutrient that appears in the FOP nutrition symbol could confuse consumers as to the meaning of the nutrition symbol and thereby undermine the effectiveness of the symbol, amendments to the FDR are needed in order to prohibit the use of nutrient content claims on the front of food packages when they are about a nutrient appearing in the symbol. An exception is required, however, for "reduced in" claims (items 20, 33 and 38 in the *Table of Permitted Nutrient Content Statements and Claims*) because such claims are used to indicate to the consumer that a product has been processed, formulated, reformulated or otherwise modified to contain less of the nutrient compared to the regular version of the food (i.e., the similar reference food). For example, a manufacturer's chicken noodle soup with 25% less sodium than the regular version of the same manufacturer's chicken noodle soup may carry a "reduced in sodium" nutrient content claim even if it displays a "high in sodium" nutrition symbol. To help protect the integrity of the nutrition symbol when a nutrient content claim or other nutrition-related statement does appear on the front of food packages, restrictions on the size of such claims and statements are prescribed in these regulations.

Repealing the table of permitted nutrient content statements and claims following section B.01.513 and incorporating by reference into the FDR the *Table of Permitted Nutrient Content Statements and Claims* provides Health Canada with greater flexibility and allows greater efficiency in the

future to update the contents of the table following the evaluation of scientific information and the decision to allow a claim. Doing so is consistent with Health Canada's efforts in recent years to use regulatory tools, such as incorporation by reference, to improve the regulatory frameworks for food additives, food contaminants and adulterants, food reference amounts and NFt formats. Additionally, updating certain other provisions for other nutrition-related statements at the same time allows for some needed updates to current requirements (e.g., updating the age categories in certain provisions that refer to foods intended solely for children under two years of age, to reflect the new dietary reference intakes published by the National Academies of Sciences, Engineering, and Medicine and NFt age groups).

III. Vitamin D fortification

Option 1: Status quo

In 2011, the National Academies of Sciences, Engineering, and Medicine published increased intake recommendations for vitamin D. According to the updated recommendations, there is a high prevalence of inadequate vitamin D intakes among Canadians. Blood levels of vitamin D, which reflect all sources including sun exposure, show that approximately 20% of Canadians are at risk of inadequacy and about 8% are at risk of being deficient. There is insufficient vitamin D in the food supply to address inadequate levels of vitamin D intake among Canadians. Since vitamin D deficiency can lead to rickets in children and osteomalacia in adults, there is a strong rationale to address this problem.

Option 2: Modifying dietary guidance

Health Canada released the updated Canada's Food Guide in January 2019. Canada's Food Guide continues to include foods that provide vitamin D. The updated Canada's Food Guide has changed the way it communicates dietary guidance, using a less prescriptive approach that no longer recommends specific numbers or sizes of servings. Including specific recommendations for a small number of foods that provide vitamin D would be incompatible with this new way of communicating guidance.

Option 3: Regulatory approach (chosen option)

Changes to the amounts of vitamin D required in milks and margarine will result in large increases to Canadians' vitamin D intakes, since these foods are the major contributors of vitamin D in the diet. Increasing the mandatory amount of vitamin D in cow's milk and margarine and the permitted amount in goat's milk acknowledges the important contribution of these foods to vitamin D intakes. These changes will increase vitamin D in the Canadian food supply. This will bring Health Canada closer to attaining its public health goal: to help promote adequate bone health in the population with a particular focus on helping to prevent or minimize risk of vitamin D deficiency without incurring risk of excessive intakes.

IV. FDR amendments related to the prohibition of PHOs

Amendments related to PHOs are required so that the FDR is consistent with the recent changes that were made to Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods*, which have the effect of prohibiting the sale of foods containing PHOs. Provisions of the FDR that refer to PHOs need to be amended to align with the ban on PHOs.

V. Labelling of foods that contain certain high-intensity sweeteners

Option 1: Status quo

Maintaining the status quo with respect to the PDP and quantitative labelling requirements would not address the issues identified with the current labelling framework.

Option 2: Regulatory approach (chosen option)

In order to bring greater consistency to the labelling of foods containing approved high-intensity sweeteners, the only viable option is to repeal the PDP and quantitative labelling provisions in question, as described herein.

Regulatory analysis

Benefits and costs

The full cost-benefit analysis (CBA) report is available upon request.

An analysis was conducted to measure the impacts of requiring an FOP nutrition symbol on prepackaged foods to help improve the health of Canadians by making the nutritional value of foods more easily understood, and changes associated with the prescribed amounts of vitamin D in cow's milk, goat's milk and margarine. Updates to regulations relating to PHOs are necessary for aligning the regulations with the ban on PHOs that came into effect in September 2018, but are not costed in this CBA as they do not impose any incremental impacts on stakeholders.

Various forms of consultations took place with stakeholders throughout the development of the CBA, including the above-mentioned series of consultations following the *Canada Gazette*, Part I pre-publication into April 2022. The consultation process began in February 2017, with the distribution of a CBA survey relating to a proposal for FOP labelling and vitamin D amounts for cow's and goat's milk and margarine. Health Canada also solicited feedback from interested Canadians on four proposed FOP nutrition symbol designs through online consultation and received close to 16,000 submissions. Following *Canada Gazette*, Part I, approximately 220 submissions were received from a range of stakeholders on the original proposal. An additional series of correspondence between Health Canada and industry stakeholder groups has

helped form the bulk of the costing input for the CBA as Health Canada has since received over 7,600 letters through writing campaigns, which have been used in support of the analysis. Six industry stakeholders provided additional comments on the CBA for consideration through the March-April 2022 consultation session.

Other sources of information used to formulate the CBA include analyses from other regulatory agencies, both within and outside of Canada, academics, non-governmental organizations, health stakeholders, and affected industry associations and firms. This includes the 2017 Agriculture and Agri-Food Canada Report "Impact Assessment of Food Labelling Regulatory Changes on the Food Processing Industry" [47] and the 2017 Food Processing Industry Roundtable "Response to the Labelling Changes Proposed by Health Canada and the Canadian Food Inspection Agency." [48]

Baseline versus Regulatory Scenario

An important first step in developing a CBA is establishing a baseline scenario against which options may be measured. For this analysis, the baseline is a scenario where the NFt exists and provides Canadian consumers with nutritional information on the products they purchase. Many Canadians would continue to use the existing nutritional information on food packages to make informed choices when selecting foods at point of purchase, either to maintain good health or to help manage diet-related noncommunicable diseases. However, many Canadians would still find the information too complex or they are too limited in either time or motivation to consult the NFt. In the baseline, Canadians would not have as much accessible information to make choices about their consumption of saturated fat, sugars and sodium. In addition, there would be insufficient vitamin D in the food supply to address inadequate vitamin D intakes among Canadians. Lastly, the presence of sweeteners in a food would be declared in the list of ingredients, with four high-intensity sweeteners [49] subject to a number of additional mandatory labelling requirements as mentioned above. The baseline is then compared with the regulatory scenario.

Under the regulatory scenario, food manufacturers must include an FOP nutrition symbol on prepackaged products that meet or exceed the established threshold for the nutrients of concern (saturated fat, sugars and sodium). Food manufacturers of cow's milk and margarine will be required to increase vitamin D amounts, and manufacturers of goat's milk that is voluntarily fortified with vitamin D will be required to increase vitamin D amounts. This will help increase Canadians' vitamin D intakes, since these foods are major contributors to vitamin D in the diet. In addition to this, the PDP labelling and quantitative declaration for aspartame, sucralose, acesulfame-potassium and neotame will no longer be a requirement.

Key Assumptions

- All costs and benefits are presented in 2021 dollars;
- A discount rate of 7% is used in the analysis;
- The analysis evaluates the costs and benefits over a 15-year period, thus the study period is presented from 2022 to 2036;
- Industry is assumed to be competitive, therefore one-time costs associated with changing labels are assumed to be absorbed by Canadian businesses. This is supported by elasticity of demand research. For example, price elasticity in Canada for food and beverage product categories is high (i.e., elasticity of -1.03 for prepackaged foods and -1.14 for non-alcoholic beverages). This suggests that Canadians have ample substitutes within product categories, thus one-time costs for labelling changes are unlikely to be passed on as direct price increases to consumers [50] [51];
- Industry is required to comply with the amendments ending on January 1, 2026, as outlined in the Food Labelling Coordination policy as the next appropriate compliance date, the analysis assumes a three and a half year transition period;
- It is assumed that manufacturers in the food industry will most likely opt to wait until the final year of the three and a half year transition period in order to sell existing product stock and exhaust older labels to reduce product and label waste; and
- A fundamental tool of applied welfare economics is the WTP model used to calculate the amount that an individual is willing to pay for an incremental unit of a good or service to measure economic benefit. Many government institutions, private corporations and academic organizations use this economic model. In this CBA, the WTP is the amount of money an individual would be willing to pay to acquire information easily on nutrients of concern in order to improve their health or avoid disease. [52]

Industry Background

There are 31,154 food and beverage industry firms operating in Canada, with an estimated total of 140,000 prepackaged products. [53] Of those 140,000 prepackaged products, roughly 80,000 require an NFt. The regulations require that those prepackaged products with an NFt that meet or exceed pre-determined thresholds for saturated fat, sugars and sodium, will also have to carry an FOP nutrition symbol; it is estimated that 57.5% of those 80,000 prepackaged food products requiring an NFt, or 46,023 products, would also require an FOP nutrition symbol and, consequently, a label redesign. As a result, the regulations will affect many firms. The food industry is the largest manufacturing employer in Canada, employing approximately 290,000 people, and is the second largest manufacturing industry in Canada with sales of $117.8 billion in 2019; [54] the food manufacturing industry adds approximately $34.8 billion to the Canadian economy annually. [55]

As is the case across the Canadian economy, the food supply chain has been negatively impacted by the COVID-19 pandemic and industry has had to make adjustments and incur additional costs in response to such constraints. According to a recent member survey conducted by Food,

Health & Consumer Products of Canada, 75% of members reported that moderate to severe labour shortages impacted their ability to supply products. [56], [57] Members reported a 15% increase in production costs over 2020, which impacted their ability to invest in capital and innovation. Members reported a 15-50% increase in the cost of paper pulp, used in cardboard packaging, and a 43% increase in the cost of key plastic packaging components. One industry stakeholder suggested that overall costs have increased by 17%; labour costs for food processing has increased by 16%. Food transportation costs have also increased in 2021, in part due to international oil prices recently hitting a 7-year high. [58]

The food industry has demonstrated strong adaptability and resilience in facing recent challenges. According to quarterly financial indicator data from Statistics Canada, the operating profit margins in the food and beverage industry quickly rebounded to 5.5% by the end of 2020, and have remained above 4.3%. [59] Manufacturers are operating at 79% capacity, which is nearing pre-pandemic levels. [60] Similar to the job vacancies for all of industry (5.4%), the job vacancy in food manufacturing is 6.0%, up from pre-pandemic levels (3.5%). [61] The number of food manufacturers have increased, surpassing pre-pandemic numbers. From February 2020 to December 2021, the real gross domestic product of the food manufacturing industry grew by 5.0%. [62] In comparison, the Canadian economy expanded 0.4% over the same period. [63]

Consumer Preferences

Studies carried out in the mid-1990s found that 90% of Canadians considered nutrition to be very important in their choice of foods, and 71% of Canadians said that the NFt influenced their buying decisions. [64] Despite widespread use and public education campaigns, consumers struggle to understand and apply the nutrition information displayed in the NFt. [65], [66] Furthermore, despite high levels of self-reported understanding, many Canadians demonstrate significantly lower levels of comprehension in "functional" tasks in which they are required to apply the nutrient information in the NFt. For example, a study found that approximately one third of Canadian adults could not comprehend basic information in the NFt, such as identifying the calorie content and the %DV of nutrients. [67]

The effects of the COVID-19 pandemic on Canadians have shifted how consumers purchase foods, increasing their desire for reading labels to better understand ingredients and which foods they should avoid. [68] Approximately 70% of sampled Canadians reported "health" as the most important factor when considering which food items to purchase, ahead of the economy (52.7%) and the environment (28.3%). [68] These changes in consumer behaviour signals an improvement in overall food literacy, but many consumers are still struggling with healthy eating in the midst of the COVID-19 pandemic.

Consumers with lower levels of literacy find the quantitative information difficult to understand and rely to a greater extent on symbols and simple cues. There are substantial and persistent disparities in consumer understanding and use of the NFt information. Studies have shown that vulnerable populations, such as those with lower socioeconomic status or with marginal health literacy, have greater challenges in understanding and using the NFt. [69] A series of focus groups conducted in Canada found that participants with marginal health literacy were more likely than those with adequate health literacy to choose "healthier" foods based on FOP cues compared to the NFt and list of ingredients. [70]

Approximately 49% [71] of Canadians reported understanding the information in the NFt; increasing the consumer comprehension of the product label and content by including an FOP nutrition symbol could improve these results. Studies suggest that when consumers value present benefits over future costs but are faced with repeated choices within a short time span (such as choice of food to purchase), large and costly mistakes can arise when each decision made is a suboptimal decision. [72]

Direct Costs

Costs to Industry

As of 2017, industry stakeholders reported that there were approximately 140,000 SKUs prepackaged foods in Canada with a label, of which only 80,000 required an NFt, not all of which will require a nutrition symbol or vitamin D fortification. According to food label data collected by Mintel (Global Market Research & Market Insight), more than 7,800 new products with NFts may have entered the market since 2017. [73] However, this data does not account for products that have been discontinued within the same span of time. Since Mintel's Global New Products Database is not representative of the entire food supply and products are subjectively assessed as being new entrants, Health Canada cannot confidently state if there are currently more or less than the 80,000 SKUs of prepackaged food products assumed to carry an NFt. For *Canada Gazette*, Part I, it was assumed, based upon Health Canada's own estimates and consultation submissions, that 47% of all prepackaged products with an NFt, equivalent to approximately 37,600 SKUs, would require a nutrition symbol. [74] Since *Canada Gazette*, Part I, additional analysis conducted using Health Canada's own estimates, led to an increase in the number of prepackaged products anticipated to be impacted.

Following policy changes relating to the expansion of certain exemptions, it is now estimated that approximately 57.5% of products that have an NFt, or 46,023 products, have one or more nutrients of concern at or above the established thresholds. [74] It is assumed that the average number of SKUs represents the average number of products, creating a one-to-one ratio between product and SKU count.

The cost estimates, which are presented as a cost per SKU, include the following factors that were identified by industry stakeholder organizations as costs to comply with the regulations:

- *Waste costs associated with disposing of old labels and potentially old product;*
- *Design costs, whether carried out in-house or contracted out externally;*

- *Printing and label plates;*
- *Use of colour for the label;*
- *Labour and new administrative compliance costs;*
- *Coming into force and transition period; and*
- *Timing of the regulations relative to other regulations proposed or currently in force*

Costing estimates were provided by industry stakeholder organizations, reports from other jurisdictions where an FOP label has been implemented, industry reports and case studies from an extensive literature review. Canadian industry groups were able to provide estimates for the following sectors:

- *Non-alcoholic beverages and large manufacturers of processed foods;*
- *Eggs, poultry and meat processing;*
- *Retail and grocery products that are produced in-house or private label;*
- *Dairy;*
- *Importers and exporters of food products; and*
- *Baking and milling industry.*

For *Canada Gazette*, Part I, cost estimates were based on an FOP nutrition symbol that contained colour beyond just black and white placing the cost per SKU at $23,260 (2017 CAD). Based on industry feedback that indicated their preference to use a black and white symbol in order to significantly reduce costs, the proposed regulations were amended to require a black and white nutrition symbol rather than a colour symbol. For *Canada Gazette*, Part I, cost estimates were also based on a transition period of approximately four years. Health Canada will now be aligning the end of the transition period for the FOP regulations to January 1, 2026, as outlined in the Food Labelling Coordination policy, reducing the originally proposed transition period by approximately six months. Based on industry feedback, this will result in increased costs. Industry also indicated that, due to the COVID-19 pandemic and existing constraints on the food and beverage supply chains, overall costs to conduct a label change have increased by up to 17%. Accounting for inflation and considering the current volatility of the food and beverage industry in Canada as a result of the current economic climate (e.g., the COVID-19 pandemic, labour shortages, supply chain issues, etc.), the costs to conduct a label change to include a black and white nutrition symbol could range from $13,473-$23,146 in 2021 constant dollars. The CBA now assumes the higher-bound cost of $23,146 per SKU to better reflect current conditions. Applying the higher-bound cost provided by industry represents a 19% increase in the cost of a label change. These updated values also closely align with per SKU costs provided in 2020 by the food and beverage industry in response to conducting a label change for supplemented foods (*Regulations Amending the Food and Drug Regulations (Supplemented Foods)* [75]). Stakeholders indicated their preference that the nutrition symbol be black and white because nearly all product labels already contain these colours (i.e., the NFt, list of ingredients). A number of stakeholders expressed concerns regarding any potential increase in cost associated with having to include additional colour and colour plates in order to be in compliance with the proposed regulations. A black and white FOP nutrition symbol label costing $23,146 per SKU and affecting 46,023 SKUs translates to a one-time cost of $1.07 billion or $869.54 million present value (PV) based on a transition period of three and a half years for industry to comply with the FOP labelling provisions.

With regard to label adjustments in the NFt to reflect new vitamin D amounts, there are approximately 2,000 SKUs that will be impacted by these regulations. For *Canada Gazette*, Part I, industry provided an estimated average cost per SKU (rather than a range of costs) to comply with the amended vitamin D amounts of $10,000 (2017 CAD) per SKU. Since *Canada Gazette*, Part I, industry has not suggested an increase to this cost estimate; however, accounting for inflation to 2021 constant dollars, this cost estimate has increased to $10,709 per SKU. The cost of conducting the initial changes to the vitamin D amounts, which would trigger the label change, has been deemed insignificant by industry. Thus, the one-time cost to industry to make label changes associated with the changes to vitamin D amounts is $21.42 million or $17.48 million PV based on a transition period of three and half years.

Costs for changes to the sweetener labelling requirements were determined to be negligible as the regulations are repealing certain labelling requirements for foods containing high-intensity sweeteners, and it is assumed that industry will coordinate the remaining mandatory changes with other label changes in this package.

The total direct cost to industry due to the FOP and vitamin D changes amounts to $1.09 billion or $887.02 million PV over a 15-year time period, based on a transition period of three and a half years. Table 1 below provides a sensitivity analysis to illustrate how the length of the transition period provided to industry in order to comply with the amendments is expected to influence their costs, the benefits to Canadians and consequently, the net benefit.

Costs to Government

With these amendments in place, the Canadian Food Inspection Agency will incur an annualized average cost of $867,503 or $7.90 million PV over a 15-year time period, based on a transition period of three and a half years. The Canadian Food Inspection Agency will continue to be responsible for the compliance and enforcement of prepackaged food products and inspection activities will continue to be subject to Canadian

Food Inspection Agency's existing risk-based approach. Costs will be incurred in support of implementation and the increased resources required for compliance and enforcement activities as well as training for inspectors on the assumption that there would be a one percent increase in response activities in regards to labelling complaints.

Table 1: Length of the Transition Period

Number of Years to Transition (approx.)	Total Costs (PV) [76]	Total Benefits (PV)	Total Net Benefit (PV)
3 years	$1,019,145,971	$2,328,490,557	$1,309,344,586
3.5 years	**$894,925,801**	**$2,328,490,557**	**$1,433,564,756**
4 years	$720,802,534	$2,203,028,966	$1,482,226,432
4.5 years	$604,708,917	$2,203,028,966	$1,598,320,049
5 years	$457,166,711	$2,070,376,889	$1,613,210,178

Indirect Costs

The CBA considers the primary cost of the regulations to be the one-time compliance cost to conduct labelling changes to incorporate the FOP nutrition symbol. However, a number of industry stakeholder respondents to the CBA survey identified reformulation as being a major cost consideration for implementing the FOP nutrition symbol. Therefore, reformulation is treated as an indirect cost, rather than a direct cost, because it is one possible adjustment that manufacturers may make in response to the regulations; however, the regulations do not require manufacturers to reformulate.

The effects of FOP labelling on product reformulation have been observed in Chile, which implemented a "high-in" warning symbol on products that contain nutrients of concern at a specific threshold in 2016. By reformulating products, the distribution of nutrients of concern for more food groups shifted just below the thresholds in order to avoid including an FOP nutrition symbol on the labels. [77] Requiring Canadian industry to include an FOP nutrition symbol on their packages in order to disclose certain attributes of their products will likely lead to reformulation as an alternative action, but will most likely occur for products already close to the thresholds established.

After the first year of implementation in Chile, the proportion of products required to carry the symbols was significantly reduced from 51% to 44%, suggesting that companies reformulated products. [77] Most frequent reductions were in the proportion of "high in" sugar products (beverages, milks and milk-based products, breakfast cereals, sweet baked products, and sweet and savory spreads), going from 80% to 60% of products, and "high in" sodium products (savory spreads, cheeses, ready-to-eat meals, sausages, and soups), going from 74% to 27% of products. Based on industry's responses to the CBA survey, Health Canada estimates that approximately 20% of the 46,023 affected SKUs may be reformulated to reduce at least one nutrient of concern to avoid placing an FOP nutrition symbol on their product. This is further supported by evidence presented in Chile, where after only six months following implementation, 18% of food products in general opted for reformulation. [78]

Although the Chilean study resulted in 18% of the SKUs opting for reformulation, Health Canada's analysis assumes that 20% of all SKUs, or 9,205 SKUs, will end up choosing to reformulate their products. Based on figures provided through industry consultations in 2017, the cost to reformulate can range from $75,000 and $100,000 (2017 CAD) per product line. Accounting for inflation to 2021 constant dollars and acknowledging the current economic climate affecting the food and beverage industry in Canada (e.g., the COVID-19 pandemic, labour shortages, supply chain issues, etc.), the CBA now assumes the higher-bound cost of $107,093 per product line. Thus, the total one-time cost of reformulating those products to avoid carrying an FOP nutrition symbol is estimated to be $985.75 million.

Given that overall prices of food were not impacted in Chile as a result of FOP labelling being introduced, reformulation is not expected to raise the price of food products in general. New products are introduced each year to anticipate or meet changing consumer preferences while existing products are also introduced with variations to their content. These new products may have different ongoing marginal costs than others in the same category (from using more or less expensive ingredients). While reformulation may occur in response to the introduction of FOP labelling, Health Canada cannot determine exactly how the resultant inclusion or removal of ingredients would impact the price of a new product introduced solely as a result of FOP labelling. [79] In the case of the breakfast cereal market in Chile, new products that did not carry an FOP nutrition symbol were initially introduced at a 2% price increase over existing products. The net result was a 0.15% increase in the price of cereals considered. Given the demand for healthier alternatives and the increase in options of products at various price points, general price increases were not observed. It is hypothesized that the lack of significant effects in Chile on labour market outcomes or gross margin of profits could be due to manufacturers producing a range of options within categories of both "high-in" and not-high-in substitutes (e.g., firms producing sugar-sweetened beverages and bottled water); and/or reformulation of products to avoid the "high-in" thresholds. [80]

Qualitative Costs

The following costs are identified as a result of the regulations; however, their impacts are non-quantifiable:

- The regulations could place added pressure on industry as a whole given the current economic situation (e.g., COVID-19 pandemic, labour shortages, supply chain issues, etc.)

Given the current pressures faced by industry with supply chain shortages, increased production costs, and increased food transportation costs, the regulations could pose additional pressures on industry. Food categories for which price increases are predicted (e.g., dairy, fruit and vegetables) are less impacted by FOP labelling. For example, in the dairy category, cheese that meet the %DV calcium threshold (10% per serving size or reference amount, whichever is greater, for reference amounts of 30 g or 30 mL or less, or 15% DV per serving size or reference amount, whichever is greater, for reference amounts of greater than 30 g or 30 mL) and milk will be exempt from FOP labelling, while only 36% of yogurt products are expected to require an FOP symbol on the label.

Following the implementation of FOP labelling in Chile, data indicated that consumer prices were not affected by the cost of FOP labelling requirements. [81], [79] A recent study found, that 18 months after implementation of the FOP labelling regulations, there was no noticeable effect on employment nor on real wages, when comparing food industries likely affected by regulations with those not affected. [80] While Chile observed large declines in purchases of foods with the FOP nutrition symbol over the first 36 months, employment and impacts on other economic outcomes (i.e., real wages and gross profit margins) were considered negligible. [80] To help alleviate these costs in Canada, industry will be provided with a transition period ending on January 1, 2026 to adapt to the new regulations and new packaging, while liquidating any existing inventory.

- Opportunity costs of resources being used to comply with the regulations, rather than being used for product innovation

For some stakeholders, managing label changes due to the regulations may tie up resources from their regulatory, purchasing, packaging, data compliance, quality assurance and marketing departments. Other stakeholders may need to hire consultants and/or require foreign contractors to help manage the industry-wide demand for label changes. Some manufacturers may need to move resources away from other initiatives, possibly resulting in less progress or investment made on other projects that may drive innovation. This could impact sector competitiveness between like-products as some manufacturers are able to progress on other potentially innovative projects while others are investing resources in response to the regulations.

- Loss of market share for some food industry companies due to the requirements for carrying an FOP nutrition symbol

The regulations may result in a substitution effect whereby consumers move away from products carrying an FOP nutrition symbol to those products that do not have a nutrition symbol resulting in a shift in market share. Those manufacturers that have made a significant number of changes to their products to improve their nutrition levels may benefit from this shift in market share. According to a study conducted on the implementation of FOP labelling in Chile, the policy shifted consumption towards unlabeled products, that these effects persisted over time and that most of the decrease in demand for labelled products was compensated for by an increase in demand for unlabelled products. [79] Consumer price increases are not expected due to price elasticity of food in Canada which shows the competitive nature of the food market in Canada. [82] Data from Chile, supported by economic theory, suggests that demand will shift towards products that do not have an FOP symbol. [79] Initially, the supply of products without a symbol will not meet the new demand and prices may temporarily increase. On the other hand, the supply of products with an FOP symbol will initially exceed the new demand and prices will likely decrease to stimulate demand and to recapture market share. The one-time costs for labelling changes are unlikely to be passed on as direct price increases to consumers, and over time, prices are expected to equalize for products with and without a symbol in the same category, for example, as is the case currently for soups “lower in” versus “higher in” sodium.

- Loss of consumer choice for some products

The regulations may discourage international competitors to sell their products in Canada due to the requirement to put an FOP nutrition symbol on the front of their products that meet or exceed the established threshold for one or more of the three nutrients of concern. Should there be less international goods imported into Canada, it may reduce consumer choice in terms of product variety.

- Potential for negative substitution of ingredients

It is possible, that in order to avoid an FOP nutrition symbol, some reformulation may occur that includes ingredients some consumers may perceive as negative, including high-intensity sweeteners, emulsifiers and preservatives. These ingredients require approval before they can be safely used in food. If products are reformulated as such, Health Canada’s oversight over all food additives will help ensure that it is done in a safe manner.

- Limitations with the use of retail scale labels and implementing the FOP nutrition symbol

Industry feedback suggests that some retail companies may face limitations of retail scale labelling. Some retailers’ ability to print an FOP nutrition symbol on scale labels may be a challenge depending on the equipment currently in use; some may require replacement of outdated scale labelers, which could further increase the costs to industry beyond that included in the CBA.

Direct Benefits

The benefits calculated in the CBA are strictly due to the direct impact of an FOP nutrition symbol; it is assumed that an NFt exists in the baseline.

Canadian consumers have shifted their purchasing behaviour as important factors, including health and wellness, safety, social impact and their overall experience, increasingly influence their decision-making. Health and wellness, recognized as one of the most important factors influencing the increase in the amount consumers are willing to pay, consists of a set of attributes ranging from nutritional content to all-natural

ingredients to fewer artificial ingredients. [83]

Food prices in Canadian grocery stores are increasing. According to the annual Food Price Report, Canadian food prices will likely increase by 5-7% in 2022, more notably for dairy, bakery and vegetables. [84] In total, excluding restaurants, food prices increased by 3.9% in 2021, using consumer price index changes. In 2021, the general inflation rate was the highest since the early 2000's, driven by external factors, including rising food prices. According to Statistics Canada, there are 14,978,941 households in Canada spending on average $7,536 per year on groceries. [85], [86] This would mean that Canadians spend over $112.88 billion on food per year.

After 18 months of implementation of the *Law of Food Labelling and Advertising* in Chile, 93% of those surveyed reported understanding the information delivered by the FOP symbols and 48% reported using the symbols to compare foods when purchasing products. Of those that reported using the FOP symbols at point of purchase, 79% indicated that their purchase was influenced. According to additional studies on the impact of Chile's new law, the population has recognized, supported and understood the regulations, with around 50% using the FOP "high-in" label when purchasing foods. The use of FOP labelling could help Canadian consumers who are still struggling with healthy eating in the midst of the COVID-19 pandemic.

Based on the Chilean experience and the supporting literature indicating that consumers place value on nutrition labelling, this analysis assumes that Canadians would value the information provided by the FOP nutrition symbol, represented as their WTP for this information. A consumer's WTP for the nutritional information provided by FOP labelling is defined as the maximum price one consumer is willing to spend in order to purchase one product (SKU). Based on Jason Abaluck's paper titled *What Would We Eat if We Knew More: The Implications of a Large-Scale Change in Nutrition Labelling,* the CBA uses a WTP model to assess the benefits of the new regulations. This implies that, on average, some consumers are willing to pay an additional amount each year for groceries, in order to access the information that FOP labelling provides.

According to Statistics Canada, there are 14,978,941 households in Canada and it is assumed that there is one consumer per household who conducts grocery shopping activities. [87] It has been estimated that 49% of Canadian households understand the information in the NFt. [88] It is assumed that the remaining 51% of Canadian households may gain value from the FOP nutrition symbol. Of the households who may gain value, 80% have indicated that they would be willing to pay more for existing and new products that are considered healthier. [89] This means that approximately 40.8% of Canadian households would be willing to pay for the additional information provided by an FOP nutrition symbol. Applying the WTP model used in Abaluck's research, the CBA assesses the benefit based on the assumption that households would be willing to pay for the nutritional information FOP labelling provides and will gain $49 per year in increased annual welfare gains, as it allows them to make healthier food choices. The total benefits as measured by individual's WTP for the additional information provided by FOP nutrition labelling ranges from $38-$60 in annual welfare gains to those directly using the FOP nutrition symbol, with an average of $49. [90], [91] It is estimated that over a 15-year period, total direct benefits due to the value of additional information from nutritional labelling, as measured by Canadian's WTP, will amount to $2.33 billion PV or $255.66 million annualized based on a 1.2% annualized growth rate in the number of households within Canada. [92]

The data Health Canada has applied in its analysis illustrates a WTP of less than 1%, which is a low-end estimate, compared to data presented in other jurisdictions. Two available studies show rates of 5.9% and 11% in Europe. [93], [94] The WTP in Chile has been found to be 11% based on real consumer purchasing data. [95]

This CBA provides a sensitivity analysis to account for the uncertainty surrounding the value people may place on the FOP nutrition symbol with an annual welfare gain that could range from $38-$60; the CBA also provides a sensitivity analysis for labelling uptake.

Indirect Benefits

The CBA considers the primary benefit of the regulations as the value that people place on being better informed about the nutrient content of the foods they purchase. The potential exists for other impacts, such as the impact of behaviour changes on the risk of becoming ill in the future. It is acknowledged above that changes in nutrient consumption due to better information may reduce the risk of diseases such as cardiovascular disease, cancer, diabetes and musculoskeletal conditions — an intended outcome of the regulations. Should this outcome be attained, there may be other induced impacts, including improved productivity and the potential for savings in health care expenditures. As such, the analysis acknowledges the potential for future savings qualitatively.

As per the Public Health Agency of Canada's Economic Burden of Illness in Canada calculations prior to the COVID-19 pandemic, the direct costs (e.g., hospital, physician and pharmaceutical costs) of the four primarily impacted diseases (cardiovascular disease, cancer, diabetes and musculoskeletal disease) amounts to $28.16 billion annually (2021 CAD). Taking a simplified approach, if the reduction in risk of disease is assumed to be directly proportional to a reduction in health care spending, then health care costs could decrease by up to 1.5%, resulting in a savings of up to $422.34 million in a given year. While this savings is not considered the primary benefit of FOP labelling, it is worth noting as a potential downstream impact of the regulations.

Qualitative Benefits

The following benefits are identified because of the regulations; however, their impacts are non-quantifiable:

- Time savings for consumers not having to search for nutrient information by making it directly accessible

Displaying the FOP nutrition symbol on the front of the package prominently, as opposed to the side or back of the package as in the case of the NFt, will help consumers reduce the amount of time it takes to become familiar with the nutritional content of the product and allow them to make choices at the point-of-purchase more quickly. According to a grocery shopping experience study conducted internally at Health Canada, the use of an FOP nutrition symbol reduces the time to make healthier choices by approximately 17 seconds. An easy to understand label will reduce this time by allowing consumers to make quicker comparisons for similar products.

- Improved consumer access to easy-to-use information on foods high in saturated fat, sugars and sodium to help reduce consumption of these nutrients and reduce risk to health

There is a possibility that by selecting foods that do not carry an FOP nutrition symbol, certain noncommunicable diseases can be prevented. Analysis in Chile on the use of FOP labelling showed that approximately 48% of consumers reported using the symbols to compare foods, and of these, 79% indicated that their purchase was influenced. [96] As a result, the analysis showed that "high in sugar" drink consumption decreased by 24% and cereals by 26%. [97], [98] It is estimated that the FOP symbols were responsible for declines of 37% of sodium purchased and 27% of sugar purchased. [99] For example, by managing the intake of foods high in sodium, there is a possibility that the onset of cardiovascular disease could be delayed and in some instances, prevented.

- Help promote adequate bone health among Canadians

One of the objectives of the regulations is to increase vitamin D in the food supply to promote adequate bone health among Canadians without incurring risk of excessive intakes. The amendments will increase vitamin D amounts required in cow's milk and margarine, and permitted in goat's milk, to help bring Canadians' vitamin D intakes closer to intake recommendations.

- Trickle-down effects of healthy family eating habits will help improve eating habits of future generations

Healthy eating habits that are learned at an early age have been demonstrated to carry into adulthood. It is anticipated that the regulations will have lasting and long-term positive effects which cannot be captured quantitatively. There is also the further benefit of preventable noncommunicable diseases due to the avoidance of unhealthy eating.

- Increased potential for product reformulation with more positive nutritional values

Reformulating products is one possible adjustment that manufacturers may make in response to the regulations in order to avoid applying an FOP nutrition symbol on product labels and could improve the nutritional characteristics of consumed prepackaged products. This could lead to an improved nutritional profile of food and beverages. According to the National Heart Foundation of Australia, improving the nutritional profile of items with the lowest nutritional quality would lead to significant improvements in the average consumption per person of the nutrients of concern. [100] An evaluation comparing the nutrition profiles of products before and after the first year of Chile's FOP law found significant reductions in products required to carry FOP nutrition symbols, suggesting companies reformulated their products to improve overall health profiles. [101]

- Consumer shift in purchasing behaviour from foods with an FOP nutrition symbol to foods without an FOP nutrition symbol resulting in potential increase in market share of foods without an FOP nutrition symbol

The regulations could lead to a substitution effect for those products carrying an FOP nutrition symbol. Manufacturers whose products will not require an FOP symbol could benefit as their products may look comparatively better than those products requiring an FOP nutrition symbol (e.g., with a wide variety of breakfast cereals available, the consumer may be more likely to select products without an FOP symbol) and are most likely be purchased over a comparable product. According to a study conducted on the implementation of FOP labelling in Chile, the policy shifted consumption towards unlabeled products and that these effects persisted over time. It also suggested that most of the decrease in demand for labeled products were compensated for by an increase in demand for unlabelled products. [102] As a result, manufacturers are anticipated to adjust supply accordingly. Similarly the price of products with a symbol increase as supply is reduced to meet the new demand. While it is not possible to predict the precise shift in consumer demand between products with or without an FOP symbol it is assumed the amount of money spent by households on foods and beverages will remain constant. [103]

Summary

For *Canada Gazette*, Part I, costs and benefits were projected over a 10-year period based on the assumption that costs to Canadian industry would be experienced within the first year of the proposed four-year transition period. However, based on additional stakeholder feedback, the 10-year period used to project costs and benefits has been extended to become a 15-year period since it can be assumed that industry will defer the one-time compliance costs into the final year of the transition period.

For *Canada Gazette*, Part I, cost estimates were based on an FOP nutrition symbol that contained colour beyond just black and white with a range between $15,505-$31,010 per SKU, placing the cost per SKU at $23,260 (2017 CAD). For *Canada Gazette*, Part I, cost estimates were also based on a transition period of approximately four years. In response to the new Food Labelling Coordination policy, industry will now have until January 1, 2026 to come into compliance with the new regulations, reducing the originally-proposed transition period by approximately six months. Based on industry feedback, this will result in increased costs. Cost estimates used for *Canada Gazette,* Part I have been revised to account for a black and white symbol only, inflation to 2021 constant dollars, a shortened transition period to three and a half years and assumes

the higher-bound cost estimate considering the current economic climate (e.g., the COVID-19 pandemic, labour shortages, supply chain issues, etc.). The CBA now estimates the cost to conduct a label change to include a black and white nutrition symbol could range from $13,473-$23,146 per SKU (2021 CAD); it is assumed that the higher-bound cost of $23,146 per SKU (19% increase) better reflects current conditions. Additionally, for *Canada Gazette*, Part I, it was also estimated that 47% of all prepackaged products with an NFt (equalling approximately 37,600 SKUs) would require a nutrition symbol. Accounting for exemptions since *Canada Gazette*, Part I and additional analysis on the number of prepackaged products anticipated to be impacted, it is now estimated that approximately 57.5% of all product SKUs with an NFt will require a nutrition symbol; this represents 46,023 SKUs.

For *Canada Gazette*, Part I, costs to conduct a labelling change as a result of the increase in vitamin D amounts were estimated to be $10,000 per SKU (2017 CAD). This has since been revised to $10,709 per SKU to account for inflation to 2021 prices.

In order to implement these amendments and ensure compliance, the Canadian Food Inspection Agency will also incur an annualized average cost of $867,503 or $7.90 million PV over a 15-year time period, starting in year one. The total direct costs of the amendments to both industry and Canadian Food Inspection Agency are expected to be an annualized average of $98.26 million or $894.93 million PV.

Benefits in *Canada Gazette*, Part I, were assessed as the reduced burden on health care costs. Upon further review, the CBA now assesses reductions in risk of disease due to improved nutrition as indirect impacts and downstream health care spending savings qualitatively. As such, the direct impact of these regulations is presented as the value that households place, in terms of WTP, for the added information that FOP nutrition symbols provide. The direct benefits are estimated to be an annualized average of $255.66 million or $2.33 billion PV over a 15-year period starting in year three. A summary of benefits, costs and net benefit is presented below. A net PV (benefit) of $1.43 billion is anticipated over 15 years.

Cost-Benefit Statement

Number of years: 15; 2022-2036

Base year for costing: 2021

Present value base year: 2022

Discount rate: 7%

Monetized Costs

Impacted stakeholder	Description of cost	Base year (Year 1)	Other relevant years (Year 3)	Final year (Year 15)	Total (present value)	Annualized value
Industry	**(One-Time Cost) FOP Nutrition Symbol: $23,146/SKU**	$0	$1.07B	$0	$869.54M	$95.47M
	(One-Time Cost) Vitamin D: $10,709/SKU	$0	$21.42M	$0	$17.48M	$1.92M
Government	**(Ongoing) Implementation, Compliance and Enforcement Activities**	$0.66M	$1.10M	$0.30M	$7.90M	$0.87M
All stakeholders	**Total costs**	**$0.66M**	**$1.09B**	**$0.30M**	**$894.93M**	**$98.26M**

Monetized Benefits

Impacted stakeholder	Description of benefit	Base year (Year 1)	Other relevant years (Year 3)	Final year (Year 15)	Total (present value)	Annualized value
Canadians	**Willingness to Pay for Nutritional Information (WTP)**	$0	$299.99M	$346.15M	$2.33B	$255.66M
All stakeholders	**Total benefits**	**$0**	**$299.99M**	**$346.15M**	**$2.33B**	**$255.66M**

Summary of Monetized Costs and Benefits

Impacts	Base year (Year 1)	Other relevant years (Year 3)	Final year (Year 15)	Total (present value)	Annualized value
Total costs	$0.66M	$1.09B	$0.30M	$894.93M	$98.26M
Total benefits	$0	$299.99M	$346.15M	$2.33B	$255.66M
NET IMPACT	**-$0.66M**	**-$787.76M**	**$345.85M**	**$1.43B**	**$157.40M**

Quantified (non-$) and Qualitative Impacts

Positive Impacts

- Time savings for consumers not having to search for nutrient information by making it directly accessible;
- Improved consumer access to easy-to-use information on foods high in saturated fat, sugars and/or sodium to help reduce consumption of these nutrients;
- Help promote adequate bone health among Canadians;
- Trickle-down effects of healthy family eating habits will help improve eating habits of future generations;
- The increased potential for product reformulation with more positive nutritional value; and
- Consumer shift in purchasing behaviour from foods with an FOP nutrition symbol to foods without resulting in a potential increase in the market share of foods without an FOP nutrition symbol.

Negative Impacts

- The regulations could place added pressure on industry as a whole, given the current economic situation (e.g., COVID-19 pandemic, labour shortages, supply chain issues, etc.);
- Opportunity costs of resources being used in order to comply with the regulations rather than product innovation;
- Loss of market share for some food industry companies due to the requirements for carrying an FOP nutrition symbol;
- Loss of consumer choice for some products;
- Potential for negative substitution of ingredients; and
- Limitations with the use of retail scale labels and implementing the FOP nutrition symbol.

One-for-one rule

There are currently no reporting requirements or costs associated with the demonstration of compliance as a result of these amendments. Therefore, it has been determined that the "One-for-One" Rule does not apply, as the amendments do not impose any new administrative burden on business.

Small business lens

The Policy on Limiting Regulatory Burden on Business defines a small business as any business, including its affiliates, which has fewer than 100 employees or less than $5 million in annual gross revenues. This definition is based on commonly used definitions for what is considered a "small" business in Canada, including micro businesses, which have fewer than 5 employees or less than $30,000 in annual gross revenues. There are approximately 26,700 small enterprises in Canada that could be affected by these amendments, representing close to 89.8% of all food manufacturers and retailers in Canada: 23% are food manufacturers (including retail and commercial bakeries); 2% are soft-drink manufacturers; 29% are food and beverage wholesaler-distributors; and 46% are retail stores. Due to the often restricted access to capital that small businesses have, four provisions have been specifically designed to provide flexibility and reduce the impact on small businesses:

- *An estimated transition period of three and a half years to allow small businesses to exhaust their existing product and label stock, without having to throw away products;*
- *Requirement for a nutrition symbol only on prepackaged products containing nutrients of concern at or above established thresholds instead of on all prepackaged products;*
- *Inclusion of an exemption for products sold in road-side stands, craft shows, flea markets, fairs, farmers' markets and sugar bushes; and*
- *Requirement that the nutrition symbol be in black and white, instead of incorporating a more costly coloured labelling scheme*.

NAICS *	Industry Sector	Small	All Enterprises	% Micro and Small
311	Food manufacturing	8 045	8 949	89.9%
312	Beverage and tobacco product manufacturing	300	337	89.1%
413	Food, beverage and tobacco wholesaler-distributor	11 006	11 429	96.3%
445	Food and beverage stores	7 331	10 439	83.8%

* North American Industry Classification System

The following options were considered when determining the effect of the regulations on SMEs and large food manufacturers.

1. Scope of FOP nutrition symbol

The FOP model (i.e., a mandatory "high in" system for specific nutrients) is less costly than other models that were considered. Under these regulations, only prepackaged products high in one or more of the three nutrients of concern must carry the nutrition symbol. The potential cost of other possible FOP models, such as fact-based, summary and "traffic light" models, is much greater. This is because these systems, which make use of multiple colours, highlight both positive and negative nutrients or provide an overall rating of the food, would apply to all foods, not just those high in one or more of the three nutrients of concern.

If the higher-bound cost per SKU of $23,146 is applied to all 80,000 SKUs, assuming that a simple black and white fact-based approach (e.g., a 'Facts Up Front' approach) is required for every label, the total PV cost would increase by an additional $786 million. If additional colours were required as part of the FOP labelling, such as in application of a "traffic light" approach, the total PV costs would increase by an additional $1.27 billion. Using a mandatory "high in" approach, only a percentage of SKUs with an NFt are be subject to FOP labelling and would not require any additional colours (i.e., only black and white); this is the least costly in comparison to all other options.

2. Exemption for micro firms processing and selling products

Products that are sold at road-side stands, craft shows, flea markets, fairs, farmers' markets and sugar bushes by the same person(s) who produced them are exempt from the requirement to carry a nutrition symbol in keeping with what is currently included in the exemptions from displaying an NFt. While it is difficult to identify the precise number of such firms operating within a given year, as these enterprises tend to come in and out of operation, it is possible to use the proxy of farmers' markets. There are 508 identified farmers' markets in Canada, according to a national study conducted in 2009. [104] The average market has 25 vendors, and each vendor in turn averages one to five employees. The total annual sales from vendors at these markets are estimated to be $1.03 billion. These regulations include an exemption for the food products of these 12,700 firms.

The estimated costs on small businesses are summarized in the following table. The one-time compliance cost for implementation is estimated at $605.35 million PV or $22,672 per small business. There are no administrative burden costs associated with the regulations and thus the total costs are equal to compliance costs. The equivalent annual amortized payments of the regulations over 15 years is $66.46 million in total or $2,489 per small business.

While there are no other specific mitigation measures, the needs of small businesses were taken into consideration during the development of the regulations.

Small Business Lens Summary

Number of small businesses impacted: 26,700

Number of years: 15; 2022-2036

Base year for costing: 2021

Present value base year: 2022

Discount rate: 7%

Activity	Annualized value [105]	Present value
Compliance Cost	$66,464,359	$605,351,665
Total compliance cost	$66,464,359	**$605,351,665**
Cost per impacted small business [106]	$2,489	$22,672

Regulatory cooperation and alignment

In the spirit of regulatory cooperation, these regulations aim to align with the United States rules to the extent possible.

I. Key difference: FOP nutrition labelling

Canadian food labels differ from those used in the United States due to Canada's bilingual language requirements and use of metric (not imperial) units of measurements. It is important to note that food products produced in Canada exclusively for export will not be required to carry an FOP symbol. Differences between Canadian and United States labelling requirements would not affect foods destined for the United States market.

Both Canada and the United States require nutrition labelling on prepackaged products, such as the NFt and the list of ingredients, with the same overall policy objective: to enable consumers to make informed choices about their food to help them attain better health outcomes.

Canadian FOP labelling requirements are justified as a legitimate public policy objective. They are part of the larger *Healthy Eating Strategy* to help reduce the incidence of noncommunicable diseases, to ease the burden of these diseases on Canada's health care system, and to help improve the health and well-being of Canadians. At the same time, the FOP labelling requirements build on existing nutrition labelling tools in Canada and address their limitations. These regulations do not create trade barriers that favour Canadian goods. All food products, domestic and

imported, are subject to the same regulations. While some manufacturers may decide not to sell their products in Canada, the global food industry acknowledges that it must shift towards healthier foods to meet increasing consumer demands globally.

Manufacturers in the United States have initiated a voluntary fact-based FOP system (e.g., 'Facts up Front'). This approach was not chosen by Health Canada as research consistently shows that this type of FOP approach, which is neither simple nor interpretive, is more difficult for consumers to understand and is less effective. Therefore, this system does not meet the stated objectives of these regulations.

While the United States has not adopted a mandatory FOP labelling system, other countries have, such as Chile, Mexico, Israel, Peru, Uruguay, Brazil and most recently Argentina.

II. Key similarity: Nutrient content claims and other nutrition-related statements

Canada's decision to permit representation of the amount of alcohol in beverages containing 0–0.5% alcohol does not conflict with United States' practices in quantitative declaration whereby beverages may make a declaration "contains less than 0.5% alcohol by volume." Furthermore, the applicable age categories for food intended solely for children "under four years of age," updated to reflect the new DV age categories, are now aligned with the United States.

III. Key similarity: Vitamin D fortification

In the United States, the fortification of vitamin D in cow's milk is mandated at the state level, rather than the federal level. If vitamin D is added to milk, it must be present at ~1 µg/100 mL, as per the United States Food and Drug Administration's milk standard (21 CFR 131.100). This is similar to the amounts prescribed by the FDR (0.880–1.174 µg/100 mL). In 2016, the Food and Drug Administration permitted vitamin D fortification above the amount prescribed in the milk standard based on a petition received from industry. It now allows up to 2.1 µg vitamin D/100 mL, which is very close to the amount allowed in Canada's current regulatory amendment (2 µg/100 mL). While the Food and Drug Administration has not amended its milk standard, milks that are fortified in excess of levels stipulated in the standard must be named with a nutrient content claim such as "high vitamin D milk."

With respect to margarine, it can be optionally fortified with vitamin D in the United States, permitted at a lower level than in Canada (8.3 µg/100 g in the United States vs. 26 µg/100 g in Canada, the amount allowed in Canada's current regulatory amendment).

IV. Key similarity: Prohibiting PHOs

The United States and Canada use different means to reach the same public health objective. The classification of PHOs as an adulterating substance is unique to Canada. However, on June 17, 2015, the United States Food and Drug Administration published its final determination removing the generally recognized as safe (GRAS) status for PHOs. While this does not constitute an outright ban in the United States, it will effectively prohibit the use of PHOs in foods until such time as manufacturers or other interested parties can successfully petition the Food and Drug Administration for food additive approval for one or more specific uses of PHOs. Any such petition would require data demonstrating a reasonable certainty of no harm of the proposed uses. On May 18, 2018, the Food and Drug Administration confirmed its denial of a food additive petition requesting approval for limited uses of PHOs. The Food and Drug Administration's review of the petition found insufficient evidence to show that the requested uses of PHOs are safe. By June 18, 2018, companies were to have reformulated their products to remove PHOs or have obtained approval from the Food and Drug Administration for specific food additive uses. This compliance date has been extended using a phased approach for certain uses of PHOs to allow time for products produced prior to June 18, 2018 to work their way through distribution. As such, by January 1, 2021, both petitioned and non-petitioned uses of PHOs should be in compliance with the new rules. [107]

Similarly, in Canada, should evidence come to Health Canada's attention indicating a tolerance below which PHOs would not present a risk to health, the incorporated by reference *List of Contaminants and Other Adulterating Substances in Foods* could be amended to prescribe a maximum level below which a food containing PHOs would not be considered adulterated. To date, no such evidence has been identified or submitted to Health Canada for consideration.

V. Key similarity: Labelling of foods containing high-intensity sweeteners

Repealing the PDP and quantitative declaration labelling requirements for foods containing the four high-intensity sweeteners aligns with the United States, which does not have such labelling requirements. Furthermore, providing more flexibility in the wording to be used to alert people with phenylketonuria to the presence of phenylalanine would allow for the use of the United States statement as a possible option for the mandatory phenylalanine statement on the labels of foods containing aspartame.

Rationale

Chronic diseases, such as cardiovascular disease, musculoskeletal disease, cancer and type 2 diabetes, remain a major public health concern in Canada and continue to place an increasing burden on Canadians, health systems, the economy and workplaces. Together, these four chronic diseases accounted for approximately $26.38 billion annually in direct health care expenses. Diet is a modifiable risk factor for chronic disease and an important component of Canadians' health. There is well-established scientific evidence that healthy diets both promote overall health and help protect against disease. The current food environment makes it increasingly difficult for Canadians to make healthy choices. There is widespread availability of inexpensive foods and beverages high in saturated fat, sodium and sugars, and Canadians are consuming these nutrients in excess of recommended limits.

Nutrition information on food labels provides product-specific information to help Canadians make informed food choices. In Canada, the NFt, nutrient content claims and health claims are the main types of regulated nutrition information on food labels. However, these tools have limitations and further action is required to help Canadians reduce health risks.

FOP labelling complements the NFt and balances the nutrient content claims, health claims, and other marketing information on the front of food packages. It offers consumers a simplified and visible indicator to help them make choices that support reductions in excessive intakes of nutrients of concern and, consequently help reduce risks to their health. There is evidence to support the role of FOP labelling in helping consumers identify healthier food options.

Many FOP systems are currently used in Canada. The result is a proliferation of various symbols and different criteria that leads to a lack of consistency, making it difficult for consumers to decipher the information between systems. A voluntary approach would not ensure a consistent use of the symbols for products high in saturated fat, sugars and sodium. A mandatory FOP "high in" system, conversely, creates a consistent and credible source of information that all consumers can rely on for quick and easy guidance on key nutrients of concern. It may also help encourage manufacturers to reformulate their products to avoid triggering the requirement to display the nutrition symbol. The selected approach is consistent with Health Canada's mandate to help protect the health and safety of Canadians.

Increasing the amount of vitamin D in milks and margarine will help bring Canadians' vitamin D intakes closer to intake recommendations, thereby improving their bone health.

Several options were considered to reduce the cost and burden for industry, particularly small businesses, in implementing these regulations. Options considered were:

- A transition period for many of the amendments to minimize the cost of complying with new labelling requirements and allow time to deplete current label stock; and
- Conditionally exempting the following products from the requirement to carry a nutrition symbol on their label:
  - individual servings of food sold for immediate consumption and that have not been subjected to a process to extend the durable life, including special packaging products,
  - products sold only at a road-side stand, craft show, flea market, fair, farmers' market or sugar bush by the person who prepared and processed the product,
  - products prepared and processed from ingredients at retail, including from a pre-mix if an ingredient other than water is added to the pre-mix during preparation and processing, and
  - products sold only in the retail establishment where packaged, if labelled by means of a sticker and the available display surface is less than 200 cm^2.
- Fully exempting the following products from the requirement to carry a nutrition symbol on their label:
  - whole, partly skimmed and skim cow's milk (unflavoured and flavoured) as well as cream and goat's milk sold in refillable glass containers.

Health Canada's analysis has determined that these amendments are the most appropriate way to proceed. A net PV benefit of $1.43 billion is estimated based on a willingness to pay model for the information provided by FOP nutrition labelling and the direct costs of the regulations required over a 15-year period, assuming a transition period of three and a half years.

Strategic environmental assessment

In accordance with the *Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, a strategic environmental assessment preliminary scan was completed and concluded that a detailed analysis was not required because these regulatory amendments have no environmental impact.

Gender-based analysis plus

Sex, gender, health literacy and other socio-economic factors were taken into account during the development of these amendments to the FDR.

Sex, gender, education, income, age, culture

Data from the 2015 Canadian Community Health Survey show that men consume more sodium than women. Sugars and saturated fat intake for both sexes similarly exceeded recommendations. The *How Healthy are Canadians?* report shows different rates of chronic conditions amongst the sexes. Across sub-populations, Indigenous communities and low-income citizens have higher prevalence of chronic conditions than non-Indigenous Canadians and those within a higher income bracket, respectively.

Health Canada's objective was to develop an FOP labelling approach that would work for as many Canadians as possible. An extensive literature review was conducted and demonstrated the complex interplay between biological and social determinants such as sex, gender roles, income, and age on diet-related chronic disease rates in Canada.

- A *2016 Statistics Canada* report suggests that women with low education and low income are more likely to be diagnosed with diet-related chronic diseases than women with higher education and income.
- Research showed women are more likely than men to use nutrition labels, which is likely linked to traditional gender roles. [108], [109] Men were more likely to use labels if they had diet-related chronic diseases or conditions. [110]
- The *2015 Tracking Nutrition Trends* report notes food label use increases with age, with usage starting at 51% for consumers 18 to 34, and peaking at 69% for consumers aged over 65.
- Women may be impacted more by FOP labelling as they are more likely to be responsible for food shopping and for the cooking. Considerations made during meal preparation, such as fat and sodium levels, the adequacy of vegetables and grains, and sugar content, could be directly impacted by these regulations.

The results of the literature review indicate a universal approach is required to meet the needs of the diversity of Canadians, not only based on patterns of the use of labels, but also based on risk factors associated with different sub-populations.

Health literacy considerations to reduce health disparities

Health literacy refers to the ability to manage the demands encountered in daily health tasks, such as using nutrition labelling to be able to identify foods high in saturated fat, sodium and/or sugars; as well as interpreting, evaluating, and using nutrition label information to self-manage specific dietary goals, or to reduce disease risk with the selection of healthier foods. Health literacy is increasingly seen as an important contributor to the health of Canadians, and is linked to health disparities. [111] According to the *Health Literacy in Canada: a Healthy Understanding* (PDF) report, approximately 60% of Canadians have low levels of health literacy. Presenting key and relevant nutrition information on food labels in a way that all Canadians, in particular those disadvantaged by risks of limited or marginal health literacy, can notice, process, evaluate, and use it to make healthier food choices can help address these challenges and better meet the needs of the increasingly diverse Canadian population. [112]

Health Canada conducted consumer research in a grocery store to test the efficacy of the proposed FOP labelling approach in helping consumers make healthier food choices. [113] Throughout this study, many factors affecting Canadians' food buying decisions including gender, social, cultural, and other demographics were considered. For example, a conscious effort was made to include Indigenous peoples, seniors and youth and at least 10% of the participants were francophone. The key factor considered was health literacy. To ensure that the pool of respondents reflected the health literacy status of Canadians (approximately 60% marginal vs. 40% adequate), a validated tool was used to screen during participant recruitment. The research results showed that FOP labelling, regardless of the symbol design, is more effective than current labelling practices at helping consumers of varying health literacy levels quickly and easily identify foods high in saturated fats, sugars, or sodium.

While the needs of and impacts on key populations were considered, rather than target a specific population, Health Canada prefers a universally understood symbol followed by clear, simple language that indicates a food is high in nutrients of concern. This proposed approach was adopted to ensure that a diverse range of Canadians are able to make healthy choices, and more broadly, improve overall health outcomes across the country.

Implementation, compliance and enforcement, and service standards

Implementation

Regulated parties are given a transition period ending on January 1, 2026 to comply with the provisions relating to the FOP nutrition symbol, the phenylalanine statement, nutrient content claims and vitamin D fortification. This period of time will allow sufficient time for regulated parties to make the necessary changes to their labels and to use up any existing stocks of products or labels already printed to comply with existing requirements.

Ongoing public education efforts will accompany these regulatory amendments to help consumers understand how best to use the information on the labels to make informed food choices.

Compliance and enforcement

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and the FDR as it relates to food. While it is the responsibility of the industry to comply with regulatory requirements, compliance will be monitored as part of ongoing domestic and import inspection programs. Inspection activities will continue to be subject to Canadian Food Inspection Agency's existing risk-based approach and it will conduct enforcement and compliance verification according to usual policies and procedures. Costs will be incurred in support of implementation and for compliance and enforcement activities as well as training for inspectors.

Health Canada will continue to provide guidance to Canadian Food Inspection Agency on health risk assessments and implementation of these regulatory amendments. In addition, Health Canada has developed guidance for industry on the FOP labelling requirements, which is available from the Department upon request.

A phased-in approach is important in order to give industry and Government time to adapt to the new requirements as well as provide the opportunity for the development of education and compliance tools. Health Canada and Canadian Food Inspection Agency will advise industry

on a Government of Canada implementation plan that will describe how key activities will be managed, such as responding to inquiries, delivering of information sessions, and updating of inspection and compliance-promotion tools. In addition, the Canadian Food Inspection Agency will outline a phased-in approach to compliance and enforcement of the various components of these regulations over the transition period.

Performance measurement and evaluation

Health Canada will implement the program evaluation requirements of the Treasury Board Secretariat *Policy on Results* with respect to certain elements of these regulations (i.e., FOP labelling, vitamin D fortification) through the Food Safety and Nutrition Performance Measurement Strategy, the results-based management tool that measures, monitors and reports on expected results of the Food Safety and Nutrition Program. More specifically, during the transition period ending on January 1, 2026, Health Canada will incorporate monitoring and data collection pertaining to the implementation of these regulations as part of this strategy. In particular, changes in Canadians' nutrient intakes will be monitored and the quality of the food supply will be reported.

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Footnotes

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