Canada Gazette, Part I, Volume 152, Number 6: Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Nutrition Symbols, Other Labelling Provisions, Partially Hydrogenated Oils and Vitamin D)

February 10, 2018

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

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

Executive summary

Issues: Average intakes of sodium, sugars, saturated fats and *trans* fats remain above recommended levels in the Canadian population. Unhealthy diets with high levels of these nutrients are risk factors for overweight and obesity and chronic non-communicable diseases (NCDs), 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 measures are needed to provide clear and consistent front-of-package information and updated nutrient content claims to help protect Canadians from the risks of chronic diseases related to excess consumption of foods high in these nutrients.

In addition to the increasing rate of NCDs, about 20% of Canadians are at risk of vitamin D inadequacy, while about 8% are at risk of deficiency. These rates are

higher in certain identified subpopulations, including those with dark skin and those who are obese. 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 Governor in Council (GIC) 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 for efficient and timely updates to these nutrient content claims in response to new scientific evidence. 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 in 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, this is inconsistent with the labelling of foods containing other approved sweeteners and of foods containing other ingredients of concern (such as priority allergens), none of which are subject to similar PDP and quantitative declaration labelling requirements.

Description: The proposed Regulations would amend the FDR to require front-of-package (FOP) labelling for prepackaged products containing nutrients of public health concern (sodium, saturated fats and/or sugars) at or above a certain threshold to enable Canadians to more easily identify foods high in these nutrients and make healthier and more informed decisions. The proposed amendments would also repeal the Table of Permitted Nutrient Content Statements and Claims following section B.01.513 and incorporate it by reference in the FDR. Doing so would enable Health Canada to more efficiently amend such claims in response to evolving science.

The proposed amendments would also increase vitamin D fortification levels in milk, goat's milk and margarine to help bring the vitamin D intakes of Canadians closer to the 2011 recommendations of the National Academy of Medicine (NAM), formerly the Institute of Medicine (IOM). Given the decision to prohibit the sale of foods that contain PHOs by adding PHOs to Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods*, pursuant to the Notice of Modification -

Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods (Ref. No. NOM/ADM-C-2017-3), amendments to the FDR are proposed 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, the proposed amendments would 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 phenylalanine statement on foods containing aspartame are also proposed to improve its prominence on the label.

Cost-benefit statement: Costs were estimated based upon the inclusion of all regulatory options that were presented during stakeholder consultations. Using a survey approach, respondents indicated that the cost would be approximately $894.6 million (in 2017 dollars) or $836.1 million net present value using a 7% discount rate as per Treasury Board requirements. The total cost estimate, based on a number of cost-reducing initiatives in the proposed Regulations (i.e. an approximately 4-year transitional period to align with other food regulatory activities), would be understood to be a maximum industry cost burden. The quantified present value benefits are estimated to be $3.19 billion over 10 years, assuming a 1.5% reduction (compounded annually) in direct and indirect health costs in four chronic diseases (i.e. cardiovascular disease, malignant neoplasm, diabetes mellitus, and musculoskeletal disease). It is assumed that consumers, when given easily accessible information to make healthy food choices, would experience reductions in negative health outcomes over time and these benefits would then compound over time. The anticipated net benefit present value to Canadians would be $2.36 billion over 10 years. The transitional period of approximately 4 years was chosen to reduce the cost of implementing the labelling amendments. This would align with the end of the transitional period for the nutrition labelling regulations (see footnote 1) that came into force in December 2016, which would be amended by the proposed Regulations to extend by an additional year to December 2022.

"One-for-One" Rule and small business lens: The proposed amendments would not add any new administrative burden to industry; therefore, the "One-for-One" Rule does not apply. There are approximately 26 700 small and medium enterprises (SME) within the food manufacturing and retail sector that would be impacted by the amendments. Given that the cost impact is greater than $1 million, the small business lens would apply. The transition period of approximately four years to

align with the end of the amended transition period of the nutrition labelling regulations was selected instead of five years, which would reflect the flexible option. This represents an additional cost to SME of $216.8 million; however, anticipated benefits would be realized at an earlier date.

Domestic and international coordination and cooperation: Food labels on prepackaged products in Canada will always differ from those used in the United States (U.S.) 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 this proposed regulatory package, which support the *Healthy Eating Strategy*, are aligned with or similar to U.S. requirements (e.g. high-intensity sweeteners).

With respect to mandatory FOP labelling, currently there is no equivalent U.S. requirement for foods containing nutrients of public health concern at or above a certain threshold. This said, other jurisdictions have adopted various systems of mandatory or voluntary FOP labelling. Chile, for example, implemented in 2016 the mandatory FOP labelling of foods high in nutrients of concern. The Codex Alimentarius Commission, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) 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.

Background

Chronic diseases, also known as non-communicable diseases (NCDs), are an increasing global epidemic. NCDs kill 38 million people per year according to the World Health Organization (WHO) and are the leading cause of premature death and disability globally. The major chronic diseases — cardiovascular disease (heart disease and stroke), some cancers, type 2 diabetes, and chronic respiratory disease — are the single greatest cause of preventable illness worldwide. The World Economic Forum has declared NCDs a greater threat to global economic development than fiscal crises, natural disasters and pandemic influenza. 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 NCDs 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 Non-communicable Diseases in 2011, the Heads of State and government committed to a Political Declaration and Action Plan to develop multisectoral national policies and to adopt whole-of-government approaches to NCDs. They recognized that prevention must be the cornerstone of a global response to NCDs. In response, the global community has identified actions and set voluntary global targets to prevent and control NCDs. This includes adopting policies, legislation and regulation and implementing policies to promote healthy diet through sodium reduction, 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 WHO Commission on Ending Childhood Obesity (ECHO) 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. ECHO'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 understandable front-of-package 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 in March 2016 a comprehensive report: *Obesity in Canada: A Whole-of-Society Approach for a Healthier Canada*. 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. 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 prevent chronic diseases and promote health through education, surveillance, monitoring, national and community-based programming, the prevalence of NCDs continue to increase in cardiovascular diseases, chronic respiratory diseases, cancer and especially type 2 diabetes. Dietary risks were the number one risk factor for the disease burden in Canada (56% of Canadians).

Furthermore, the rates of risk conditions for NCDs, that are obesity and hypertension, continue to be high in Canada. Obesity is a key driver of chronic disease in Canada: one in three children

is overweight or obese, and over one in four adults is 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 chronic diseases is urgent.

The economic burden of chronic diseases affected by diet and other modifiable risk factors is estimated at $26.7 billion annually in 2008 (adjusted to 2017 dollars).

Health Canada, acting within its mandate to promote health and safety and to prevent injury 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 is part of a broader *Vision for a Healthy Canada* that includes pillars in *Healthy Living* and *Healthy Minds*. The *Healthy Eating Strategy* will use legislation, regulation, education, monitoring, surveillance, and national and international collaboration to improve the food environment and make healthy food choices easier for Canadians. It includes the transformation of the Canada Food Guide, introducing restrictions to the marketing of unhealthy food to children, eliminating industrially produced *trans* fat and reducing sodium in the food supply, updating labelling requirements for the list of ingredients and the Nutrition Facts table, (see footnote 2) and improving front-of-package 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 reconfirmed 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 *A Food Policy for Canada* of the Minister of Agriculture and Agri-Food. The Policy seeks to promote healthy living and safe food by putting more healthy, 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, as mandated by the Prime Minister.

Issues

I. Lack of clear and consistent front-of-package information on key nutrients of concern

The former Institute of Medicine (IOM), now the National Academy of Medicine (NAM), concluded that sodium intakes above 2 300 mg per day (equivalent to about one teaspoon of salt) increase blood pressure, which is a major cause of cardiovascular-renal diseases. The daily average sodium consumption of Canadians is currently estimated to be 3 400 mg, well above the recommended limit.

Excess sugars intake can lead to tooth decay and excess calorie consumption, the latter being a contributing factor to overweight and obesity. Obesity is a risk factor for cardiovascular disease, type 2 diabetes and some forms of cancer. The WHO recommends that individuals reduce their intake of free sugars to less than 10% of total energy intake, which is equivalent to about 50 g per day based on a 2 000 calorie reference diet. Data indicates that most Canadians have intakes above the WHO recommendation.

Additionally, the NAM recommends that saturated fat intake be as low as possible while consuming a nutritionally adequate diet. The Joint Expert Consultation of the Food and Agriculture Organization of the United Nations (FAO) and the WHO recommends that saturated fat intake not exceed 10% of total energy intake, which is approximately 20 g per day for a 2 000 calorie reference diet. The estimated Canadian population average intake of saturated fat is approximately 10% of energy (20 g) and has remained relatively stable in subsequent years. These intake data mean that many Canadians have saturated fat intakes above the FAO/WHO recommendation.

Given the risks to Canadians' health due to continued excess consumption of foods high in sodium, sugars and saturated fat, additional measures are needed to reduce the consumption of these nutrients of public health concern. Current regulated nutrition information, such as the Nutrition Facts table and nutrient content and health claims, provide valuable healthy eating information to consumers. Given that the front of the package is 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 would provide quick and easy guidance to assist consumers in making choices that help prevent injury to their health. FOP labelling would also balance voluntary nutrition claims that highlight positive attributes of foods and help consumers who may have difficulties understanding and using the Nutrition Facts table due to limited health literacy. According to *A Vision for a Health Literate Canada: Report of the Expert Panel on Health Literacy*, 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 at risk of limited health literacy, can access, understand, evaluate and use to

make their food choices is of paramount importance to the health of all Canadians.

II. Need for updates to nutrient content claims

The FDR currently 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"). The conditions apply to nutrient content claims in advertisements and on food labels.

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. Amending nutrient content claims and/or their associated conditions of use currently requires regulatory amendments to the FDR by the Governor in Council (GIC). However, documents incorporated by reference may allow more efficient or timely updates to requirements in response to new scientific evidence.

The FDR also allow for various current market practices that reference nutrients, but they 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 per 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.

Currently, some specific provisions for nutrient content claims use "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 levels of vitamin D fortification

Vitamin D is a nutrient that helps the body use calcium and phosphorus to help 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 in adults. Fortified foods, primarily milk, are the major dietary source of vitamin D for Canadians. The FDR set requirements for the addition of vitamin D to foods in Canada.

Health Canada recognizes that it is challenging for all Canadians to meet the current vitamin D intake recommendations through the current food supply. Approximately 20% of Canadians are at risk of vitamin D inadequacy, while about 8% are at risk of deficiency. Some subpopulations, such as those with dark skin and those who are obese, are at additional risk of vitamin D deficiency. Increasing the amount of vitamin D in the food supply would alleviate some of these concerns.

IV. Prohibition of 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 sources of industrially produced *trans* fats are partially hydrogenated oils (PHOs), which are produced through a process called partial hydrogenation. PHOs are often used to manufacture 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 (CHD), one of the leading causes of death in Canada. Large observational population studies (see footnote 3) have shown that the risk of CHD 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 NAM and the WHO, 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. 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. As a result of this decision, certain amendments to the FDR are required, including adding the definitions of "partially hydrogenated" and "fully hydrogenated," removing references to PHOs and ensuring the language in the FDR is consistent with that of the incorporated list.

V. Labelling requirements for certain high-intensity sweeteners

Sweeteners, including high-intensity sweeteners, are regulated as food additives in Canada. To date, Health Canada has authorized a number of food additives for use as sweeteners, of which some are high-intensity sweeteners. (see footnote 4)

As with all food additives, the presence of sweeteners in a food must be declared in the list of ingredients (LOI). In addition to this "core" food labelling requirement, foods containing any of the four high-intensity sweeteners aspartame, sucralose, acesulfame-potassium and neotame are also subject to the following additional 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 with the LOI; 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 (PKU). 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 PKU 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 all 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 (PKU), 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 high-intensity sweeteners (e.g. saccharin, steviol glycosides), and such labelling is not required for ingredients of concern, such as priority 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.

Objectives

The objectives of the proposed 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 sodium, sugars and/or saturated fat to help reduce consumption of these nutrients.

II. Enable efficient and timely updates to nutrient content claims in the future.
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 prohibition on the sale of foods that contain PHOs.
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. Front-of-package nutrition labelling

The proposed Regulations would amend the FDR to add a new front-of-package (FOP) labelling requirement for foods containing nutrients of public health concern (sodium, saturated fats and/or sugars) at or above a certain threshold to enable Canadians to more easily identify foods high in these nutrients and help reduce potential health risks.

General rules

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

***Nutrition symbol and its attributes*:** The nutrition symbol and its attributes would be described in the *Directory of Nutrition Symbol Formats*, which would be incorporated by reference into the FDR. A definition for this Directory is proposed, as well as a hierarchy of formats for both a standard format (with an English and a French version) and a bilingual standard format. Additional research and a separate and parallel consultation process will be undertaken over the coming months to finalize the design of the nutrition symbol. Further information is available on the Government of Canada's website. (see footnote 5)

***Thresholds for prepackaged products for the general population*:** The proposed thresholds for prepackaged products would align with 15% of the Daily Value (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, or per 50 g for foods that have a serving of stated size and reference amount less than 50 g and that contain at least 5% of the DV of the nutrient of concern per reference amount or serving of stated size, whichever is greater. If a food exceeds the threshold for sodium, sugars and/or saturated fat, then the FOP nutrition symbol for that

nutrient (or nutrients) would have to appear on the label.

The proposed 15% DV threshold is based on analyses that took into account intake recommendations, dietary survey data [Canadian Community Health Survey (CCHS), Cycle 2.2, Nutrition (2004)], and food composition data. Based on this CCHS data, daily consumption of foods exceeding the 15% DV threshold would lead to excess intakes of sugars, sodium and saturated fats; hence, increase the risk of adverse health outcomes associated with these nutrients. Based on food composition data, the proposed thresholds are consistent with a recommended overall healthy eating pattern. Foods to choose more often, such as fruits and vegetables, would not be required to display a nutrition symbol, whereas many foods whose consumption should be limited, such as cookies, ice cream, sausages and sugar-sweetened beverages would likely display the symbol. It is noteworthy that the proposed 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.

Reference amounts are standardized amounts of foods, set out in Health Canada's *Table of Reference Amounts for Food*, that are typically consumed at an eating occasion. In general, the serving of stated size must be set as close as possible to the reference amount following the criteria set out in the *Table of Reference Amounts for Food*, but may also differ from these amounts, in the case of foods represented as "single servings" or foods sold in pre-portioned units.

The requirement to adjust to 50 g would apply only to foods that contain at least 5% of the DV of the nutrient of concern per reference amount or serving of stated size, which is consistent with the threshold for the "source of" nutrient content claim. According to dietary intake data, excess intakes of nutrients of concern are the consequence of consuming two types of foods. The first type is foods that are high in the nutrient of concern due to the large amount typically consumed. The per serving of stated size and per reference amount bases for calculating the amount of the nutrient are intended to identify these foods. The second type is foods that are typically consumed in smaller amounts but that are concentrated sources of these nutrients. For example, in the case of sugars, categories with smaller reference amounts (less than 50 g), such as jams and preserves, confectionery, breakfast cereals and sweet baked goods, make up approximately 25% of total sugars intake. The per-50 g basis for calculating the amount of the nutrient is needed to ensure that foods that make a significant contribution to excess intakes display the FOP nutrition symbol.

The 50 g basis is also consistent with the approach taken for nutrient content claims to ensure they are not used in a misleading manner. The 50 g basis is applied to prevent claims such as "low in sodium" and "low in saturated fat" from being displayed on foods that are high in the

nutrient of concern on a per weight basis but that are consumed in such small amounts at a single eating occasion that the disqualifying thresholds are not met. Similarly, displaying the FOP nutrition symbol on foods with smaller reference amounts would ensure that consumers are not misled to believe that such foods are not high in sodium, sugars and/or saturated fat and that they do not contribute to excess intakes of these nutrients.

Some exceptions are proposed to the above-mentioned approach. There is evidence for the dietary replacement of saturated fat with monounsaturated and polyunsaturated fat in reducing the risk of chronic disease. Therefore, Health Canada is proposing to make an exemption from this small reference amount adjustment for saturated fat, provided that the product meets the criterion for a cardio-protective fatty acid profile (no more than 30% of total fat content of the food is composed of saturated fat and/or *trans* fatty acids).

***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, proposed thresholds for foods intended solely for children one year of age or older but less than four years of age would be linked to 15% of the DV for that age category, following the approach described above for the general population.

***Thresholds for prepackaged meals and main dishes*:** The thresholds proposed for prepackaged meals and main dishes that have a serving of stated size of at least 200 g would be based on 30% of the DV rather than 15%. This higher threshold is necessary because these products contribute more nutrients to the diet than do individual foods.

Exemptions

For technical, nutritional or practical reasons, the following food categories would be exempt from the requirement to display a nutrition symbol. The conditional and full exemptions align with those for the Nutrition Facts table. The full exemptions have been expanded to include foods for which there is scientific evidence for a protective effect on health. These are foods which Health Canada does not want to discourage consumption.

***Conditional exemptions*:** In line with the exemptions from displaying a Nutrition Facts table, the following prepackaged products would be conditionally exempt from the nutrition symbol requirements:

- Alcoholic beverages with more than 0.5% alcohol (these products are conditionally exempt from nutrition labelling requirements 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 that are not ground, or raw single ingredient marine and freshwater animal products (since

these products are considered less standardized than ground meats, which make deriving accurate nutrient values challenging);
- 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 roadside stand, craft show, flea market, fair, farmers' market or sugar bush by the person who prepared and processed the product (to alleviate the impact of the nutrition symbol 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 packaged, if labelled by means of a sticker and the available display surface is less than 200 cm^2 (due to 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 would 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 paragraph B.01.401(2)(b), subsection B.01.401(3) or section B.01.467 of the FDR are present. For example, this exemption would be lost if the label refers to calories or a specific nutrient, the food contains added vitamins or mineral nutrients, or the label or advertisement for a food contains a nutrient content claim.

***Full exemptions*:** Exemptions that always apply to the NFt would also apply in the case of the nutrition symbol.

The following prepackaged products would be fully exempt from the nutrition symbol requirements:

- Fresh, frozen or canned vegetables and fruits or any combination of these foods without any added ingredients except water and approved food additives (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);
- 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)];
- Individual portions of food that are solely intended 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)];

- Cow and goat's milk products sold in refillable glass containers (since the available labelling space is limited to the lid, and to help alleviate the impact on small businesses);
- Non-flavoured whole and partly skimmed milk, obtained from any animal, in liquid or powder form (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 recommended in Canadian dietary guidance; it is not necessary to exempt skim and 1% milk as they would not meet the threshold for a "high in saturated fat" symbol);
- Whole eggs, in fresh, liquid, frozen or powdered forms (meet the criterion for a cardio-protective fatty acid profile and sits right at the 15% DV threshold);
- Sweetening agents, as defined in subsection B.01.001(1), which include sugar, honey, syrups and molasses (these products are all or mostly all sugars and are used by consumers for sweetening purposes in different amounts depending on application, such as coffee/tea, baked goods, toppings, etc. Having a nutrition symbol for "high in sugars" on these products would be redundant);
- Salt for table use or general household use and salts listed in Division 7 of the FDR, specifically celery salt, garlic salt, and onion salt (similar to the situation for sugar, it would be redundant to require a "high in sodium" nutrition symbol on a package of salt); and
- Individual operational rations for military use (since a nutrition symbol could discourage this population from consuming rations formulated to meet their specific needs).

In addition, the use of the nutrition symbol would be prohibited on the following categories of foods for special dietary use in divisions 24 and 25 of the FDR: formulated liquid diets, foods represented for use in a very low energy diet, 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 was discouraged as a result of an FOP nutrition symbol.

Since there are no DVs for sodium, sugars and saturated fat applicable to infants six months of age to less than one year of age, foods targeted to this age group would also be prohibited from carrying a nutrition symbol. This would be 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 —, the proposed 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 proposed formatting requirements for the nutrition symbol would be included to ensure legibility:

- The size of the symbol would be proportional to the size of the principal display surface (PDS) of the package (including small options for small packages) and is listed as part of a hierarchy in a manner similar to the existing hierarchies for the Nutrition Facts table formats;
- A minimum buffer zone would be specified for each symbol in the *Directory of Nutrition Symbol Formats*, which creates a safe area around the nutrition symbol and ensures it is distinct from the background. The size of the minimum buffer zone is relative to the size of the symbol. While background textures or patterns in the label design may appear within the buffer zone, no text could appear within the buffer zone;
- The symbol would be oriented in such a manner that its text is readable from left to right and is parallel with the base of the package; and
- The symbol would have a minimum distance from the edge of the PDS in the case of cylindrical containers.

***Location of the nutrition symbol*:** The nutrition symbol would be required to be placed on the upper 25% of the PDP on most packages. Placing the nutrition symbol in a consistent location across products would facilitate consumers' ability to quickly and easily notice the symbol. This is consistent with feedback from consumers during consultation and focus group testing. To accommodate package design of foods that are packaged in horizontal packages where the height of the PDS is less than its width, the nutrition symbol must be displayed on the right-most 25% of the PDP.

***Use of other voluntary nutrition and health-related statements, claims or symbols on the PDP*:** Any quantitative statement as described in section B.01.301 of the FDR and nutrition or health-related statement, claim or symbol described in sections B.01.311, B.01.503 to B.01.513 and subsection B.01.601(1) would not be permitted to appear on the top area of the PDP (either the top or right-most 35%) of a product that carries a nutrition symbol. If these messages are used in close proximity to the nutrition symbol, they could reduce consumers' ability to quickly identify and interpret the nutrition symbol. This would undermine the effectiveness of the nutrition symbol, which is there to provide quick and easy guidance to help consumers make informed choices, and its message. In the case of any nutrition or health-related statements,

claims or symbols that appear on the remaining 65% of the PDP, it is proposed to require that the height of the text used in the statement or claim (either in upper case letters or the tallest ascender of lower case letters in the text) not exceed two times the height of its equivalent on the nutrition symbol.

***Imitation symbols*:** A provision would protect the integrity of the nutrition symbol by prohibiting the use of any other symbol on food packages that so closely resembles the nutrition symbol that it is likely to be mistaken for it.

II. Nutrient content claims and other nutrition-related statements

In order to enable more efficient and timely updates to nutrient content claim requirements, the table of nutrient content claims following section B.01.513 of the FDR would be repealed and incorporated by reference in the FDR as a new Table of Permitted Nutrient Content Statements and Claims. This approach would be consistent with provisions regarding other tables that were recently incorporated by reference as part of the 2016 nutrition labelling regulations (e.g. the Table of Daily Values, the Directory of Nutrition Facts Table Formats and the Table of Reference Amounts for Food). This repeal would require some consequential amendments to the FDR in order to replace references to "the table following section B.01.513" with "the Table of Permitted Nutrient Content Statements and Claims" (the Table).

Section B.01.509 would also be repealed, as the "unsweetened" claim currently permitted in this provision would now be included in the Table of Permitted Nutrient Content Statements and Claims. A number of other changes would also be made to the Table to be incorporated by reference. These proposed changes along with the proposed Table are provided in the *Notice of Proposal: Incorporating by Reference the Table of Permitted Nutrient Content Statements and Claims* (Reference No. NOP/ADP-NCC-2017-1), which is available on the Government of Canada's website for review and consultation. (see footnote 6)

The FDR would also be amended 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 would provide factual information for consumers. Currently, this information is not permitted on beverages containing 0.5% alcohol or less by volume, which does 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" would be updated to reflect the new DV age categories, which have also been implemented under the 2016 nutrition labelling regulations.

III. Vitamin D fortification

The FDR would be amended to increase the level of vitamin D in cow's milk, goat's milk and margarine. For consistency with the new DV for vitamin D, quantities described in the FDR would be based on micrograms (µg) rather than international units (IU). For clarity and ease of calculation, the amendments to the goat's milk provisions and the milk standards would 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 levels of vitamin D, currently prescribed in the milk standards, would be replaced with a single level of 2 µg/100 mL (the current range is equivalent to 0.9 to 1.2 µg/100 mL). For margarine, the FDR would be amended to increase the level of vitamin D to 26 µg/100 g (the FDR currently prescribe an amount equivalent to no less than 13.3 µg/100 g and no more than 17.5 µg/100 g).

IV. FDR amendments related to the prohibition of PHOs

Given the decision to prohibit the use of PHOs in foods, targeted amendments to the FDR are required to define "partially hydrogenated" and, in order to enhance clarity, 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 would be replaced with "oils that have been fully hydrogenated" or "fully hydrogenated X oil," to eliminate all references to PHOs.

V. Labelling of foods containing certain high-intensity sweeteners

Health Canada is proposing to repeal 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 with the LOI.

The mandatory requirement that the label of foods containing aspartame declare the presence of phenylalanine is being retained. However, to bring further prominence to this statement and to further align Canadian and U.S. labelling requirements, changes would be made to how the statement may be expressed. The following format and placement specifications would also be

prescribed in the FDR:

- Products containing aspartame must either include the statement "Phenylketonurics: contains phenylalanine" or a statement to the effect that aspartame contains phenylalanine.
- The phenylalanine statement must follow the LOI and may appear on the same line as the LOI or on a separate line (and before any allergen-related "contains" statement and/or precautionary declaration). This statement would be in bold, would have a font size consistent with the requirements for other text in the delineated list of ingredients area, and would be prescriptive with respect to the wording for the option that refers to "Phenylketonurics" but not with respect to the wording of the other option (the requirement for which would remain as currently worded in the FDR).
- The sequence of statements following the LOI 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 LOI 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 is provided 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.

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 require the use of prescriptive wording for the declaration, which was not the intent. The FDR would therefore be 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 nuts" and "May contain fish."

VII. Coming into force and transitional provisions

The proposed Regulations would come into force upon publication in the *Canada Gazette*, Part II, with the exception of provisions related to vitamin D, which would have a six-month delayed coming into force.

The proposed Regulations would modify the end date of the original transition period for the 2016 nutrition labelling regulations, from December 14, 2021, to December 14, 2022. The other components of this regulatory proposal would also be subject to a transition period ending in December 2022. This alignment of transition periods would allow sufficient time for industry to change its labels and use existing label stock to comply with current requirements. The only exceptions are the provisions related to PHOs, which come into force upon publication in the *Canada Gazette*, Part II, without any transition period.

Alignment of the transition period for the proposed Regulations with that of the 2016 nutrition labelling regulations is proposed to facilitate the required changes. Manufacturers can choose to comply with one set of requirements before the other, as long as they comply with all requirements by December 14, 2022. This measure gives manufacturers flexibility in managing their label changes.

However, milk and margarine that comply with either the new vitamin D fortification provisions or the new NFt provisions in the 2016 nutrition labelling regulations must comply with the other. This is necessary because the DV for vitamin D was increased as part of the 2016 nutrition labelling regulations, and updates to vitamin D levels, which are not commensurate with the change to the DV, will be reflected in the "% DV" amount listed on the NFt. To minimize consumer confusion, the transition to new vitamin D levels and the new DV must happen simultaneously such that the % DV on product labels changes only once. This is also the reason for the proposed six-month delayed coming into force for the provisions related to vitamin D, so that manufacturers will have sufficient time to update labels if they have already complied with the nutrition labelling regulations introduced in December 2016.

Regulatory and non-regulatory options considered

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 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

Many Canadians use the existing nutrition information on food packages to make informed choices when selecting foods, either to maintain good health or to help manage diet-related chronic diseases. However, they still find the information too complex or are limited either in time or motivation to consult the information. Maintaining the status quo would not give

Canadians as much information, nor make information as accessible for them, to make choices about their consumption of sodium, sugars and saturated fat.

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 19% of packaged foods between March 2010 and April 2011. 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 are also considered FOP nutrition labelling systems; Smiles in Metro stores and Guiding Stars in Loblaws stores are examples of shelf-tag systems.

The vast majority of health stakeholders and many consumers agree that the status quo does not protect the health of Canadians. 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 also 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 set 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, prepublished 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 (recommended option)

At the international level, the NAM, formerly the IOM, which was commissioned in 2011 by the U.S. Congress to develop guidance on FOP labelling, supported the use of such labelling (see footnote 7) and recommended the use of a single, standardized FOP system that can be easily understood by most consumers to simplify and clarify nutrition information.

In addition, the joint WHO/FAO international food standard setting body, the Codex Alimentarius Commission, through its Codex Committee on Food Labelling (CCFL), supported 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 CCFL, which includes representatives from 53 countries and 19 non-governmental and international organizations, unanimously endorsed a proposal (see footnote 8) to consider the role of Codex in providing guidance on FOP nutrition labelling to

governments and industry. The CCFL further encouraged member countries that were planning to develop and implement FOP labelling systems, to proceed with their work. (see footnote 9)

In Canada, considerable interest in FOP nutrition labelling has been 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 (sodium, sugars and saturated fat) is viewed by Health Canada as the best enhancement to current food labels to help reduce Canadians' 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.

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

(a) Traffic light approach

Traffic light systems provide a high, medium or low rating for each nutrient of concern. Such an approach is not proposed because research shows that consumers find it difficult to use traffic light labels when there is a combination of different colour ratings. To alleviate the cognitive burden, consumers focus on avoiding foods with red, or high, ratings. Research also shows that comparisons among products can be challenging with this type of label. Also, traffic light symbols can create a health "halo" on foods that are not necessarily consistent with dietary guidance. For example, a soft drink could display two green ratings (saturated fat and sodium) and one red rating (sugars).

(b) National Academy of Medicine's approach

The U.S. Government funded the NAM to provide recommendations on an FOP system. The approach, published in 2012, 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 within the symbol. Such an approach is not proposed because consumers

could have difficulty understanding which nutrients are targeted or why a food is labelled with the symbol. Furthermore, due to the use of stars or checkmarks, the NAM symbol could be perceived as a government endorsement of foods that meet one or more nutrient criteria, which is not the objective of this proposal.

(c) Summary approach

Summary approaches use calculations to rate the nutritional profile of a food. This type of approach includes both nutrients of concern as well as positive ones. Such an approach is not proposed because studies have shown that consumers are less likely to identify better food choices using summary schemes, compared to nutrient-specific approaches. Furthermore, it can create a health "halo" effect, similar to the traffic light option. Last but not least, it would be less likely to encourage the availability of foods with lower amounts of sodium, sugars and saturated fats, compared to an approach that provides explicit interpretive information on these nutrients. Many of the existing summary approaches currently used in Canada are based on proprietary algorithms from the private sector, retail industry or food industry that extend to characteristics beyond just the nutrient profile of the food.

(d) Fact-based approach

Fact-based systems such as Facts Up Front or Guideline Daily Amounts 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 type of approach is not proposed because research shows that among all of the options, fact-based approaches are the least easy for consumers to understand and use. Fact-based approaches do not reduce the cognitive burden of interpreting nutrition information, compared to the Nutrition Facts table. Consumers are better able to evaluate food products that use simple, interpretive systems (such as "high in" statements) compared to fact-based systems.

(e) "High in" approach (recommended approach)

The "high in" approach would be the most effective FOP labelling strategy. It would complement existing labelling measures to enable Canadians to make choices that would help them improve their health and reduce their risks of chronic disease. As an important part of a comprehensive suite of policies, the "high in" approach is the preferred option to achieve the objectives of this proposal. The proposed approach provides quick and easy guidance on foods that are high in saturated fat, sodium and/or sugars because the symbol is noticeable, simple, informative and interpretive. It does not require consumers to reconcile different combinations of high, medium and low ratings for nutrients of concern, nor does it require consumers to

interpret nutrient amounts or % DV to make a decision. The proposed approach also encourages manufacturers to offer foods with amounts of sodium, sugars and saturated fat below the established thresholds to avoid the use of the nutrition symbol.

Option 3: Voluntary government-led approach

Voluntary implementation of a government-led approach would not achieve the objectives of this proposal. With a voluntary approach, manufacturers may choose not to display a symbol, particularly on foods with an unfavourable nutrient profile. Early evaluations of the Health Star Rating system in Australia and New Zealand indicate that adoption has been poor. Two years after implementation, only 5% of packaged food and beverages displayed the symbol in New Zealand. 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 New Zealand, most products that display the symbol have higher ratings; very few display low ratings. 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 lower in sugars, sodium and saturated fats.

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 address key challenges relating to efficiently amending nutrient content claims and nutrition-related statements. For example, the GIC regulatory amendment process is still required to make regulatory changes, including those based solely on scientific or technical information. This is a lengthy process and Health Canada has at its disposal regulatory authorities, such as incorporation by reference, which allow for more efficient and responsive regulation of such claims. Finally, changes are required to certain nutrient content claims and nutrition-related statements to ensure consistency with the new FOP labelling requirements proposed in this regulatory proposal.

Option 2: Regulatory approach (recommended option)

Currently, manufacturers may voluntarily choose to use nutrient content claims on their food labels. However, the conditions of use for nutrient content claims and nutrition-related statements are prescribed in the Regulations. Repealing the table of permitted nutrient content statements and claims following section B.01.513 and incorporating by reference the Table of Permitted Nutrient Content Statements and Claims would provide Health Canada with greater

flexibility and add 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 would be 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 would allow for some needed updates to current requirements (e.g. updating the age categories to reflect the new dietary reference intakes (DRIs) published by the NAM and NFt age groups).

III. Vitamin D fortification

Option 1: Status quo

In 2011, the NAM 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. These rates are higher in certain subpopulations, including those with dark skin and those who are obese. 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

In order to improve the vitamin D intakes of Canadians, Health Canada considered modifying dietary guidance (i.e Canada's Food Guide) by making adjustments to the amounts and types of foods that are recommended to be consumed by Canadians. However, since there are few foods that contain vitamin D in the Canadian food supply, increasing the vitamin D intake would be limited to increasing the recommended amounts of milk and/or margarine that should be consumed, which is not feasible or realistic. Health Canada also considered recommending a dietary supplement. Drawbacks to this approach (e.g. compliance likely to be poor in those who could benefit most, possible increase in health disparities, added cost to the consumer) outweighed the benefit.

Option 3: Regulatory approach (recommended option)

Changes to the levels of addition for foods that must contain vitamin D would result in large increases to Canadians' vitamin D intakes, since these foods are the major contributors to vitamin D in the diet. Increasing the mandatory level of vitamin D to be contained in milk and margarine 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 promote adequate bone health in the population with a particular focus on preventing or minimizing risk of deficiency without incurring risk of excessive intakes.

IV. FDR amendments related to the prohibition of PHOs

The proposed amendments described in this package are required for consistency with the proposal to prohibit the sale of foods containing PHOs. Without also making these amendments to the FDR, the prohibition would be incoherent: the FDR would contain certain food standards that would permit the use of PHOs as ingredients, while the inclusion of PHOs in the *List of Contaminants and Other Adulterating Substances in Foods* would deem those foods to be adulterated.

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 (recommended 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 proposed in this regulatory package.

Benefits and costs

The cost-benefit analysis (CBA) sought to quantify the proposed benefits and costs of making amendments to the FDR with respect to the content of nutrition labels on prepackaged products sold in Canada. The amendments include the addition of requirements for prepackaged products to carry a new front-of-package (FOP) nutrition symbol where the prepackaged product meets or exceeds set thresholds for one or more nutrients of concern. They also include an increase to the amount of vitamin D in milk, goat's milk and margarine. The analysis identified two groups that would be directly impacted by the amendments: Canadian consumers and the Canadian food manufacturing and retail industry. The proposed changes to the labelling requirements for foods containing certain high-intensity sweeteners and to nutrient content claims would not present any additional cost to industry. All calculations of cost and benefit occur over a 10-year period, and the net present value is discounted by 7% as required by the Treasury Board Secretariat. (see footnote 10)

According to the Public Health Agency of Canada, approximately four out of five Canadians have at least one modifiable risk factor for chronic disease. (see footnote 11) Healthy eating is a modifiable risk factor and an important component of Canadians' health, which in turn can have a direct impact on the Canadian economy. Time away from work due to sick days and lost productivity due to ill health represent indirect health costs that can lead to lost economic production. Further, the health of the population is of importance to policymakers, since health care spending in Canada, when federal health transfers and respective provincial/territorial (P/T) health budgets are considered, is one of the largest expenditures by governments. A report by the Canadian Institute for Health Information (CIHI) projected that direct health care costs alone were close to $215 billion in 2014, representing approximately 11% of the Canadian gross domestic product (GDP) in 2014. Direct costs in this case would not only include coverage for health services in P/T jurisdictions (i.e. hospital and health practitioner care, drug formulary), but also costs for insurers, such as drug benefits schemes, and out-of-pocket expenses for services not covered through public or private insurance.

There are approximately 31 154 firms operating in Canada that would be directly or indirectly affected by the proposed amendments, of which approximately 26 700 would be small or medium-sized enterprises (SMEs). The food manufacturing industry alone accounted for approximately $112.2 billion in yearly revenues and injected approximately $27.8 billion into the Canadian economy. (see footnote 12) Canadian manufacturers in the catchment of the CBA represent non-alcoholic beverage manufacturers; eggs, poultry and meat processing; retail and grocery products that are produced in-house or through private label; raw dairy or refined products; importers and exporters of food products (for example cake icing manufacturing and distribution, confectionery produced abroad and imported into Canada); the baking and milling industry; and large manufacturers of processed foods. Approximately 37 600 products, measured as stock keeping units (SKUs), would be impacted by the nutrition symbol amendments. It is estimated that 2 000 milk and margarine SKUs would be affected by the vitamin D amendments, based upon 2016 data from AC Nielsen.

The CBA examined whether health outcomes, therefore health spending, could be reduced for four different chronic diseases that were most linked to diet and nutrition. The selected diseases were cardiovascular disease, malignant neoplasms, diabetes mellitus and musculoskeletal disease. These four diseases accounted for approximately $26.7 billion annually in both direct and indirect health expenses and represented approximately 52% of all-cause mortality in 2013. (see footnote 13)

The FOP amendments are based on the assumption that offering consumers a simplified and visible indicator on foods that are high in sugars, sodium and saturated fats would gradually decrease their risks of chronic diseases related to excess consumption of foods high in these

nutrients over time. A conservative approach of a 1.5% improvement in health outcomes was applied to estimate the anticipated benefits for the four chronic diseases. By comparison, the approach taken by the U.S. Food and Drug Administration (FDA) in its assessment of benefits from improved nutrition labelling used a 3% benefit measure for the label as a whole (i.e. NFt, ingredients list, health claims), measured as a population welfare gain. The improvement in health outcomes was compounded annually over 10 years. Anticipated savings were calculated to be approximately $429 million annually over a 10-year period. It is anticipated that total benefits would amount to $3.19 billion or $2.36 billion net present value. It is anticipated that the impact of a small improvement in health outcomes would be compounded over a 20–30 year period.

The Canadian food industry provided costing input through a consultation and survey process coordinated by the respective industry groups. Industry groups were asked to provide all costs associated with changing their FOP product label. These estimates were based upon policy input shared in the pre-consultation white-paper *Toward Front-of-Package Nutrition Labels for Canadians*, which was open for comment from November 14, 2016, to January 13, 2017. The survey, in order to minimize the response burden on industry, used a broad policy approach in the creation of questions for respondents; therefore, some industry estimates take into account some provisions that may fall outside of the scope of the proposed rule. In order to remain conservative in the CBA estimates, industry was asked to provide estimates based upon the highest cost scenario; however, in most instances, estimates were provided for minor, medium and major label changes. Allowing the option of providing the highest cost scenario also allowed industry stakeholder groups to provide costing data, since one of their greatest concerns was an underestimation of costs in an area that would directly affect their membership. Using this approach meant industry impacts would not be underestimated.

Industry input was also based on the assumption that the transition period for FOP labelling would be three years. Stakeholder input on label change also indicated that a five-year transition would reduce costs by 50%. While data specifically for a four-year transition was not submitted, if a linear relationship is assumed, costs would fall between those two limits of $583.0 million and $1.17 billion. Furthermore, the proposed change to the Nutrition Facts table transition period would reduce the burden on industry of making that label change as well, further benefiting industry by allowing it to make one label change during the proposed transition period, and giving additional flexibility to time such a change with other label changes done for market purposes.

Due to the variability of figures provided by industry respondents and the need to include all industry input, an adjusted weighted figure was used to collate and account for all cost estimates. The adjusted weighted figure applies the mean value of all submitted values within

the response range (i.e. mean) of each cost per stock keeping unit (cost/SKU) value and applies a higher weight to products from major manufacturers following the assumption that their proportion of cost-intensive printing requirements would be higher than the mean. Using a cost-per-SKU estimate that applies an adjusted weight, the cost per SKU would be $23,260 or $817.4 million in net present value (NPV) as a one-time compliance cost to industry. If the mean (i.e. medium range estimate) is used, the average cost per SKU would be $17,445 or $613.0 million NPV.

Table 1: Cost-benefit analysis (all values in 2017 dollars) (see note *)

A. Quantified impacts ($)				
	Base Year **Year 1**	**Final Year** **Year 10**	**Total (PV)**	**Annualized Average**
Benefits **Indirect cost savings**				
Cardiovascular disease	$1.56M	$1.79M	$12.46M	$1.67M
Malignant neoplasm	$2.81M	$3.26M	$22.44M	$3.01M
Diabetes mellitus	$0.21M	$0.24M	$1.65M	$0.22M
Musculoskeletal disease	$0.042M	$0.048M	$0.335M	$0.045M
Total indirect health care cost savings	$4.62 M	$5.33M	$34.47M	$4.95M
Direct cost savings				
Cardiovascular disease	$197.09M	$225.35M	$1.57B	$210.94M
Malignant neoplasm	$64.53M	$73.78M	$514.73M	$69.06M
Diabetes mellitus	$36.72M	$41.98M	$292.88M	$39.30M
Musculoskeletal disease	$97.44M	$111.41M	$777.28M	$104.29M
Total direct healthcare cost savings	$395.77M	$452.52M	$3.16B	$423.58M
Total benefits	**$400.38M**	**$457.84M**	**$3.19B**	**$428.53M**
Cost **Industry — one-time compliance**				
FOP nutrition symbol: $23,260/SKU	$874.58M		$817.4M	

Vitamin D: $10,000/SKU	$20.0M		$18.69M	
Total cost	**$894.58M**	**$0**	**$836.05M**	
Net benefit	**–$494.2M**	**$457.84M**	**$2.36B**	
B. Qualitative impacts				

Benefit

Reduced loss of productivity due to morbidity resulting from unhealthy eating patterns.

Adoption of healthy eating habits as a child leading to healthy eating habits as an adult.

Positive vital health indicators.

Improved health outcomes and prevention of certain chronic diseases for Canadians as a whole.

Potential increase in market share for some food commodities and foods not impacted by the FOP nutrition symbol (fruits and vegetables, pulses, etc.).

Extension of NFt transition allows the possibility of further savings due to only having to make one label change to cover both requirements by 2022.

Cost

Increases in labelling costs may have to be absorbed by Canadian consumers due to increases in food prices to recover costs.

Opportunity costs lost from product innovation in order to comply with proposed Regulations in approximately three years.

Loss of market share due to carrying an FOP nutrition symbol.

Note *

If following consultations, a black and white symbol is chosen, the cost of the FOP nutrition symbol would be reduced to $603.7 million or $564.2 net present value.

Using a one-time compliance cost that applies a weight-adjusted average cost per SKU provides the most accurate estimate of total industry costs based upon all input received by industry, while a median figure corresponds to the most common cost per SKU figure provided by industry. If the mean and mean weight-adjusted estimates are extrapolated to a cost per company, estimates are between $20,934 and $27,912 (including manufacturers and impacted retailers) in individual company compliance burden. A greater compliance burden would be borne by major manufacturers.

The estimated costs to implement the proposed vitamin D amendments used the highest cost per SKU estimate provided in the survey responses, which was $10,000/SKU or $18.69 million NPV, in order to avoid any chance of underestimating the proposed regulatory impact. The majority of these costs were associated with changes required to adjust the Nutrition Facts

table (NFt) and would be unique to the proposed Regulations. They would not include any activities from previous regulatory amendments to the product label (i.e. NFt and list of ingredients). The costs associated with fortifying products with vitamin D to the proposed levels was identified as negligible in the survey responses.

The estimated costs and benefits of these amendments are shown in Table 1, with a present value health benefit of $3.19 billion over a 10-year period. Estimated costs to industry amount to a present value of $836.1 million, while net present value benefits amount to $2.36 billion. The anticipated benefits to consumers would be slightly less than three times greater than the costs.

A full cost-benefit analysis report containing a more detailed analysis will be made available upon request.

Costs

Costing estimates were provided by industry organizations through a costing survey consultation process, and supplemented by policy consultation submissions and case studies from a literature review. Jurisdictional comparisons were limited, as Canada is one of a few countries to propose the implementation of a mandatory FOP nutrition symbol. Costing input and assumptions for the proposed vitamin D amendments are related to updates to the Nutrition Facts table (NFt), while costs to increase the amount of vitamin D were determined to be negligible based upon industry feedback.

There are an estimated 80 000 product SKUs currently on the market; however, not all would require a nutrition symbol or vitamin D fortification. Based upon industry responses and consultation submissions, it is estimated that approximately 47% of all product SKUs would require a nutrition symbol; this represents 37 600 SKUs. Further, the proposed vitamin D fortification regulations are conservatively estimated to impact 2 000 SKUs. Canadian industry groups provided estimates from the following sectors:

- non-alcoholic beverages;
- eggs, poultry and meat processing;
- retail and grocery products that are produced in-house or under a private label;
- dairy;
- importers and exporters of food products;
- baking and milling; and
- large manufacturing corporations of processed foods.

A number of respondents submitted their costing estimates referencing a report created for Agriculture and Agri-Food Canada's Food Processing Industry Roundtable (FPIRT), which

represents the food and beverage companies and associations within the processing sector. The FPIRT's key objectives are to understand the challenges and opportunities faced by the industry as well as the state of the business environment in Canada, and develop industry–government actions to improve the competitiveness, profitability and growth of the food industry.

The report from the FPIRT titled *Response to Labelling Changes Proposed by Health Canada and the Canadian Food Inspection Agency* estimates the compliance costs related to the nutrition labelling regulations, introduced in December 2016, and the proposed labelling changes from the Canadian Food Inspection Agency's Food Labelling Modernization initiative, as well as Health Canada's front-of-package labelling initiative.

Due to the approximately four-year implementation period for the proposed FOP nutrition symbol regulations, it was assumed that more external resources would be required in order to comply with the proposed amendments. Total costs are provided over a low, medium and high range; all estimates include a cost-weighted adjustment. Within the cost estimates, which are presented as costs per SKU ($/SKU), industry stakeholder organizations identified the following factors as implications on costs due to the proposed amendments:

Front-of-package label

The reformatting of the whole product label and the timing of when these changes would occur represent the highest cost factors faced by the Canadian food industry.

In order for new labels to be created, new graphic designs would have to be developed. Costs are most dependent on whether or not the design is being done internally or externally and the length of time required to complete the design change. A number of respondents indicated that a longer transition period could significantly reduce these costs; however, nearly every respondent acknowledged that all changes to the product label would be made at the same time. Therefore, many manufacturers indicated that no changes would be made to their product label until all proposed labelling regulations were finalized, which would decrease the time to design the new labels and increase these associated costs significantly. This cost analysis only includes costs associated with the changing of the FOP nutrition system. Design costs alone ranged from $2,000/SKU to $12,000/SKU; the majority of costs were close to $10,000/SKU.

There are a multitude of methods by which, and many different label surfaces on which, a label can be printed. Regardless of which method is used, the creation of a new printing plate is required. Industry did raise some concerns regarding the label size, specifically whether or not it would be required to increase to the total product package size in order to comply with the proposed FOP regulations. Further, respondents indicated that given the implementation of a

nutrition symbol with colours other than black, the costs of additional colours could reach as high as $15,000/SKU on colour plates alone. The estimated costs of creating new printing plates ranged from $2,000/SKU to $8,000/SKU; the majority of costs were estimated to be $5,000/SKU.

The physical label cost and the packaging that the label must be printed on were highly variable. Industry estimates ranged from $700/SKU to $10,000/SKU. The higher end of the estimate would represent a label with many colours and unique printing requirements, such as on aluminum cans.

Stakeholders indicated their preference that the nutrition symbol be black because nearly all product labels already contain this colour (i.e. the nutrition facts table, list of ingredients). A number of stakeholders expressed concerns regarding the increase in cost of having to include additional colours and colour plates in order to be in compliance with the proposed Regulations. Estimates provided by stakeholders indicated that these costs could lead to an additional $1,500 to $15,000/SKU, dependent upon the package and label complexity (i.e. printing on a paper box versus on an aluminum can). The proposed Regulations do not stipulate the colour of the nutrition symbol. The nutrition symbol must be presented in accordance with the applicable figure in the *Directory of Nutrition Symbol Formats*. This includes matters such as colour. If it is decided following consultation that a black and white label would be used, the total estimated costs of the FOP nutrient symbol would be reduced to a range of between $409.2 million to $798.3 million or $363.7 million to $746.1 million present value; the package cost would decrease to approximately $603.7 million or $564.2 net present value.

As labour costs will be associated with all aspects of the label design, many respondents found this category of questions difficult to answer. As a means of avoiding any risk of double counting, respondents were encouraged to consider their compliance burden. Labour in this instance is assumed to be human capital costs due to the proposed regulatory amendments. Some examples of tasks could be product focus groups to test package usability; coordination with regulatory authorities; or in-house or external staffing required to comply with new regulatory changes, such as updates to the product website. These costs ranged from $700/SKU to $6,500/SKU. The CBA assumes that the calculated labour costs only include one-time incremental costs to meet the requirements of the proposed Regulations. Therefore, it is assumed that no new administrative burden will be placed on industry in regard to reporting and compliance.

The length of the transition period has been identified by the food manufacturing industry as a major determinant of costs. In consultations with food manufacturer stakeholder groups, it was noted that a longer transition period would allow manufacturers to sell existing product stock and exhaust their older labels, thereby reducing product and label waste. Some survey respondents indicated that internal/external labour costs and the amount of waste associated

with paper stock would be extremely high with an 18-month to 3-year transition period. Many respondents indicated that estimated costs to industry could double if the transition period were less than 5 years. It is assumed that figures provided during the consultation period reflect a 3-year transition period and not a 5-year transition period; therefore, assumptions have been made to reflect the proposed 4-year transition period.

Table 2: Sample of FOP label costs; 37 600 SKUs

Level of change	Cost of label production (per SKU)	Total
Low	$15,505	$582,988,000
Mean	$17,445	$655,932,000
Medium (Weight-adjusted)	$23,260	$874,576,000
High	$31,010	$1,165,976,000

Based on input from industry, calculations were completed for three scenarios: a minor, a medium, and a major label change. A description of these costs is provided in Table 2. Each type of label change was calculated by taking the average of each cost component, where identified, at each label change level (i.e. minor, medium or major) and applying an additional weight-adjusted increase to the mean to better reflect the higher estimates. This adjustment was made in order to account for the disproportionately high number of labels of highest printing complexity, such as aluminum and plastic labels, which could be most affected by the proposed FOP nutrition symbol. The high estimates were applied an additional weighting in order to better reflect the potential higher cost impact for these companies. When this higher weighting is provided to the higher per SKU estimates, the average cost per label shifts up from a mean of $17,445/SKU to $23,260/SKU.

The total estimates for a four-year transition period reflects a weighted cost average figure of $23,260/SKU for approximately 37 600 labels or roughly 47% of the total SKUs in the Canadian market across 31 154 potentially affected Canadian businesses. The total cost of the proposed FOP regulations is anticipated to be $874.6 million or $817.4 million NPV.

Vitamin D fortification

Respondents were in favour of the proposed increase to vitamin D in milk, goat's milk and margarine. An increase in the amount of vitamin D required in these products would mean that the percentage of Daily Value in the NFt would appear more favourable to consumers referencing the product label. Moreover, this would be in keeping with the new Daily Values implemented in the nutrition labelling regulations introduced in December 2016.

Industry indicated that costs associated with increasing the amount of vitamin D were negligible; however, it stated that changes would have to be made to the NFt in order to accurately list the total vitamin D content. For this reason, respondents provided costs associated with updating the product label over a three-year transition period. The costs are very similar to those presented for changes to the NFt and the list of ingredients pursuant to the December 2016 nutrition labelling regulations. It was estimated that approximately 2 000 milk and margarine SKUs would be impacted by the proposed Regulations and the cost to change their label to reflect these new values would be $10,000/SKU; therefore, costs of vitamin D fortification would be $20 million or $18.69 million NPV.

Comparison with international jurisdictions

Few international jurisdictions have implemented mandatory FOP nutrition symbol initiatives. FOP food labelling schemes do exist in other countries; however, unlike the proposed Canadian regulations, most of these other schemes are voluntary or in the proposal stage. Examples include the Traffic Lights label (United Kingdom), the Health Star Rating (Australia/New Zealand) and the Nutri-Score label (France).

At the time of writing this Regulatory Impact Analysis Statement, a mandatory FOP labelling scheme exists in three jurisdictions: Chile, Ecuador and Mexico. However, costing data is only available for Chile. Estimates were not available on a per SKU basis; however, total industry costs in Chile were anticipated to be US$71 million, which reflects costs for relabelling, design change, new graphics and label losses or exhaustion of old product labels. Reformulation was identified as additional costs but was not estimated. The total number of products (which could include multiple product SKUs within a single product line) anticipated to be impacted by the regulations in Chile was approximately 9 550. If this estimate were scaled up to the Canadian food manufacturing sector, costs would be estimated to be approximately CAN$369.8 million. This estimate would be lower than the Canadian low estimate referenced in Table 2.

Since the United States does not have a mandatory FOP labelling system, alignment opportunities between the two jurisdictions would not exist; therefore, costs for Canadian manufacturers and importers would represent low economies of scale and could explain the high Canadian cost per SKU estimates.

Reformulation

A number of industry groups and individual company respondents to the survey identified reformulation as being a major cost consideration for implementing the nutrition symbol. Respondents indicated that there would be significant pressure on their product lines due to the proposed FOP requirements. For many manufacturers, there is a belief that carrying a nutrition symbol would be detrimental to their sales or reputation; therefore, to alleviate a

potential loss of their market share or reputation, reformulation would be strongly considered.

Based on figures provided through industry consultations, the average cost to reformulate is between $75,000 and $100,000 per product line (this could encompass multiple SKUs). It has been estimated through stakeholder engagement by Health Canada that approximately 20% of impacted industry would opt for reformulation for at least one nutrient of concern. The total reformulation cost due to the proposed Regulations could be between $564 million and $752 million.

While one of the desired outcomes of the proposed FOP regulations is the reformulation, where possible, of products high in sugars, sodium and saturated fats, the proposed Regulations would not require manufacturers to reformulate their products. It would be the decision of each individual business to determine whether it is most cost-effective to reformulate any products that could be required to carry a nutrition symbol; therefore, these costs are not quantified in this analysis. Since reformulation is a business decision and not mandated by the proposed Regulations, one could not include benefits from reformulation, as this activity may not occur. However, the additional year of transition would allow manufacturers to reduce the impact on revenues should they choose to reformulate, as they would have more time to find alternative ingredients or recipes.

With respect to changes to vitamin D levels, respondents indicated that reformulation costs associated with increasing the levels of vitamin D in milk, goat's milk and margarine would be negligible.

Non-quantifiable impacts

A number of potential cost impacts of the proposed Regulations were identified as being non-quantifiable during the consultation period, including the following:

— The potential impact of increasing package size in order to fit a nutrition symbol and its associated environmental effects. Some respondents questioned how initiatives to decrease their package sizes for environmental reasons could continue when the PDP space allocated for a nutrition symbol could result in an increase of their package size.

— Costs associated with the proposed amendments would most likely be passed on to Canadian consumers. There is no information available at this time to determine by how much these costs could increase; however, margins with the food manufacturing industry are slim, so an increase would be expected.

— Loss of certain products for sale on the Canadian market due to the sale of the product no longer being cost-effective. Some companies may pull their product from the Canadian market because they perceive the proposed Regulations as being restrictive. Canada has a large geographic area and low population density, which already presents many distribution

challenges; new food regulations could exacerbate this situation.

— Consumer tastes are changing and food manufacturers have been faced with pressures to produce innovative products to meet this demand. Some respondents indicated that many of these initiatives would need to be paused while updates to their product labels are underway; this was presented as an opportunity cost.

— Loss of market share due to consumers no longer purchasing certain products carrying a nutrition symbol.

The estimated one-time compliance cost to the Canadian industry would range from $603.0 million to $1.37 billion for the proposed nutrition symbol and vitamin D regulations, assuming that costs of a four-year transition would represent costs that fall between those of a three-year or a five-year transition. The combined average cost per SKU, using an adjusted weighted average, would be $23,260/SKU for 37 600 products requiring an FOP nutrition symbol, in addition to $10,000/SKU for 2 000 milk, goat's milk and margarine products subject to the new vitamin D levels. It is estimated that this would lead to a one-time total cost to the Canadian food manufacturing industry of $894.6 million, or $836.1 million in net present value dollars. This estimated one-time cost would represent 0.8% of the total $112.2 billion in annual gross revenues for the Canadian food manufacturing industry.

Distribution analysis

Most of the major food manufacturing is located in Ontario and Quebec; however, manufacturing facilities are located in nearly every province and territory according to industry consultations. There is a possibility that some manufacturing could be disrupted in order to comply with the proposed Regulations.

Some industry stakeholders indicated there is a risk that some products could cease to be sold within the Canadian market if manufacturers were unable to comply with the proposed Regulations (e.g. because of complex packaging or uniquely shaped containers). However, provisions for label scaling make this unlikely, and therefore should not be of concern. Some manufacturers, as well as Canadian grocers, have moved towards labelling products with certain nutrient content claims (i.e. low in sodium, low in fat). This practice could provide a comparative advantage over other products within the same category that do not carry claims. This advantage would be particularly apparent where other products within the same segment would be carrying an FOP nutrition symbol. Firms whose products are affected by FOP labelling may lose consumers who will choose products that do not carry a nutrition symbol; conversely, those firms that have few or no products that require a nutrition symbol will benefit. Given that spending in this sector is unlikely to change overall, meaning consumers will not spend less on food, the sector is not likely to lose as a whole, although individual firms will see changes in

revenues.

The proposed Regulations are not expected to limit consumer choice or adversely affect certain Canadian demographics. In fact, a simplified nutrition symbol on the front of the package may be of benefit to individuals who have difficulty comprehending the NFt.

Other cost considerations

The approval of the nutrition labelling regulations on December 14, 2016, with a five-year transition period ending on December 14, 2021, means that the food manufacturing industry may have made two sets of changes to their product labels. Industry has indicated that some firms have held off updating their NFts and lists of ingredients, opting instead to wait to see what the proposed FOP regulations would require, so that they could make one label change instead of two sets of changes, which is more costly. For these firms, the extension of the transition period to 2022 provides additional flexibility around the timing of a label change to coincide either with a label change made for business purposes or to time the FOP and NFt label change together to minimize the regulatory burden.

The cost-benefit analysis assumes that the *Directory of Nutrition Symbol Formats* (Directory) incorporated by reference will not change over the 10-year period of the analysis. Some of the requirements, such as the dimensions of the symbol, the characters, the colour and the minimum buffer, will be set out in the Directory, which is incorporated by reference on an ambulatory basis.

Benefits

The proposed FOP amendments are intended to provide Canadians with a simplified and visible indicator that would help them make choices that support reductions in excessive intakes of nutrients of concern, which in turn would help reduce risks to their health. An extensive literature review using peer-reviewed journals, academic position papers, government publications and stakeholder consultations yielded articles that directly linked the use of a nutrition label to many health improvement outcomes; however, few provided a measurable population-wide benefit estimate or figure. Consequently, a number of assumptions were made as a means to address this knowledge gap and to provide clear benefit estimates.

The framework that formed the basis of the benefit assumption relates to what prompts individuals to behave in a manner that is either beneficial or detrimental to their health. The health belief model, (see footnote 14) a widely accepted conceptual framework used to examine population health behaviour, is a tool used to gauge the adoption of healthy behaviour by individuals and is based on whether the individual perceives a threat to his or her health and whether this perceived threat is great enough to change behaviour. A review of the literature

indicated that consumer reliance on labels is usually high during the beginning of a label change campaign and then gradually decreases over time. The analysis for this CBA assumes a rate of reliance on FOP labelling (i.e. the continued use of a label) of 75% (increased from 50% when compared to the NFt label and ingredient list) for individuals who would refer to the proposed nutrition symbol and, by extension, the NFt and list of ingredients on the back or side of the package. This higher rate of reliance is based on the assumption that there is a nutrition symbol displayed in a more prominent location on the front label (i.e. visible to all customers at all times) and that it provides information in a quick and legible format. The benefit calculation assumes that a percentage of the population would stop using the label, so the 75% is applied as an adjuster.

The indicated use (i.e. the percentage of the population in question referring to a label) of the information on product labels ranges from approximately 44% to as high as 88%. This estimate is based on a variety of demographic variables. The majority of studies found during the literature review indicated an overall label use rate of between 60% and 75%; these two percentages formed the basis of the calculations used to determine the benefits of the proposed FOP regulations. It was assumed that due to the nutrition symbol being prominent on the PDP, reliance on the label would remain high. The literature revealed a number of common characteristics of individuals who would most likely use an NFt and, by extension, product labels on packages: individuals who are female, university-educated, have a middle income or greater, are the primary food purchaser and primary food preparer, and are a parent/guardian of younger children; people with specific dietary requirements (i.e. related to their health); and people who were aware of the relationship between diet and disease. However, a number of studies examined targeted nutrition labelling interventions, and regardless of socio-economic status, disease status or whether targeted education campaigns occurred, it was concluded that all members of Canadian society have an equal opportunity to benefit from the proposed FOP amendments. Moreover, as the NFt can be complex and difficult for some consumers to understand and use, those populations which struggle with literacy and numeracy issues would especially benefit from a simplified, interpretive tool such as the proposed FOP labelling.

The benefit calculation in the CBA assumed that a modest 1.5% improvement in health outcomes for cardiovascular disease, diabetes mellitus, malignant neoplasms, and musculoskeletal disease would amount to savings in direct and indirect health system costs, based on the selection of products with or without a nutrition symbol. The anticipated benefit was calculated by considering the following elements: the higher visibility of the nutrition symbol compared to the NFt; the fact that the format is easier to comprehend; and the selected nutrients that would trigger the requirement to carry an FOP nutrition symbol. Therefore, the

benefit calculation in the CBA only accounts for Canadians diagnosed with one of the four chronic diseases most linked to diet and who would benefit from a more informed selection of food products (i.e. consumers could avoid or minimize the purchase of products carrying an FOP nutrient symbol). The anticipated benefit from increasing the vitamin D content in milk, goat's milk and margarine products is assumed to be included within the benefit calculations for musculoskeletal disease, given the role of vitamin D in calcium absorption. Further, a study was undertaken to compare the benefits of the NFt in different jurisdictions, as there is a lack of quantifiable information available relating to mandatory FOP nutrition symbols. Even when the NFt figures were adjusted, the 1.5% estimate was determined to be at the lower bound of the anticipated benefit range. The 1.5% improvement was applied to the economic burden of illness calculations by the Public Health Agency of Canada (see footnote 15) and is compounded annually over 10 years. The cost savings are compounded annually because health improvement is assumed to be cumulative over time. Some dietary decisions could have an immediate impact, such as a reduction in blood sugars (i.e. better control for patients suffering from diabetes mellitus), while others could have longer-term benefits, such as an improved consumption of fruits and vegetables leading to a reduction in cardiovascular disease. Further, the benefit effects are anticipated to disseminate into other areas, such as prevention of disease in populations not yet suffering from the four diseases covered in the analysis. Further, in order to test the validity of the numbers, two other methods of calculating population benefits (i.e. willingness to pay and benefits of using disease-specific labels) were adjusted to the Canadian population in order to determine whether the 1.5% reduction in disease costs would yield similar results. These four disease groups account for approximately $26.7 billion (adjusted to 2017 CAN$) in yearly direct and indirect costs, as described in Table 3.

Table 3: Cost of nutrition-linked diseases in Canada (2017 dollars)

Illness	Costs (2017 dollars)		
	Direct	Indirect	Total
Cardiovascular diseases	$13,139,200,000	$104,100,000	$13,243,300,000
Malignant neoplasms	$4,301,700,000	$187,100,000	$4,488,800,000
Diabetes mellitus	$2,447,700,000	$13,800,000	$2,461,500,000
Musculoskeletal disease	$6,494,900,000	$2,800,000	$6,498,700,000
Total	**$26,383,500,000**	**$307,800,000**	**$26,691,300,000**

A sensitivity analysis showing estimated benefits, using the economic burden of illness, was calculated for 1%, 1.5%, 2% and 3% reductions in health care costs; figures are provided in

Table 4. A 1.5% improvement in consumer health due to label use would lead to an average annual reduction of $428.5 million in health care costs. Over a 10-year period, it is anticipated that total benefits would amount to $4.29 billion or $3.19 billion in present value discounted at 7%.

Table 4: Estimated benefits using economic burden of illness (EBIC) for 1%, 1.5%, 2% and 3% reductions in health care costs compounded annually (see footnote 16)

Percentage Benefit

Year	1%	1.5%	2%	3%
1	$266,922,720	$400,384,081	$533,845,441	800,768,161
2	$269,591,948	$406,389,842	$544,522,350	824,791,206
3	$272,287,867	$412,485,689	$555,412,797	849,534,942
4	$275,010,746	$418,672,875	$566,521,053	875,020,990
5	$277,760,853	$424,953,069	$577,851,474	901,271,620
6	$280,538,462	$431,327,365	$589,408,503	928,309,769
7	$283,343,846	$437,797,276	$601,196,673	956,159,062
8	$286,177,285	$444,364,235	$613,220,607	984,843,834
9	$289,039,058	$451,029,699	$625,485,019	1,014,389,149
10	$291,929,448	$457,795,144	$637,994,719	1,044,820,823
Total over 10 years	**$2,792,602,233**	**$4,285,199,275**	**$5,845,458,636**	**$9,179,909,556**

It was determined by Health Canada that a 1.5% reduction in health burden for the four chronic disease groups would be the most appropriate and conservative measure when calculating the benefits of the proposed regulatory amendments. This assumption was tested for validity using two tests used in the calculation of NFt benefits with a 25% increase in ongoing reliance on labels, based on the assumption that a more visible and easier to comprehend label would have a higher rate of use than the NFt, which contains more nutrient information and is located on the back or side of the package label.

Test 1 — Percentage reduction in cost due to label use, by disease

It was found through the literature review that an improved diet could reduce coronary heart disease and stroke mortality by 20%, and cancer and diabetes mortality by at least 30%. A further calculation was made for reductions in morbidity for coronary heart disease and stroke by 10% and cancer and diabetes morbidity by 15%.

A reduction in mortality and morbidity was not provided for musculoskeletal disease. It was assumed that mortality would be least affected by diet, while morbidity would be most affected; therefore, 10% mortality and 15% morbidity rates were used in the formula.

Using the figures above, and assuming a label use of 60% and 75% and a continued rate of reliance on labels of 75%, these values were tested against the economic burden of illness calculations by disease group. The tests demonstrated similar results to the estimated 1.5% reduction in illness for both the 60% and 75% rates of label use that were equivalent to a 1.14% and a 1.42% reduction in health costs.

Test 2 — Welfare gain estimate from label use, Canadian population

This test was adapted from the U.S. FDA and includes the entire Canadian population, not simply the population of Canadians diagnosed with one of the four diseases of focus. This assumption states that the years following the initial regulation of nutrition labels lead to a $0.07 to $0.11 welfare gain per day, which equates to a $25 to $40 gain annually. Given that the changes being put forward for FOP nutrition symbols are in fact amendments to the current system, the full estimate of the welfare gain will most likely not be realized to the full extent. The revised calculation will reduce the benefits by 25%, with the underlying assumption being that the amendments would augment existing welfare gains through improved product disclosure. The standard label use figures of 60% and 75% were applied to account for Canadians who read the label. This test multiplies the anticipated welfare gain by the Canadian population, and then makes adjustments for label use and compliance. The results ranged from a 1.51% to 3.02% reduction in health care costs, which exceeds the conservative benefit figure of 1.5%.

It was determined that the 1.5% was within the range of anticipated benefits using two different methodologies adjusted to the current Canadian population.

Over a 10-year period, it is anticipated that the total present value benefits would amount to $3.19 billion in direct and indirect cost savings to the health system and, by further extension, to the Canadian economy. It is anticipated that the impact of a small improvement in health outcomes would be compounded over a 20- to 30-year period.

The total net present benefit, spread over 10 years and discounted by 7% as mandated by the Treasury Board Secretariat, would be $2.36 billion in indirect and direct savings to the health system and Canadian economy through a 1.5% decrease in four chronic diseases most associated with diet.

"One-for-One" Rule

There are currently no reporting requirements associated with food package labelling and none

would be proposed. Therefore, it has been determined that the "One-for-One" Rule does not apply, as the amendments will not impose a new administrative burden on business.

Small business lens

The small business lens applies to regulatory proposals that affect small business and would impose a nationwide cost over $1 million annually. The Treasury Board Secretariat defines a small business as any business, including its affiliates, that has fewer than 100 employees or between $30,000 and $5 million 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. Of these, 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 reduce the impact on small businesses.

NAICS(see note *)	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%

Note *: North American Industry Classification System

The following options were considered when determining the effect of the proposed Regulations on SMEs and large food manufacturers.

1. Scope of FOP nutrition symbol

The proposed FOP model (i.e. a mandatory "high-in" system for specific nutrients) is less costly than other models that were being considered. Under the current proposal, only foods 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 average weighted cost per SKU of $23,620 is applied to all 80 000 SKUs, assuming that either a fact-based or "traffic light" approach would be required for every label, the total cost will increase by an additional $986.2 million.

2. Exemption for micro firms processing and selling products

Products that are sold by the same person(s) that produced them and are sold at places such as farmers' markets, craft shows, roadside stands, sugar bushes, and flea markets would be 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 estimate the size of the exemption using the proxy of farmers' markets. There are 508 identified farmers' markets in Canada, according to a national study conducted in 2009. (see footnote 17) 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. The proposed amendments would maintain this exemption for the food products of these 12 700 firms.

3. Alignment of the transition period with that of other regulatory initiatives

The end of the proposed transition period for the proposed FOP labelling regulations would align with the end of the transitional period for the December 2016 nutrition labelling regulations. While this leads to a higher cost per SKU since the change must occur over approximately four years as opposed to industry's preference for five years, the alignment allows all changes to be made at the same time. The flexible option demonstrates what the costs would be if an additional five-year transition period for the proposed FOP amendments was added following the end of the transitional period for the 2016 nutrition labelling regulations. The transition period for NFt ends on December 14, 2022; the transition provision for the proposed FOP labelling regulations would end on the same date.

While the cost per company is over a quarter of the cost for a four-year transition period versus a five-year period, alignment enables the removal of duplicate activities and benefits could be realized at an earlier date; in this example, benefits could be realized one year earlier. If the benefits are extrapolated and calculated for one year of health system improvement, an additional delay of one year in the transition period could cost the Canadian economy an approximate additional amount of $420 million in missed benefits.

Flexibility analysis

	Initial Option	**Flexible Option**

Transition period	*Four-year Transition Period*		*Five-year Transition Period*	
Number of firms	26 700		26 700	
	Annualized Average	***Present Value***	***Annualized Average***	***Present Value***
Compliance cost	$23,260	$21,738	$16,020	$14,972
Administrative cost	$0	$0	$0	$0
Cost per company	$27,912	$26,086	$19,224	$17,966
Total costs of all options	*$745,250,400*	*$696,496,200*	*$513,280,800*	*$479,702,880*

(i) Assumes 1.2 labels per SME.
(ii) The three-year scenario assumes that FOP and NFt labelling changes would have aligned transition periods.
(iii) Assumes that the cost for the FOP labelling changes would be the same as that for the NFt, adjusted for inflation at the 2016 rate (1.64%) for five years.

While the flexible option would reduce the cost per SKU for FOP nutrition symbols by nearly a quarter, it would do so at the cost of delaying the onset of anticipated health benefits. The initial option, while not providing the cheapest cost per SKU, does seek to align the transitional provision for the FOP labelling proposal with the transitional provision for the December 2016 nutrition labelling regulations. This option could have been more expensive if the dates were not aligned.

The initial option was selected due to a desire to align the transitional provisions for all label changes; however, it would add approximately $216.8 million in present value to SMEs.

Consultation

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

(1) Pre-consultation 1:
- (i) proposed new FOP nutrition label for foods high in sugars, sodium or saturated fats;
- (ii) proposed changes to nutrient content claims and other nutrition-related statements; and
- (iii) proposed changes to the labelling of certain high-intensity sweeteners.

(2) Pre-consultation 2:
- (i) proposed prohibition on the use of partially hydrogenated oils (PHO) in foods.

The pre-consultations consisted of online consumer and technical surveys, accompanied by two consultation documents: *Toward Front-of-Package Nutrition Labels for Canadians* and *Toward the Prohibition of Partially Hydrogenated Oils in the Canadian Food Supply*. Both surveys closed

January 13, 2017. Approximately 2 155 comments were received (1 600 for Pre-consultation 1 and 555 for Pre-consultation 2) from a range of stakeholders, including consumers, food industry, retailers, health organizations, health professionals, consumer advocacy groups, scientific experts, academics and provincial and territorial governments.

In addition, the following engagement activities were also undertaken:

- **March 2015:** A proposal for a revised vitamin D fortification policy was discussed with experts at a Best Brains Exchange (BBE) 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 PKU 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 PKU program, and dieticians involved in the care of individuals with PKU.
- **December 2016:** Health Canada conducted focus group testing on certain elements of the FOP proposal, namely symbol design, size and location, with 14 groups in 6 cities across Canada. The purpose was to assess how consumers understood and used the range of proposed nutrition symbols.
- **January and February 2017:** After the preconsultations, Health Canada met with academic experts and key health and industry stakeholders to provide further information on the FOP labelling proposal to provide the rationale for the proposed FOP approach. This included the option analysis of the different FOP labelling systems that were considered.
- **March 2017:** Health Canada engaged with stakeholders on the FOP and PHO proposals at the annual Health Canada (HC) and Canadian Food Inspection Agency (CFIA) 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* (Reference Number NOP/ADP-C-2017-3) signalling 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 one-day meeting with stakeholders and experts

to discuss FOP labelling evidence and options for the nutrition symbol design.

On October 24, 2016, the Minister of Health announced a new approach regarding transparency of stakeholder communications for healthy eating initiatives. All meetings and correspondence in which views, opinions, information and requests for information are relayed with the intent to inform development of policies will be published online, including the name of the organization, as well as the topics and purpose of discussion. An overview of all those engagements with stakeholders, including the proposals described in this regulatory package, is provided online on the *Meetings and correspondence on healthy eating* web page. From October 2016 to July 2017, Health Canada had 109 direct interactions with stakeholders on the healthy eating strategy, 75 of which were specific to labelling. Health Canada remains committed to openness, transparency and meaningful engagement with Canadians on healthy eating initiatives. Canadians will have more information available than ever and will have more opportunities to participate in discussions on government policies and priorities.

Summary of comments and responses

I. FOP nutrition labelling

Comments on the proposed FOP approach

Overall, consumers strongly supported the proposed FOP approach, stating that they believe it would help support informed decision-making. Health stakeholders were also supportive because it is consistent with international consensus on addressing NCDs 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, citing a lack of sufficient research on the proposed system and its effectiveness, with some proposing alternate voluntary approaches that have been supported by industry associations or developed by individual companies.

Health Canada's response

As described above, Health Canada conducted an options analysis prior to selecting the proposed approach, as described in the "Regulatory and non-regulatory options considered" section of this Regulatory Impact Analysis Statement. The proposed approach is the recommended option to complement the suite of existing healthy eating tools in order to address nutrition-related chronic diseases.

Comments on the proposed nutrients of concern

Some consumers and health stakeholders questioned the nutrients of concern selected. Several commented that free sugars or added sugars should be the focus, rather than total sugars,

since total sugars includes sugars naturally present in fruits, vegetables, and dairy products. Some stakeholders indicated that the evidence did not support the selection of saturated fat as a nutrient of public health concern, while some representatives from the dairy industry commented that the source of saturated fats should be taken into consideration stating that saturated fats from dairy products do not have negative health impacts. Others requested that *trans* fats be included. Some respondents, including consumers, industry representatives, and health stakeholders felt that calories should be included, because calories are of most concern from a public health perspective for obesity. Others asked Health Canada to wait for the results from the 2015 Canadian Community Health Survey (CCHS) to be released prior to selecting the nutrients of public health concern.

Health Canada's response

Health Canada selected sodium, sugars, and saturated fats for the FOP proposal 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 survey data from the 2004 CCHS indicates that Canadians consume these nutrients in excess of recommended limits. Data from the United States indicates that intakes of sodium and saturated fat have not changed significantly over a similar timeframe. As a result of this evidence and the severity of the NCD problem, Health Canada determined that it was appropriate to take action now.

In addition, these nutrients are widespread in the Canadian food supply. For example, 77% of sodium in the Canadian diet comes from processed foods, despite efforts in recent years to reduce it. This is significant because Canada ranks second among 80 countries in annual retail sales per capita of ultra-processed food and drink products (Pan American Health Organization, 2015). In 2012, Health Canada set voluntary sodium reduction targets for 94 food categories and asked manufacturers to reach these targets by the end of 2016. These voluntary targets were established to help reduce the average sodium intake of Canadians from 3 400 mg per day (2009) to 2 300 mg per day by the end of 2016. A survey in early 2016 of 15 of these categories showed varying degrees of improvement in most categories, but not all. These data, which were shared at Health Canada's Symposium on Sodium Reduction in Foods (October 2016) and subsequently made public in March 2017, indicate that more needs to be done to meet the targets and reduce sodium intake. An FOP system, for instance, can help nudge consumers to actively seek out lower sodium alternatives. Health Canada's sodium monitoring results were published on January 15, 2018, in the report *Sodium Reduction in Processed Foods in Canada: An Evaluation of Progress toward Voluntary Targets from 2012 to 2016*. At the 2016 Symposium, many food industry representatives indicated that while they continue to reduce sodium in processed foods, consumer demand ultimately drives their reformulation

efforts.

A similar situation exists for sugar. A recent survey showed that two thirds of 40 000 prepackaged products and beverages in Canada contain added sugars. Another study found that 64% of the sugars found in processed foods are added or sourced from fruit juice, syrup or honey. Taken together, these findings indicate that enhanced labelling measures are necessary to help consumers make informed choices that help reduce risks to health and further encourage manufacturers to offer foods with lower levels of these nutrients.

Total sugars were selected for the proposed FOP approach to ensure consistency with other labelling policies and because most foods that would exceed the proposed thresholds for sugars are foods with added sugars. Results from Health Canada's food composition analysis confirm that the total sugars threshold of 15% of the DV for prepackaged products and 30% of the DV for prepackaged meals and main dishes with a serving size of 200 g or more, combined with the adjustment for foods with small reference amounts, would identify foods high in added sugars and/or free sugars that contribute most to Canadians' sugars intake.

Saturated fat is included in the proposed FOP approach as it aligns with national and international policies that identify it as a key nutrient of concern. For example, many government-led FOP systems highlight saturated fat. The strength of the evidence related to saturated fatty acids from dairy sources is not sufficient to support exempting foods high in these fats from the requirement to display the proposed nutrition symbol (the exception being milk containing 2% and 3.25% milk fat, as explained in the list of full exemptions above). Calories are not included in the proposed 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.

Concerns with unintended impacts of FOP labelling

Several consumers and health stakeholders expressed concern that the proposed approach would encourage reformulation that does not improve the nutritional value of the product. For example, a sugar-reduced product could be reformulated to increase the fat and sodium content. Some commented that there could be confusion because the principal display panel (PDP) often already displays voluntary claims and other nutrition-related information; this other nutrition-related information could be seen as contradicting the message the nutrition symbol is attempting to convey. To help prevent confusion, some felt that other nutrition-related information should be prohibited or limited on products required to carry the proposed nutrition symbol. Some consumers and health stakeholders commented that any kind of FOP labelling would create additional challenges for people with disordered eating.

Health Canada's response

Health Canada has included three nutrients of public health concern to help ensure that manufacturers will not lower one nutrient of concern, such as sugars, and increase another of concern, such as saturated fat. Whereas traffic light or summary systems allow manufacturers to improve the overall rating of the food by increasing levels of lower-priority nutrients, the proposed "high in" FOP approach limits their ability to do so.

The *Food and Drugs Act* requires truthful and not misleading labels on foods. Health Canada agrees that, while truthful, voluntary positive nutrition information could limit the impact of the proposed nutrition symbol. As a result, Health Canada is proposing to prescribe the location and prominence of voluntary claims and other nutrition-related information relative to the placement of the nutrition symbol to help reduce the potential for conflicting messages.

While the FOP labelling approach is intended to help consumers make healthier choices to avoid excessive intakes of nutrients of public health concern, it may have some unintended impacts on certain individuals. Some people with disordered eating struggle to eat a balanced diet that meets their caloric requirements, which could include foods that are high in these nutrients. Health Canada will continue to consult with experts to help ensure that challenges for people with disordered eating are taken into consideration, particularly as educational resources are developed.

Comments on the need for more research

Academic experts and stakeholders noted that, given that research on FOP labelling is emerging, consumer testing is needed to ensure accurate interpretation and ease of understanding on any FOP approach.

Health Canada's response

Current evidence supports the role of simple, nutrient-specific, interpretive FOP labelling in helping consumers make informed choices, as outlined in the "Regulatory and non-regulatory options considered" section. Each FOP system has strengths and limitations that must be weighed against several factors. The choice of the proposed FOP system was guided by the alignment with and the consideration of the policy objectives, available evidence, recommendations from authoritative health organizations, the Minister's mandate, and current legislation.

In addition, Health Canada conducted focus group testing of four potential symbols provided in the *Toward Front-of-Package Nutrition Labels for Canadians* consultation document in November 2016 to inform the development of the proposed FOP approach. A total of 14 groups were tested across Canada with French- and English-speaking adults of varying levels of health literacy, including two groups of youths. Some participants questioned the credibility and

source of the symbols, given that nutrition information on the front of the package is usually for marketing purposes. Participants tended to prefer larger symbols and a consistent location for the symbols. Further consultations and consumer research will be undertaken to inform the final design of the nutrition symbol that will be included in the proposed directory of nutrition symbol formats. (see footnote 18)

Comments on the proposed nutrient thresholds

Consumers generally did not comment on the proposed thresholds. Health stakeholders expressed strong support for thresholds based on 15% of the DV, because they reinforce existing policy and are consistent with a healthy eating pattern. Health professionals confirmed that the thresholds are in line with advice they give their clients. Some health stakeholders expressed concern that higher thresholds for prepackaged meals and main dishes and the adjustment for foods with small reference amounts could obscure transparency and alignment with the NFt, particularly given the footnote stating that 15% or more is "a lot." One health stakeholder noted that the amount of sugars in prepackaged meals and main dishes would never exceed the proposed threshold of 30% of the daily value.

Some industry stakeholders suggested aligning the thresholds with those for the voluntary FOP labelling initiatives in the United States to reduce costs and to ensure that the consumers are not overexposed and desensitized to the symbol. Some industry stakeholders felt that the sodium threshold was not consistent with sodium targets set by Health Canada. The dairy industry commented that foods with natural sugars were disadvantaged as these foods have little room for added sugars whereas other products with no naturally occurring sugars have a lot of room to add sugars.

Health Canada's response

Health Canada proposed a threshold based on 15% of the DV because this level is consistent with existing policy. Furthermore, food composition analysis shows that this level would trigger the nutrition symbol on foods that should be limited according to Canada's Food Guide. Thresholds based on 15% of the DV would be more consistent with other policies in Canada such as the NFt footnote ("5% or less is a little, 15% or more is a lot") and the threshold for voluntary "high in" nutrient content claims as articulated in the CFIA online labelling tool.

The concern that the sugars threshold of 30% for prepackaged meals and main dishes is too high has merit, as there are very few (if any) prepackaged meals and 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 prepackaged meal and main dish threshold for

sugars at 30% of the DV.

The concern that the higher threshold for prepackaged meals and main dishes and the adjustment for foods with small reference amounts, although intuitive to some, could obscure transparency and alignment with the NFt may also be valid. Health Canada plans to address this concern as part of the education campaign that accompanies implementation of the proposed approach.

The voluntary sodium reduction targets that industry was asked to meet by December 2016 are intended to encourage sodium reduction in the food supply, which in turn will lead to a reduction in the population average intake. The targets were not intended to be a benchmark for a "high level" of sodium, and they vary across 94 food categories based on what was potentially feasible for each category. However, Health Canada conducted an analysis to assess alignment between the proposed thresholds and the targets set for sodium reduction. Of the options considered, the sodium threshold of 15% was most aligned with the guidance for industry on reducing sodium in processed foods.

With respect to the sugars threshold in dairy products, food composition analysis shows that the amount of sugars present in unsweetened dairy products would not exceed the proposed sugars threshold. Requiring the nutrition symbol on sweetened dairy products that exceed the threshold is consistent with recommendations from authoritative health organizations to reduce free sugars intake.

Comments on the design of the nutrition symbol and Health Canada's response

A summary of the comments and Health Canada's response are provided on the Government of Canada's website for review and consultation. (see footnote 19) Also, a report on the results of the focus group testing is published on the Library and Archives Canada website. (see footnote 20)

Comments on the location and size of the nutrition symbol

Many consumers and health stakeholders commented that the nutrition symbol should be clearly visible and prominently displayed in a consistent location so consumers can quickly identify the presence or absence of the symbol on a product.

Health Canada's response

A consistent symbol location would improve noticeability and facilitate product comparison; therefore, Health Canada has proposed to require the symbol to appear in the top or right 25% of the principal display panel (PDP). To help ensure prominence and legibility, the required size will be proportional to the size of the principal display surface (PDS) of the package. This is

similar to the approach that is used to determine the height of the characters of the net quantity declaration on prepackaged products, as well as the approach for the size of the NFt, which is dependent on the available display surface of the label.

Comments on the proposed exemptions

Consumers, health stakeholders, and some industry stakeholders did not support the exemption proposed for prepackaged sugar and salt, expressing concern that it would be unfair to exempt these products but not others with similar levels of sugars and sodium. Some consumers and health stakeholders felt that certain foods exempted from displaying an NFt (e.g. bakery goods, deli meats, sausages) should not be exempted from the nutrition symbol because they do not require precise nutrient values to determine whether or not the food should display the symbol requirement or because the reasons for the NFt exemption do not apply to the nutrition symbol. Certain health stakeholders commented that whole milk (3.25% milk fat) should be exempted because it is recommended for children under two years of age for optimal growth and development. Some also suggested that nuts and seeds be exempted because they are healthy substitutes for foods high in saturated fat. The Department of National Defence requested that individual operational rations for military personnel be exempted because the nutrition symbol could discourage this population from consuming rations formulated to meet their specific needs.

Health Canada's response

The Department is proposing to maintain the proposed exemptions, with the following changes.

For consistency, foods already exempted from displaying an NFt would not be required to display a nutrition symbol. However, Health Canada is proposing to mirror the conditions under which a food would lose the exemption from the requirement to display the NFt. This would mean that when an exempted food carries an NFt, it would no longer be exempt from the proposed FOP nutrition symbol requirement.

There is convincing evidence for a reduced risk of cardiovascular disease when saturated fat is replaced by unsaturated fat. Health Canada agrees with the comments that nuts and seeds, as well as other foods high in unsaturated fat, can be used as substitutes for foods high in saturated fat. Therefore, the exemption from the small reference amount adjustment for saturated fats in oils and their derivatives is expanded to include all foods that meet the condition that no more than 30% of total fat of a food is saturated fat and *trans* fat. The fatty acid profile of eggs aligns with this criterion and sits right at the 15% DV threshold; therefore, the nutrition symbol will not have to be displayed.

Members of the Canadian Armed Forces engaged in military operations have unique energy and nutritional requirements, particularly in extreme environments. Foods specifically formulated to meet these needs should be exempted from the proposed FOP nutrition symbol requirement. These products are not available to the general population. Hence, an exemption for prepackaged individual operation rations for military use has been added.

Health Canada is proposing to extend the exemption of milk to include whole milk (3.25% milk fat) as it is the primary source of nutrition for infants and young children, and dietary fat restriction is not recommended for children younger than two years of age.

II. Nutrient content claims and other nutrition-related statements

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

A number of changes are proposed to address current and proposed new claims, e.g. "no added sugars," "unsweetened," "free of sugars," low in sugars," "0 g sugars," and "0 g *trans* fats." A summary of the comments received and Health Canada's responses are provided in the *Notice of Proposal: Incorporating by Reference the Table of Permitted Nutrient Content Statements and Claims* (NOP/ADP-NCC-2017-1), which is available on the Government of Canada's website for review and consultation. (see footnote 21)

Comments on the representation of the amount of alcohol in beverages

Some stakeholders expressed concerns with the potential use of the term "alcohol-free," noting that individuals who have allergies or sensitivities to alcohol, or with substance abuse challenges, may be harmed.

Health Canada's response

Health Canada is proposing to move forward with the proposal to address a gap in the FDR that prevents the quantitative declaration of the alcohol level in beverages containing 0.5% alcohol by volume or less. This includes beverages that have been dealcoholized or that have never contained alcohol and are marketed to consumers as alternatives to alcoholic beverages such as "mocktails" and "virgin" drinks. Health Canada will work with the CFIA to ensure that appropriate guidance is available to manufacturers marketing products as "alcohol-free" to help ensure consumers can make informed choices.

Comments on foods intended solely for young children

One comment from a health stakeholder questioned the need for a food category intended solely for young children (e.g. toddler foods) and explained that after the age of two, children should eat according to dietary guidance with regular family meals and snacks.

Health Canada's response

New terminology to describe the age categories that correspond with those for the updated DVs was included in most, but not all, sections of the FDR as part of the 2016 nutrition labelling regulations. Maintaining consistent terminology for the same purpose within the FDR for the use of nutrient content and health claims in describing foods intended solely for young children is needed to ensure consistency among provisions for similar foods. This will slightly expand the scope of foods that are limited in their use of nutrient content and health claims from foods identified for infants and children under two years of age to those for infants and children under four years of age. Health Canada is therefore proposing to move forward with the proposal.

III. Vitamin D fortification

Comments on vitamin D fortification strategy

In March 2015, a proposal for a revised vitamin D fortification policy was discussed with experts (including Dietitians of Canada, academics, and health care professionals) at a Best Brains Exchange (BBE) co-hosted by the Canadian Institutes of Health Research and Health Canada. The proposal was to increase the mandatory level of vitamin D addition to milk, fortified plant-based beverages, and margarine, and to permit the optional addition of vitamin D to yogurt. The majority of experts were supportive or neutral toward increasing vitamin D levels in milk. Supporters of the proposal highlighted that it was important to continue with milk fortification but also to expand to other vehicles. A minority of experts disagreed with increasing vitamin D levels in milk, the main reason being that it would not reach certain subpopulations at risk. Feedback regarding margarine was divided. Supporters advised that if it is a frequently consumed product, particularly in subpopulations at risk, then it should be considered for fortification. Those with reservations expressed concern regarding the potential for mixed messages, i.e. "limit the food because of its fat content but do not limit the food because of vitamin D."

On March 31, 2017, Health Canada held a meeting with targeted industry and health stakeholders along with provincial and territorial government representatives to discuss its proposal for a multi-phased approach to updating its vitamin D fortification policy. The proposal to increase vitamin D levels in milk, goat's milk and margarine, an important part of the first phase, was a key focus of the meeting.

Overall, there was strong support from all participants for increasing vitamin D levels in milk, goat's milk and margarine by approximately twofold. Participants expressed understanding that the proposed increases to vitamin D levels would not be commensurate to the fourfold increase to the DV since Health Canada plans to extend its fortification policy to other vehicles

in the longer term. However, since the % DV on product labels will consequently drop, health stakeholders highlighted the importance of properly positioning this message through consumer education in order to maintain consumer confidence in these foods, especially milk. Some participants were interested in understanding how the changes to vitamin D levels would be reflected in dietary guidance. One industry stakeholder expressed concern regarding the volume of changes that are being required of industry within a three- to five-year period, e.g. new NFt and LOI requirements, FOP labelling, vitamin D fortification, the CFIA's Food Labelling Modernization (FLM) initiative, while another industry stakeholder countered this argument with an expression of appreciation toward Health Canada's efforts to align the timelines of the multiple initiatives as much as possible. One health stakeholder added that any delays toward implementation of the various proposals would be quite a disappointment to health practitioners who view the regulatory package as a suite of approaches that will help to move Canada toward a healthier food supply.

Health Canada's response

Health Canada agreed with the BBE experts and is proposing a multi-phased strategy to expand vitamin D fortification. The first phase will have two components: (a) increasing levels of vitamin D in cow's milk, goat's milk and margarine through amendments to the FDR, and (b) permitting the fortification of plant-based beverages and yogurt. The effectiveness of the first phase will be assessed by monitoring changes to vitamin D blood status as reported in the biennial Canadian Health Measure Survey. This assessment, in conjunction with the results from the 2015 Canadian Community Health Survey (CCHS), will inform the implementation of the second phase, which would focus on appropriate vehicles for fortification that reach subpopulations at risk of vitamin D deficiency and inadequacy. Furthermore, Health Canada will be conducting modelling in order to develop dietary guidance using these new vitamin D levels.

Comments on the use of nutrition symbols on foods fortified with vitamin D

A few industry stakeholders questioned whether milk and margarine would be required to carry the proposed nutrition symbol and, if so, whether this symbol would present a discordant message to consumers.

Health Canada's response

Health Canada notes that the purpose of mandatory or public health–driven fortification is to help reduce risks to health by ensuring the nutrient is delivered to as many people as possible regardless of what they eat. At the time, Health Canada was considering exempting milks from the requirement to display the "high in" saturated fat symbol; therefore, only flavoured sweetened milks above the threshold would be required to carry the proposed "high in sugars"

symbol. In dietary guidance, foods and beverages lower in sugar are recommended as the better choice. One stakeholder pointed out that a number of margarine products would be required to carry a nutrition symbol for sodium. Health Canada responded that education will be provided to help consumers use FOP labelling to make informed decisions. Furthermore, the requirement for FOP labelling may be an incentive for industry to reformulate their margarines to help reduce sodium levels.

IV. FDR amendments related to the prohibition of PHOs

With respect to the proposal to prohibit the sale of foods that contain PHOs by adding PHOs to Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods*, a summary of the comments received from the November 2016 pre-consultation is provided in Health Canada's *Notice of Proposal: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods* (Ref. No. NOP/ADP-C-2017-3). In September 2017, Health Canada published the *Notice of Modification: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods* (Ref. No. NOM/ADM-C-2017-3) confirming the adoption of the prohibition and the date on which PHOs will be added to Part 1 of the *List of Contaminants and Other Adulterating Substances in Foods*. The Notice of Modification provides a summary of comments received in response to the Notice of Proposal. Both notices are available on the Government of Canada's website. (see footnote 22), (see footnote 23) No pre-consultations were held on the proposed PHO-related amendments, as their scope is limited to ensuring the FDR provisions are consistent with the prohibition.

V. Labelling of foods containing certain high-intensity sweeteners

V.I Labelling of foods containing sucralose, acesulfame-potassium and neotame

The majority (approximately two thirds) of industry and health professional respondents supported the proposal to remove the additional labelling requirements that currently apply to foods containing the sweeteners sucralose, acesulfame-potassium and neotame. Consumers, however, were for the most part opposed to the proposal.

Concerns about the legibility of the list of ingredients

A key concern raised by those who opposed the proposal is that the LOI is difficult to navigate or read; therefore, many consumers simply avoid consulting it. They felt 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 three sweeteners.

Health Canada's response

Health Canada recognizes that certain consumers may have difficulty reading the LOI and that

it can be challenging for some to locate specific ingredients within the list, particularly in foods with multiple ingredients. It is for these reasons that new formatting specifications for the LOI were brought into force as part of the 2016 nutrition labelling regulations. The new requirements will make it easier to locate, read and understand the information provided in the LOI on prepackaged products. Moreover, these improvements to the legibility of the LOI coupled with the removal of the duplicative requirement to declare these sweeteners on the PDP will also help to reinforce and encourage the practice of reading the LOI.

Concerns about the use of sweeteners by food manufacturers

Another concern raised was that the removal of the declaration of these sweeteners on the PDP may promote an increase in the use of these high-intensity sweeteners by manufacturers, either due to the removal of the PDP requirement or in order to avoid the "high in sugars" nutrition symbol proposed under the FOP labelling regulations. Similar concerns with the substitution of sugars with sweeteners were expressed in response to the June 2015 regulatory proposal to require a % DV for sugars in the NFt and the proposal to require the grouping of sugars-based ingredients in the list of ingredients.

Health Canada's response

Health Canada acknowledges the possibility that some food manufacturers may choose to substitute added sugars with sweeteners in order to avoid the proposed "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 is used within the level prescribed by Health Canada. Therefore, even if there were to be increased use of sweeteners, the strict controls that are in place 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 applies to aspartame and the three 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 suggesting 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.

Concerns about the safety of sweeteners

Some respondents indicated their belief that sweeteners have uncertain safety profiles and mentioned research suggesting a correlation between the consumption of foods containing

sweeteners and obesity and type 2 diabetes. In light of these concerns, some stakeholders not only recommended retaining the additional labelling requirements for the three sweeteners in question but also extending them 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 and efficacy of the sweeteners Health Canada has approved for use as food additives. In the absence of a scientifically validated safety concern, there is no rationale for requiring PDP labelling of foods containing the three high-intensity sweeteners in question or for expanding the PDP labelling requirement to foods containing any approved sweeteners.

Health Canada reiterates that the additional labelling requirements for these sweeteners were not put in place to help mitigate a particular safety concern with these ingredients. Declaring the presence of these sweeteners on the PDP as well as their quantity near the LOI 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 these additional labelling requirements for foods containing other high-intensity sweeteners it has since approved.

V.II Labelling of foods containing aspartame

Feedback from the online surveys

The response rate to the aspartame-specific questions of the online surveys was relatively low when compared to that of the other three sweeteners. This is not surprising given that the number of Canadians with PKU is relatively small and the survey questions were targeting individuals with PKU, those caring for someone with PKU, or those with expertise in the care of individuals with PKU.

Concerns about the legibility of the LOI and the safety of aspartame

Of those who responded to these questions (the largest proportion of which were consumers), the majority did not support the proposal to repeal the additional labelling requirements for

aspartame. Similar to the feedback received on the proposal for the other three sweeteners, a key reason for opposing the proposal is a view that the LOI can be difficult to read and is often overlooked by consumers. Therefore, the view was expressed that PDP labelling should be retained to enable individuals with PKU or parents of children with PKU to easily identify products with aspartame given the risk to health. Some respondents also expressed concerns that there is an uncertain safety profile of aspartame which they considered provides a reason for retaining the additional labelling requirements.

Health Canada's response

As previously noted, Health Canada is of the view that the concerns raised regarding the legibility and readability of the LOI will be addressed by the new formatting specifications introduced in the 2016 nutrition labelling regulations, which will make it easier for consumers to locate, read and understand the information provided in the LOI.

Regarding the safety of aspartame, aspartame underwent a thorough pre-market assessment prior to its approval for use in Canada and Health Canada continues to consider any new science on the safety of aspartame and other approved food additives. The body of scientific evidence indicates that aspartame, used within its prescribed conditions of use (i.e. only in those foods and within those maximum levels of use that have been approved), is safe.

Health Canada recognizes that the declaration of aspartame on the PDP, while a duplication of what appears in the LOI, does give more prominence to the presence of this ingredient, although as previously noted, the original intent of the PDP labelling for aspartame was not as a risk mitigating measure for individuals with PKU. Rather, PDP and quantitative labelling were put in place to support the informed use of aspartame for the general population. Health Canada notes that similar PDP labelling requirements are not in place for other ingredients of concern, such as food allergens. Consumers with life-threatening food allergies rely on the LOI and any "contains" statements and/or precautionary declarations that appear under the LOI as an effective means of monitoring the foods they eat. Taking this into consideration, Health Canada is of the view that declaring aspartame in the LOI in combination with the mandatory statement about the presence of phenylalanine is sufficient to enable those with PKU to identify the presence of added phenylalanine in foods. This would also help to reinforce the practice of always reading the LOI.

Feedback from PKU groups and experts

The majority of the PKU groups and experts who were contacted between October and November 2016 indicated that the PDP declaration was not necessary, although some noted that this declaration had some use as an additional measure. Similarly, most advised that labelling the quantity of aspartame was of limited use given that patients with PKU are

generally instructed to avoid foods with aspartame altogether. However, as with the PDP declaration, some acknowledged that the quantity of aspartame could be of some use, particularly for certain adult PKU patients who may have higher phenylalanine tolerances.

For most, the declaration of aspartame in the LOI accompanied by a statement to the effect that aspartame contains phenylalanine were identified as the most critical labelling elements to retain. Two groups in particular recommended that the phenylalanine statement be made more prominent on the label and that Health Canada give consideration to adopting the wording of the statement currently required by the United States (i.e. "Phenylketonurics: contains phenylalanine").

In response to these comments, the proposal described in this regulatory package includes new format and placement specifications that are aimed at further increasing the prominence of the mandatory phenylalanine statement. In addition, the proposal also provides manufacturers with the option of either using the statement "Phenylketonurics: contains phenylalanine" or a statement to the effect that aspartame contains phenylalanine.

One respondent strongly recommended that if the proposal to remove aspartame from the PDP were to be adopted, it should be accompanied by a broad education campaign to notify the PKU community of the changes. If the proposal does proceed to adoption, Health Canada will make information available to Canadians about the labelling changes for aspartame. PKU stakeholders in particular would be proactively engaged to ensure that they clearly understand the labelling changes.

VI. Cost-benefit analysis

The Canadian food industry provided costing input through a survey process coordinated by industry stakeholder groups. Stakeholders were asked to provide all costs associated with changing their product label to include an FOP nutrition symbol and increasing the mandatory amounts of vitamin D in milk, goat's milk and margarine products. The survey formed the basis for estimates based upon policy input shared in the FOP consultation white paper that was open for comment from November 14, 2016, to January 13, 2017. The survey, in order to minimize the response burden on industry, used a broad policy approach in the creation of questions for respondents; therefore, some industry estimates may take into account some provisions that may fall outside of the scope of the proposed requirements. For the CBA estimates to remain conservative, industry was asked to provide estimates based upon the highest cost scenario; however, in most instances, estimates were provided for minor, medium and major label changes. Allowing the option of providing the highest cost scenario allowed industry stakeholder groups to provide costing data, as one of their greatest concerns was an underestimation of costs in an area that would directly affect their membership. Using this

approach meant that industry impacts would not be underestimated.

Many respondents identified the time allocated to implement the proposed changes, as well as how their labels could experience dramatic graphic design changes in order to accommodate space for an FOP nutrition symbol. The identified financial effects of the proposed Regulations were significant and costly. The Canadian food manufacturing industry was particularly concerned about how its industry, which functions under tight margins, would be able to both produce innovation products in response to changing consumer taste while be in compliance with new regulations.

Regulatory cooperation

In the spirit of regulatory cooperation, the proposed regulatory elements of this package aim to align with U.S. rules to the extent possible.

I. Key difference: Front-of-package nutrition labelling

Canadian food labels have always differed 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 are exempt from the provisions of the *Food and Drugs Act* and its regulations, as per subsection 37(1) of the Act [subject to exceptions set out in paragraph 37(1.1)(a)]. Differences between Canadian and U.S. labelling requirements would not affect those foods destined for the U.S. market.

Both Canada and the United States require nutrition labelling on prepackaged products, such as the Nutrition Facts table or panel and the LOI, with the same overall policy objectives: enabling consumers to make informed choices about their food to help them attain better health outcomes.

Specific Canadian requirements regarding FOP nutrition labelling are justified as a legitimate public policy objective and part of the larger Healthy Eating Strategy to help reduce the incidence of non-communicable diseases and 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 requirements will build on existing nutrition labelling tools in Canada and address their limitations. These regulations would not create trade barriers that favour Canadian goods. All food products, domestic and imported, would be subject to the same regulations.

However, while the United States has not yet adopted a mandatory FOP labelling system, other countries have, such as Chile, Ecuador, Mexico and most recently Israel.

II. Key similarity: Nutrient content claims and other nutrition-related statements

- Canada's proposal to permit representation of the amount of alcohol in beverages

containing 0–0.5% alcohol does not conflict with U.S. practices in quantitative declaration whereby beverages may make a declaration "contains less than 0.5% alcohol by volume."
- The applicable age categories for food intended solely for children "younger than 4 years of age," updated to reflect the new DV age categories, would now be aligned with the United States.

III. Key similarity: Vitamin D fortification

- In the United States, the fortification of vitamin D in milk is not mandated at the federal level but most states mandate fortification. If vitamin D is added to milk, it must be present at ~1 µg/100 mL, as per the FDA's milk standard (21 CFR 131.100). This level is similar to current levels prescribed by the FDR (0.988–1.217 µg/100 mL). In 2016, the U.S. FDA permitted vitamin D fortification above the level 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 Canada's current regulatory proposal (2 µg/100 mL). While the FDA has not amended its milk standard, milks that are fortified in excess of those levels stipulated in the standard must be named with a nutrient content claim such as "high vitamin D milk."
- Margarine 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. Canada's proposed 26 µg/100 g).

IV. Key similarity: Prohibiting PHOs

The United States and Canada would be using 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 FDA 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 in effect prohibit the use of PHOs in foods until such time as manufacturers or other interested parties can successfully petition the FDA 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. By June 18, 2018, companies must have reformulated their products to remove PHOs or have obtained approval from the FDA for specific food additive uses.

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 *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 would align with the United States, which does not have such labelling requirements. Furthermore, Canada would be adopting the U.S. language as a possible option for the mandatory phenylalanine statement on the labels of foods containing aspartame.

Rationale

Chronic diseases, such as cardiovascular 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, the four main chronic diseases accounted for approximately $26.7 billion annually in both direct and indirect health expenses. Unhealthy eating is a major modifiable risk factor for chronic disease 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 choices. There is a constant flow of changing and often conflicting messages. Moreover, there is widespread availability of inexpensive foods and beverages high in calories, saturated fat, sodium and sugars, and Canadians are consuming these nutrients in excess of recommended levels.

Nutrition information on food labels provides product-specific information to help Canadians make informed food choices. In Canada, the Nutrition Facts table, 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 would complement existing labelling requirements and balance the nutrition information available to consumers on the front of the package. It would offer consumers a simplified and visible indicator to help them make choices that support reductions in excessive intakes of nutrients of concern and, therefore, injury to health. There is evidence to support the role of FOP labelling in helping consumers identify healthier food options. In addition, nutrient-specific interpretive approaches most consistently help consumers to do so.

Many FOP systems are currently being 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 programs. A voluntary approach would not ensure a consistent application of the symbols for products high in sugars, saturated fat and sodium. A mandatory FOP "high in" system, conversely, would create a consistent and credible source of information that all consumers could rely on for quick and easy guidance on key

nutrients of concern. It would also help encourage manufacturers in reformulating their products. The selected approach is consistent with Health Canada's mandate to help protect the health and safety of Canadians.

The other proposed amendments included in this regulatory package are also intended to provide Canadians with improved labelling to help them make healthier food choices as well as improve the nutritional quality of food. These measures are expected to promote Canadians' health and help reduce their risks of chronic disease.

Several options were considered to reduce the cost and burden for industry, particularly small businesses, in implementing these proposals. Options considered were

- a transition period for many of the proposed amendments, aligned with the amended transition period of the 2016 nutrition labelling regulations, to minimize the cost of complying with new labelling requirements and allow time to deplete current label stock; and
- 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, and
    - products sold only at a roadside stand, craft show, flea market, fair, farmers' market or sugar bush by the person who prepared and processed the product.

Health Canada's expert analysis has determined that the proposed amendments are the most appropriate way to proceed. A net benefit present value to the Canadian population of $2.36 billion relating to a cost savings for cardiovascular disease, diabetes mellitus, malignant neoplasms and musculoskeletal disease is anticipated over 10 years from the coming-into-force date (*Canada Gazette*, Part II, publication).

Implementation, enforcement and service standards

Implementation

Regulated parties would be given a transitional period ending on December 14, 2022, to comply with the provisions of this proposal relating to the FOP nutrition symbol, the placement and legibility requirements for the phenylalanine statement, nutrient content claims, and vitamin D fortification. This period of time, which aligns with the end of the transitional period for the 2016 nutrition labelling regulations, will allow sufficient time for regulated parties to make the necessary changes to their product formulations and labels and to use up any existing stocks of products or labels already printed to comply with existing requirements.

Ongoing public education efforts would accompany these proposed regulatory amendments to help consumers understand how best to use the information on the labels to make informed food choices.

Enforcement

The Canadian Food Inspection Agency (CFIA) is responsible for the enforcement of the *Food and Drugs Act* 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, respecting the resources that the CFIA has for enforcement and compliance verification. Appropriate enforcement action will be taken based on risk. Health Canada will provide guidance to the CFIA on health risk assessments and implementation of these proposed regulatory amendments.

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 the CFIA will advise industry on a Government of Canada implementation plan that will describe how key activities will be managed, such as responding to inquiries, the delivery of information sessions, and updating of inspection and compliance-promotion tools. In addition, the CFIA will outline a phased-in approach to compliance and enforcement activities over the transition period when manufacturers may apply the regulatory provisions pertaining to each of the various components of this regulatory proposal as they were immediately before or immediately after publication in the *Canada Gazette*, Part II.

Performance measurement and evaluation

Health Canada will implement the program evaluation requirements of the Treasury Board *Policy on Results* with respect to certain elements of this proposal (i.e. front-of-package 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 December 14, 2022, Health Canada will incorporate monitoring and data collection pertaining to the implementation of these nutrition labelling amendments as part of this strategy.

Contact

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Small Business Lens Checklist

1. Name of the sponsoring regulatory organization:

Department of Health

2. Title of the regulatory proposal:

Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Nutrition Symbols, Other Labelling Provisions, Partially Hydrogenated Oils and Vitamin D)

3. Is the checklist submitted with a RIAS for the *Canada Gazette*, Part I or Part II?

☑ *Canada Gazette*, Part I ☐ *Canada Gazette*, Part II

A. Small business regulatory design

I	Communication and transparency	Yes	No	N/A
1.	Are the proposed Regulations or requirements easily understandable in everyday language?	☑	☐	☐
The proposed Regulations would be written in plain language, consistent with terminology currently used in the FDR.				
2.	Is there a clear connection between the requirements and the purpose (or intent) of the proposed Regulations?	☑	☐	☐
Yes, there are many qualitative and quantitative examples of the proposed benefits of the Regulations. The policy intent is clearly expressed and the evidence is supported.				
3.	Will there be an implementation plan that includes communications and compliance promotion activities that informs small business of a regulatory change and guides them on how to comply with it (e.g. information sessions, sample assessments, toolkits, websites)?	☑	☐	☐
4.	If new forms, reports or processes are introduced, are they consistent in appearance and format with other relevant government forms, reports or processes?	☐	☐	☑

No new forms or processes would be introduced. All reporting, compliance and enforcement would not change from the current Regulations.

II	Simplification and streamlining	Yes	No	N/A
1.	Will streamlined processes be put in place (e.g. through BizPaL, Canada Border Services Agency single window) to collect information from small businesses where possible?	☐	☐	☑

This proposal would not collect information from small businesses.

2.	Have opportunities to align with other obligations imposed on business by federal, provincial, municipal or international or multinational regulatory bodies been assessed?	☑	☐	☐

With the exception of the proposed FOP nutrition symbol and the minor differences in vitamin D fortification levels for milk and margarine, all other elements of this regulatory proposal align with existing requirements in the United States and in other jurisdictions.

3.	Has the impact of the proposed Regulations on international or interprovincial trade been assessed?	☑	☐	☐

Considerations have been given to align the proposed amendments with the standards of international trading partners, such as the United States, to the maximum extent possible. Current requirements to have bilingual labels in Canada would remain and would not be a change from the requirements that international trading partners are currently following. Member countries of the World Trade Organization (WTO) have been notified of this proposal as per the WTO Technical Barriers to Trade Agreement requirement.

4.	If the data or information, other than personal information, required to comply with the proposed Regulations is already collected by another department or jurisdiction, will this information be obtained from that department or jurisdiction instead of requesting the same information from small businesses or other stakeholders? (The collection, retention, use, disclosure and disposal of personal information are all subject to the requirements of the *Privacy Act*. Any questions with respect to compliance with the *Privacy Act* should be referred to the department's or agency's ATIP office or legal services unit.)	☐	☑	☐

There are no new requirements for submitting data or information to comply with the proposed Regulations.

5.	Will forms be pre-populated with information or data already available to the department to reduce the time and cost necessary to complete them? (Example: When a business completes an online application for a licence, upon entering an identifier or a name, the system pre-populates the application with the applicant's personal particulars such as contact information, date, etc. when that information is already available to the department.)	☐	☐	☑

All existing record-keeping requirements of industry to comply with CFIA regulations would remain unchanged.

6.	Will electronic reporting and data collection be used, including electronic validation and confirmation of receipt of reports where appropriate?	☐	☐	☑
All existing record-keeping requirements of industry to comply with CFIA regulations would remain unchanged.				
7.	Will reporting, if required by the proposed Regulations, be aligned with generally used business processes or international standards if possible?	☐	☐	☑
No additional reporting would be required as part of the proposed amendments.				
8.	If additional forms are required, can they be streamlined with existing forms that must be completed for other government information requirements?	☐	☐	☑
No additional forms would be required.				
III	**Implementation, compliance and service standards**	**Yes**	**No**	**N/A**
1.	Has consideration been given to small businesses in remote areas, with special consideration to those that do not have access to high-speed (broadband) Internet?	☑	☐	☐
Consideration has been given to small businesses in remote areas and it has been determined that these businesses would not be affected by the proposed amendments.				
2.	If regulatory authorizations (e.g. licences, permits or certifications) are introduced, will service standards addressing timeliness of decision making be developed that are inclusive of complaints about poor service?	☐	☐	☑
No regulatory authorizations are being introduced with this proposal.				
3.	Is there a clearly identified contact point or help desk for small businesses and other stakeholders?	☑	☐	☐
The CFIA would continue to perform the enforcement of the labelling requirements and would continue to be the contact point for small businesses and other stakeholders.				

B. Regulatory flexibility analysis and reverse onus

IV	Regulatory flexibility analysis	Yes	No	N/A

1.	Does the RIAS identify at least one flexible option that has lower compliance or administrative costs for small businesses in the small business lens section? Examples of flexible options to minimize costs are as follows: • Longer time periods to comply with the requirements, longer transition periods or temporary exemptions; • Performance-based standards; • Partial or complete exemptions from compliance, especially for firms that have good track records (legal advice should be sought when considering such an option); • Reduced compliance costs; • Reduced fees or other charges or penalties; • Use of market incentives; • A range of options to comply with requirements, including lower-cost options; • Simplified and less frequent reporting obligations and inspections; and • Licences granted on a permanent basis or renewed less frequently.	☑	☐	☐
Four options were proposed in the analysis as means to reduce burden on small business: • A longer transitional period of five years would allow small businesses to exhaust their existing product and label stock, without having to throw away products. • Allow for the FOP nutrition symbol to only be required on products containing nutrients of concern instead of all manufactured products. • Maintain the exemption for products sold in farmers markets and roadside stands. • Allow for the label to be printed in black and white font, instead of incorporating a more costly coloured labelling scheme.				
2.	Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, quantified and monetized compliance and administrative costs for small businesses associated with the initial option assessed, as well as the flexible, lower-cost option?	☑	☐	☐
The RIAS includes a breakdown of how the flexible options provide a number of avoided costs for small business. Each of the three options is monetized and demonstrates how these options would avoid a number of financial burdens for small business. The cost avoidance of a transition period of five years would apply to all business.				
3.	Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, a consideration of the risks associated with the flexible option? (Minimizing administrative or compliance costs for small business cannot be at the expense of greater health, security or safety or create environmental risks for Canadians.)	☑	☐	☐
The most commonly identified risk raised by stakeholders is associated with the coming-into-force period. The proposed transition period would apply to all businesses.				
4.	Does the RIAS include a summary of feedback provided by small business during consultations?	☐	☐	☑

No individual small businesses were identified during the consultation period and were assumed to be captured through industry stakeholder organizations during the consultations.				
V	**Reverse onus**	**Yes**	**No**	**N/A**
1.	If the recommended option is not the lower-cost option for small business in terms of administrative or compliance costs, is a reasonable justification provided in the RIAS?	☐	☐	☑
The flexible options are the lowest-cost option and are recommended to lessen the economic impact for small business.				

PROPOSED REGULATORY TEXT

Notice is given that the Governor in Council, pursuant to subsections 30(1) (see footnote a) and 30.5(1) (see footnote b) of the *Food and Drugs Act* (see footnote c), proposes to make the annexed *Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Nutrition Symbols, Other Labelling Provisions, Partially Hydrogenated Oils and Vitamin D)*.

Interested persons may make representations concerning the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Bruno Rodrigue, Director, Office of Legislative and Regulatory Modernization, Health Canada, 11 Holland Avenue, suite 14, Ottawa, Ontario K1A 0K9 (email: LRM_MLR_consultations@hc-sc.gc.ca). It is recommended that the reader review the regulations in conjunction with the Directory of Nutrition Symbol Formats, the Table of Permitted Nutrient Content Statements and Claims and the Nutrition Symbol Consultation as the subject matter is closely linked. Please consult the Consultation on Proposed Front of Package Labelling page [https://www.canada.ca/en/health-canada/programs/consultation-front-of-package-nutrition-labelling-cgi.html] for links to these documents.

Ottawa, December 14, 2017

Jurica Čapkun

Assistant Clerk of the Privy Council

Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Nutrition Symbols, Other Labelling Provisions, Partially Hydrogenated Oils and Vitamin D)

Food and Drug Regulations

1 (1) The definition *prepackaged meal* in subsection B.01.001(1) of the *Food and Drug Regulations* (see footnote 24) **is replaced by the following:**

prepackaged meal means a single-serving prepackaged product that requires no preparation other than heating and that

(a) contains a minimum of one reference amount of food from one of the following categories of food:

(i) milk, milk products and their alternatives, other than butter, cream, sour cream, ice cream, ice milk, sherbet and alternatives for those foods; or

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

(b) contains a minimum of one reference amount of food from one of the following categories of food:

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

(ii) breads, breakfast cereal, rice and other grains, and pasta and other alimentary pastes; and

(c) is represented or sold as a meal; (*repas préemballé*)

(2) Subsection B.01.001(1) of the Regulations is amended by adding the following in alphabetical order:

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

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

main dish means a prepackaged product that requires no preparation other than heating and that

(a) contains a reference amount of food from each of at least two of the following categories of food:

(i) milk, milk products and their alternatives, other than butter, cream, sour cream, ice cream, ice milk, sherbet and alternatives for those foods;

(ii) meat products, poultry products, marine and fresh water animal products referred to in Division 21, and their alternatives such as eggs, tofu, legumes, nuts

and seeds and spreads made from legumes, nuts and seeds;

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

(iv) breads, breakfast cereal, rice and other grains, and pasta and other alimentary pastes; and

(b) is represented or sold as a major component of a meal, other than beverages and desserts; (*plat principal*)

nutrition symbol means the symbol referred to in section B.01.351 that appears on the label of a prepackaged product; (*symbole nutritionnel*)

partially hydrogenated , in respect of a fat or oil, means a fat or oil that has been hydrogenated and has an iodine value of greater than 4; (*partiellement hydrogénée*)

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 the top, if any;

(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 lid's top surface;

(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 package's total surface area, excluding the top and bottom, if any, if it is possible for that 40% 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 on 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 food is wine that is exposed for sale, any part of the package's surface, 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 it contains 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 that is 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) Paragraph B.01.008.1(1)(d) of the Regulations is replaced by the following:

> **(d)** in regular type, subject to paragraph B.01.008.2(1)(b), subparagraph B.01.010.3(1)(a)(ii) and paragraphs B.01.010.3(1)(c), B.01.010.4(1)(c) and (d) and B.01.014(2)(a); and

(3) Paragraph B.01.008.1(1)(e) of the Regulations is replaced by the following:

> **(e)** subject to subsection B.01.014(4), 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.

(4) Subsection B.01.008.1(3) of the Regulations is replaced by the following:

(3) Despite paragraph (1)(e) and subject to subsection B.01.014(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 appearing on the label must appear in type that is the same height that is not less than 1.4 mm with identical leading of not less than 3.2 mm.

(5) Subsection B.01.008.1(4) of the Regulations is replaced by the following:

(4) Despite paragraph (1)(e) and subject to subsection B.01.014(4), a title that introduces a list of ingredients, a food allergen source, gluten source and added sulphites statement, as set out in subsection B.01.010.1(2), or a declaration referred to in subsection B.01.010.4(1) may be shown in type that is of a height that is greater than the height of the type used to show the ingredients in the list, the information in the statement or the information in the 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 a food allergen source, gluten source and added sulphites statement, as set out in subsection B.01.010.1(2), a declaration referred to in subsection B.01.010.4(1), a phenylalanine statement referred to in subsection B.01.014(1) and 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 as are contained in a prepackaged product is less than 15% of that prepackaged product

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

(b) fully hydrogenated peanut oil; and

5 (1) The portion of item 12 of the table to paragraph B.01.010(3)(a) of the Regulations in column I is replaced by the following:

Item	Column I Ingredient or Component
12	any oil or fat referred to in section B.09.002 that has been fully hydrogenated, including tallow, but not including lard

(2) The portion of items 14 to 16 of the table to paragraph B.01.010(3)(a) of the Regulations in column I is replaced by the following:

Item	Column I Ingredient or Component
14	vegetable fats or oils, except coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter, that have been fully hydrogenated
15	coconut oil, palm oil, palm kernel oil, peanut oil or cocoa butter that has been fully hydrogenated
16	marine fats or oils that have been fully hydrogenated

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 sections B.01.010.3, B.01.010.4 and B.01.014, sulphites means one or more food additives that are listed exclusively in column I of item 21 of the table to paragraph B.01.010(3)(b) and are present in a prepackaged product.

7 (1) The portion of subsection B.01.010.3(1) of the French version of the Regulations before paragraph (a.1) is replaced by the following:

B.01.010.3 (1) La mention des sources d'allergènes alimentaires ou de gluten et des sulfites ajoutés qui figure sur l'étiquette d'un produit préemballé satisfait aux exigences suivantes :

a) elle débute par un titre conforme aux précisions suivantes :

(i) il est formé par les mots suivants :

(A) s'agissant de la version française de la mention des sources d'allergènes alimentaires ou de gluten et des sulfites ajoutés, « Contient » ou « Contient: »,

(B) s'agissant de la version anglaise de la même mention, « Contains » ou « Contains: »,

(ii) il est en caractères gras,

(iii) il figure sans qu'aucun texte imprimé ou écrit ni aucun signe graphique ne soit intercalé entre lui et la suite de la mention;

(2) Paragraph B.01.010.3(1)(a.1) of the Regulations is replaced by the following:

(a.1) appear, in respect of each linguistic version, after the phenylalanine statement referred to in subsection B.01.014(1) or, if there is none, after the list of ingredients appearing in the same language and, in either case, without any intervening printed, written or graphic material;

(3) Subparagraph B.01.010.3(1)(a.2)(ii) of the Regulations is replaced by the following:

(ii) if the list of ingredients and the phenylalanine statement referred to in subsection B.01.014(1), if any, and the declaration referred to in subsection B.01.010.4(1), if any, are differentiated by means of a solid-line border or solid lines in accordance with paragraph B.01.008.2(2)(a) and subparagraphs B.01.010.4(1)(a)(ii) and B.01.014(2)(b)(iv), respectively, within the border or the lines;

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

(a) the declaration must be shown immediately after the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2) or, if there is none, immediately after the phenylalanine statement referred to in subsection B.01.014(1) or, if there is none, immediately after the list of ingredients and must appear:

(i) on the same continuous surface as the list of ingredients,

(ii) against the same background colour as that of the list, and

(iii) if the list of ingredients, the phenylalanine statement referred to in subsection B.01.014(1), if any, and the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, are

differentiated by means of a solid-line border or solid lines in accordance with paragraph B.01.008.2(2)(a), subparagraph B.01.014(2)(b)(iv) and subparagraph B.01.010.3(1)(a.2)(ii), respectively, within the border or the lines;

(b) the declaration must appear without any intervening printed, written or graphic material between it and the list of ingredients or the phenylalanine statement referred to in subsection B.01.014(1), if any, or the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, that immediately precedes it, except that a solid line may appear before the declaration if the declaration begins on a different line than that on which the list of ingredients or the phenylalanine statement referred to in subsection B.01.014(1) or the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, that immediately precedes it ends;

(c) the declaration must appear in bold type if it begins on the same line as that on which the list of ingredients or the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, or the phenylalanine statement as set out in subsection B.01.014(1), if any, that immediately precedes it ends and it is not introduced by a title; and

(d) the title that introduces the declaration, if any, must appear in bold type if the declaration begins on the same line as that on which the list of ingredients or the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, or the phenylalanine statement referred to in subsection B.01.014(1), if any, that immediately precedes it ends.

(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 two versions must not begin and end on the same line except in the case of a prepackaged product that 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 include the statement "Phenylketonurics: contains phenylalanine" or a statement to the effect that aspartame contains phenylalanine.

(2) The statement set out in subsection (1)

(a) must appear in bold type, and

(b) must appear, in respect of each linguistic version,

(i) immediately after the list of ingredients, either on the same line as the last

ingredient on the list of ingredients appearing in the same language or on a new line but before the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, or if there is no such statement, before the declaration referred to in subsection B.01.010.4(1), if any, without any intervening printed, written or graphic material,

(ii) on the same continuous surface as the list of ingredients,

(iii) against the same background colour as that of the list, and

(iv) if the list of ingredients, the food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, and the declaration referred to in subsection B.01.010.4(1), if any, are differentiated by means of a solid-line border or solid lines in accordance with paragraph B.01.008.2(2)(a) and subparagraphs B.01.010.3(1)(a.2)(ii) and B.01.010.4(1)(a)(ii), respectively, within the border or the lines.

(3) If the English and French versions of the statement set out in subsection (1) appear on the same continuous surface of the label, the two versions must not begin and end on the same line, except in the case of a prepackaged product that has an available display surface of less than 100 cm^2.

(4) Any food allergen source, gluten source and added sulphites statement as set out in subsection B.01.010.1(2), if any, or a declaration referred to in subsection B.01.010.4(1), if any, may appear on the same line as the statement described in subsection (1) if the title of the food allergen source, gluten source and added sulphites statement and the title of the declaration, if any, or the declaration itself if no title appears, are provided in a type that is of a height that is at least 0.2 mm greater than the height of the type of the statement set out in subsection (1).

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 Section B.01.301 of the Regulations is amended by adding the following after subsection (3):

(4) Despite subsections (1) and (2), if the label of a prepackaged product carries a nutrition symbol, no declaration referred to in subsections (1) and (2) may be shown, as the case may be, except if it appears on the nutrition facts table,

(a) on the right-most 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(a); or

(b) on the top 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(b).

(5) Any declaration referred to in subsections (1) and (2) that is displayed on the lower- or left-most 65% of the principal display panel of the product's label , as the case may be, must comply with the following dimensions:

(a) the height of upper case letters, if any, must not exceed two times the height of upper case letters, excluding any accents, on the nutrition symbol; and

(b) the height of the tallest ascender of lower case letters, if any, must not exceed two times the height of the tallest ascender of lower case letters on the nutrition symbol.

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

(g) the statement required by subsection B.01.014(1);

14 Section B.01.311 of the Regulations is amended by adding the following after subsection (5):

(6) Despite subsections (2) and (3), if the label of a prepackaged product carries a nutrition symbol, no statement or claim referred to in those subsections may be shown, as the case may be,

(a) on the right-most 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(a); or

(b) on the top 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(b).

(7) Any statement or claim referred to in subsection (2) or (3) that is displayed on the lower- or left-most 65% of the principal display panel of the product's label, as the case may be, must comply with the following dimensions:

(a) the height of upper case letters, if any, must not exceed two times the height of upper case letters, excluding any accents, on the nutrition symbol; and

(b) the height of the tallest ascender of lower case letters, if any, must not exceed two times the height of the tallest ascender of lower case letters on the nutrition symbol.

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

Nutrition Symbols

Mandatory Information

B.01.350 (1) Subject to subsections (2) to (6), a prepackaged product that contains a nutrient set out in column 1 of the table to this section must carry a nutrition symbol on the principal display panel of its label to indicate that the product, as offered for sale, is high in that nutrient if the amount of the nutrient, calculated as a percentage of the daily value, meets or exceeds the threshold set out in columns 2 to 4, as applicable.

(2) To determine if the label of a prepackaged product must carry a nutrition symbol under subsection (1), the percentage of the daily value of the nutrient in the product is calculated on the basis of the amount of the nutrient, by weight,

(a) per 50 g of the product, if the serving of stated size and reference amount of the product are less than 50 g and the percentage of the daily value of the nutrient in the product, per serving of stated size or per reference amount of the product, whichever is greater, is 5% or more; or

(b) per serving of stated size or per reference amount of the product, whichever is greater, in all other cases.

(3) Despite subsection (2), if no more than 30% of the total fat content of a prepackaged product is composed of saturated fat and *trans* fat, the percentage of the daily value of saturated fat is calculated on the basis of the amount of saturated fat, by weight, per serving of stated size or per reference amount, whichever is greater.

(4) Subsection (1) does not apply to the following prepackaged products:

(a) a fresh, frozen or canned vegetable or fruit, or any combination of those foods, that do not have any added ingredients, other than water or any food additive referred to in section 2 of a marketing authorization;

(b) those that have an available display surface of less than 15 cm^2;

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

(d) 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;

(e) non-flavoured whole and partly skimmed milk, obtained from any animal, in liquid or powder form;

(f) whole eggs, fresh or in liquid, frozen or dried form;

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

(h) salt for table or general household use, celery salt, garlic salt and onion salt; and

(i) individual rations for use in military operations.

(5) Subsection (1) does not apply to the following prepackaged products if they do not carry a nutrition facts table in accordance with paragraph B.01.401(2)(b), subsection B.01.401(3) or section B.01.467:

(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; and

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

(6) A prepackaged product intended solely for infants less than one year of age, a formulated liquid diet, a human milk substitute, a food represented as containing a human milk substitute or a food represented for use in a very low energy diet must not carry a nutrition symbol on their label.

TABLE

Thresholds Requiring a Nutrition Symbol

Item	Column 1 Nutrient	Column 2 Threshold for prepackaged products other than those referred to in columns 3 and 4	Column 3 Threshold for prepackaged products intended solely for children one year of age or older but less than four years of age	Column 4 Threshold for prepackaged meals and main dishes with a serving of stated size of 200 g or more
1	Saturated fat	15% of the daily value for the sum of saturated fat and trans fat indicated in column 3 of Part 1 of the Table of Daily Values.	15% of the daily value for the sum of saturated fat and trans fat indicated in column 2 of Part 1 of the Table of Daily Values.	30% of the daily value for the sum of saturated fat and trans fat indicated in column 3 of Part 1 of the Table of Daily Values.

2	Sugars	15% of the daily value for sugars indicated in column 3 of Part 1 of the Table of Daily Values.	15% of the daily value for sugars indicated in column 2 of Part 1 of the Table of Daily Values.	30% of the daily value for sugars indicated in column 3 of Part 1 of the Table of Daily Values.
3	Sodium	15% of the daily value for sodium indicated in column 3 of Part 1 of the Table of Daily Values.	15% of the daily value for sodium indicated in column 2 of Part 1 of the Table of Daily Values.	30% of the daily value for sodium indicated in column 3 of Part 1 of the Table of Daily Values.

Presentation of Nutrition Symbol

B.01.351 (1) The nutrition symbol includes one or more words to indicate that a prepackaged product is high in saturated fat, sugars or sodium, or any combination of those nutrients, and an attribution of the message to Health Canada, all of which are surrounded by a solid-line border.

(2) The nutrition symbol must be presented in one of the following formats in accordance with the applicable figure in the Directory of Nutrition Symbol Formats:

(a) standard format, which is shown in two separate versions, one in English and one in French; or

(b) bilingual standard format, in which the words on the symbol are in both official languages.

(3) If the nutrition symbol is presented in a bilingual standard format, the order of languages may be reversed from the order shown in the applicable figure of the Directory of Nutrition Symbol Formats.

B.01.352 (1) The nutrition symbol of a prepackaged product which contains the nutrients set out in column 1 of the table to this section that meet or exceed the threshold referred to in subsection B.01.350(1) and that has a principal display surface area of a range set out in column 3 must be presented in accordance with the figure in the Directory of Nutrition Symbol Formats set out in column 2.

(2) For greater certainty, the nutrition symbol must be presented in accordance with the applicable figure in the Directory of Nutrition Symbol Formats, having regard to matters such as the dimensions of the symbol, the characters, the colour and the minimum buffer.

(3) The nutrition symbol may be displayed with larger dimensions than those set out in the applicable figure in the Directory of Nutrition Symbol Formats if it is enlarged in a proportional manner vertically and horizontally.

TABLE

PART 1

Standard Format

Item	Column 1 Nutrients that meet or exceed threshold	Column 2 Figure in Directory of Nutrition Symbol Formats	Column 3 Range of principal display surface area
1	**Saturated fat, sugars and sodium**	1.0(E) and (F)	600 cm^2 < principal display surface
	Saturated fat and sugars	1.1(E) and (F)	
	Sugars and sodium	1.2(E) and (F)	
	Saturated fat and sodium	1.3(E) and (F)	
	Saturated fat	1.4(E) and (F)	
	Sugars	1.5(E) and (F)	
	Sodium	1.6(E) and (F)	
2	**Saturated fat, sugars and sodium**	2.0(E) and (F)	450 cm^2 < principal display surface ≤ 600 cm^2
	Saturated fat and sugars	2.1(E) and (F)	
	Sugars and sodium	2.2(E) and (F)	
	Saturated fat and sodium	2.3(E) and (F)	
	Saturated fat	2.4(E) and (F)	
	Sugars	2.5(E) and (F)	
	Sodium	2.6(E) and (F)	
3	**Saturated fat, sugars and sodium**	3.0(E) and (F)	250 cm^2 < principal display surface ≤ 450 cm^2
	Saturated fat and sugars	3.1(E) and (F)	
	Sugars and sodium	3.2(E) and (F)	
	Saturated fat and sodium	3.3(E) and (F)	
	Saturated fat	3.4(E) and (F)	
	Sugars	3.5(E) and (F)	
	Sodium	3.6(E) and (F)	

4	**Saturated fat, sugars and sodium**	4.0(E) and (F)	100 cm^2 <principal display surface ≤ 250 cm^2
	Saturated fat and sugars	4.1(E) and (F)	
	Sugars and sodium	4.2(E) and (F)	
	Saturated fat and sodium	4.3(E) and (F)	
	Saturated fat	4.4(E) and (F)	
	Sugars	4.5(E) and (F)	
	Sodium	4.6(E) and (F)	
5	**Saturated fat, sugars and sodium**	5.0(E) and (F)	30 cm^2< principal display surface ≤ 100 cm^2
	Saturated fat and sugars	5.1(E) and (F)	
	Sugars and sodium	5.2(E) and (F)	
	Saturated fat and sodium	5.3(E) and (F)	
	Saturated fat	5.4(E) and (F)	
	Sugars	5.5(E) and (F)	
	Sodium	5.6(E) and (F)	
6	**Saturated fat, sugars and sodium**	6.0(E) and (F)	principal display surface ≤ 30 cm^2
	Saturated fat and sugars	6.1(E) and (F)	
	Sugars and sodium	6.2(E) and (F)	
	Saturated fat and sodium	6.3(E) and (F)	
	Saturated fat	6.4(E) and (F)	
	Sugars	6.5(E) and (F)	
	Sodium	6.6(E) and (F)	

PART 2

Bilingual Standard Format

Item	Column 1 Nutrients that meet or exceed threshold	Column 2 Figure in Directory of Nutrition Symbol Formats	Column 3 Range of principal display surface area

1	**Saturated fat, sugars and sodium**	1.0(B)	600 cm^2 < principal display surface
	Saturated fat and sugars	1.1(B)	
	Sugars and sodium	1.2(B)	
	Saturated fat and sodium	1.3(B)	
	Saturated fat	1.4(B)	
	Sugars	1.5(B)	
	Sodium	1.6(B)	
2	**Saturated fat, sugars and sodium**	2.0(B)	450 cm^2 < principal display surface ≤ 600 cm^2
	Saturated fat and sugars	2.1(B)	
	Sugars and sodium	2.2(B)	
	Saturated fat and sodium	2.3(B)	
	Saturated fat	2.4(B)	
	Sugars	2.5(B)	
	Sodium	2.6(B)	
3	**Saturated fat, sugars and sodium**	3.0(B)	250 cm^2 < principal display surface ≤ 450 cm^2
	Saturated fat and sugars	3.1(B)	
	Sugars and sodium	3.2(B)	
	Saturated fat and sodium	3.3(B)	
	Saturated fat	3.4(B)	
	Sugars	3.5(B)	
	Sodium	3.6(B)	
4	**Saturated fat, sugars and sodium**	4.0(B)	100 cm^2 < principal display surface ≤ 250 cm^2
	Saturated fat and sugars	4.1(B)	
	Sugars and sodium	4.2(B)	
	Saturated fat and sodium	4.3(B)	
	Saturated fat	4.4(B)	

	Sugars	4.5(B)	
	Sodium	4.6(B)	
5	**Saturated fat, sugars and sodium**	5.0(B)	30 cm^2 < principal display surface ≤ 100 cm^2
	Saturated fat and sugars	5.1(B)	
	Sugars and sodium	5.2(B)	
	Saturated fat and sodium	5.3(B)	
	Saturated fat	5.4(B)	
	Sugars	5.5(B)	
	Sodium	5.6(B)	
6	**Saturated fat, sugars and sodium**	6.0(B)	principal display surface ≤ 30 cm^2
	Saturated fat and sugars	6.1(B)	
	Sugars and sodium	6.2(B)	
	Saturated fat and sodium	6.3(B)	
	Saturated fat	6.4(B)	
	Sugars	6.5(B)	
	Sodium	6.6(B)	

B.01.353 (1) Subject to subsection (2), in the case of a prepackaged product that contains an assortment of foods, the nutrition symbol or symbols must clearly indicate, for each food, the nutrients that meet or exceed the applicable threshold.

(2) In the case of a prepackaged product that contains separately packaged ingredients or foods that are intended to be consumed together, the nutrition symbol must display the nutrients that, in accordance with section B.01.350, meet or exceed the applicable threshold for the product as a whole.

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

Location of Nutrition Symbol

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

(a) in the case of a prepackaged product where the height of the principal display surface is less than its width, on that part of the principal display panel that represents the right-

most 25% of the panel; and

(b) in the case of other prepackaged products, on that part of the principal display panel that represents the upper 25% of the panel.

(2) In the case of a prepackaged product that is cylindrical in shape, the nutrition symbol must be a minimum distance of 10% of the width of the principal display surface from the edges of the left or right side of the principal display surface.

(3) The nutrition symbol must be clearly visible and distinguishable from all other information located on the label of the product.

(4) The nutrition symbol must be surrounded by a minimum buffer whose dimension is equal to or greater than that indicated for the applicable figure in the Directory of Nutrition Symbol Formats, and in which no text may appear.

B.01.356 The nutrition symbol must be oriented in such a manner that the words appearing on it are readable from left to right and are parallel with the base of the package.

B.01.357 (1) If the label of a prepackaged product carries a nutrition symbol, a person must not apply any other health-related name, statement, logo, symbol, seal of approval or mark

(a) on the right-most 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(a); or

(b) on the top 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(b).

(2) Any health-related name, statement, logo, symbol, seal of approval or mark referred to in subsection (1) that is displayed on the lower or left-most 65% of the principal display panel of the product's label, as the case may be, must comply with the following dimensions:

(a) the height of upper case letters, if any, must not exceed two times the height of upper case letters, excluding any accents, on the nutrition symbol; and

(b) the height of the tallest ascender of lower case letters, if any, must not exceed two times the height of the tallest ascender of lower case letters on the nutrition symbol.

B.01.358 A person must not, in respect of a prepackaged product,

(a) apply or use any representation, such as a word, phrase, illustration, sign, mark, symbol or design, that so closely resembles the nutrition symbol that it is likely to be mistaken for the nutrition symbol; or

(b) advertise, sell or possess it for such purposes if it carries a representation referred to in paragraph (a).

16 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 »

17 The Regulations are amended by adding the following after section B.01.501:

Labelling — Restrictions

B.01.501.1 (1) If the label of a prepackaged product carries a nutrition symbol, the representations referred to in sections B.01.503 to B.01.513 must not be shown, as the case may be,

(a) on the right-most 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(a); or

(b) on the top 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(b).

(2) Any representations referred to in sections B.01.503 to B.01.513 that are displayed on the lower- or left-most 65% of the principal display panel of the product's label, as the case may be, must comply with the following dimensions:

(a) the height of upper case letters, if any, must not exceed two times the height of upper case letters, excluding any accents, on the nutrition symbol; and

(b) the height of the tallest ascender of lower case letters, if any, must not exceed two times the height of the tallest ascender of lower case letters on the nutrition symbol.

18 (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 that which is in the form of a nutrition symbol referred to in section B.01.350;

(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;

19 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:

20 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), a person must not, on the label of or in any advertisement for a food, make a representation, express or implied, that the food is for use in a sodium-restricted diet if a nutrition symbol referring to sodium is required pursuant to section B.01.350 on the label of the food.

21 Section B.01.509 of the Regulations is repealed.

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

23 The Regulations are amended by adding the following after section B.01.600:

Labelling — Restrictions

B.01.600.1 (1) If the label of a prepackaged product carries a nutrition symbol, a statement or claim referred to in subsection B.01.601(1) must not be shown, as the case may be,

(a) on the right-most 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(a); or

(b) on the top 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(b).

(2) Any statement or claim referred to in subsection B.01.601(1) that is displayed on the lower- or left-most 65% of the principal display panel of the product's label, as the case may be, must comply with the following dimensions:

(a) the height of upper case letters, if any, must not exceed two times the height of upper case letters, excluding any accents, on the nutrition symbol; and

(b) the height of the tallest ascender of lower case letters, if any, must not exceed two times the height of the tallest ascender of lower case letters on the nutrition symbol.

24 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

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

(b) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL.

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

(c) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL.

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

(c) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL.

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

(d) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL.

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

(d) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL when reconstituted to original volume; and

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

(e) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL when reconstituted to original volume; and

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

(f) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL when reconstituted to original volume; and

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

(c) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL when reconstituted according to directions for use; and

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

(d) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL when reconstituted according to directions for use; and

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

(c) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL;

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

(d) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL; and

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

(d) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL;

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

(e) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL.

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

(d) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL.

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

(e) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL; and

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

(e) despite sections D.01.009 to D.01.011, shall contain 2 µg of vitamin D per 100 mL;

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

B.08.029 (1) Despite sections D.01.009 to D.01.011, a person shall sell only goat's milk or goat's milk powder to which vitamin D has been added if 100 mL of that food when ready to serve contains 2 µg of vitamin D.

(2) Despite sections D.01.009 to D.01.011, a person shall sell only skimmed or partly skimmed goat's milk or skimmed or partly skimmed goat's milk powder to which vitamins have been added if 100 mL of that food when ready to serve contains 2 µg of vitamin D and not less than 140 IU and not more than 300 IU of vitamin A.

(3) Despite sections D.01.009 to D.01.011, a person shall sell only evaporated goat's milk to which vitamins have been added if 100 mL of the evaporated goat's milk, when reconstituted to original volume, contains 2 µg of vitamin D and not less than 7 mg and not more than 9 mg of vitamin C, and not less than 10 µg and not more than 20 µg of folic acid.

(4) Despite sections D.01.009 to D.01.011, a person shall sell only evaporated partly skimmed goat's milk or evaporated skimmed goat's milk to which vitamins have been added if 100 mL of that food, when reconstituted to original volume, contains 2 µg of vitamin D, not less than 140 IU and not more than 300 IU of vitamin A, not less than 7 mg and not more than 9 mg of vitamin C, and not less than 10 µg and not more than 20 µg of folic acid.

42 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

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

(i) lard stearine or fully hydrogenated lard,

44 (1) Paragraph B.09.016(a) of the Regulations is 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;

(2) Paragraph B.09.016(b) of the Regulations is replaced by the following:

(b) must contain

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

(ii) despite section D.01.009, not less than 3,300 IU of vitamin A per 100 g, and

(iii) despite sections D.01.009 to D.01.011, 26 µg of vitamin D per 100 g; and

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

(v) vitamin E, if added in any amount that will result in the finished product containing not less than 0.6 IU of alphatocopherol per gram of linoleic acid present in the margarine,

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

B.14.006 Powdered fully hydrogenated cottonseed oil in an amount not greater than 0.25% of the product 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.

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

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

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

B.22.010 Powdered fully hydrogenated cottonseed oil in an amount not greater than 0.25% of the product 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.

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

D.01.001.2 (1) Despite sections D.01.004 to D.01.007 and D.02.002 to D.02.005, if the label of a prepackaged product carries a nutrition symbol, a statement or claim referred to in those sections must not be shown, as the case may be,

(a) on the right-most 35% of the principal display panel of the product's label if the symbol is placed at the location set out in paragraph B.01.355(1)(a); or

(b) on the top 35% of the principal display panel of the product's label if the symbol is

placed at the location set out in paragraph B.01.355(1)(b).

(2) Any statement or claim referred to in sections D.01.004 to D.01.007 and D.02.002 to D.02.005 that are displayed on the lower- or left-most 65% of the principal display panel of the product's label, as the case may be, must comply with the following dimensions:

(a) the height of upper case letters, if any, must not exceed two times the height of upper case letters, excluding any accents, on the nutrition symbol; and

(b) the height of the tallest ascender of lower case letters, if any, must not exceed two times the height of the tallest ascender of lower case letters on the nutrition symbol.

49 The Regulations are amended by replacing "table following section B.01.513" with "the 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 items 2 to 5 and 7 and 8 of the table to section B.01.401;

(c) the portion of subsection B.01.467(2.1) before paragraph (a) and the portion of paragraph B.01.467(2.1)(c) before subparagraph (i);

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

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

(f) the portion of subsection B.01.503(1) before paragraph (a), subsections (2.1) and (3);

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

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

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

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

(k) the portion of section B.01.508 before paragraph (a);

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

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

(n) section B.01.512;

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

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

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

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

subsection (4) before paragraph (a).

Transitional Provisions

50 (1) In this section, *prepackaged product* has the same meaning as in subsection B.01.001(1) of the *Food and Drug Regulations*.

(2) Until December 14, 2022, it is not necessary that a prepackaged product meet the requirements of the following provisions of the *Food and Drug Regulations* if the prepackaged product meets all the requirements set out in sections B.01.301, B.01.311 and B.01.401 and paragraph B.01.502(2)(a) of the *Food and Drug Regulations* as they read before the day on which these Regulations come into force or if it meets all the requirements of those provisions of the *Food and Drug Regulations* as they read before December 14, 2016:

(a) section B.01.301;

(b) section B.01.311;

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

(d) section B.01.401;

(e) section B.01.501.1;

(f) paragraph B.01.502(2)(a);

(g) subsection B.01.508(2);

(h) section B.01.600.1; and

(i) section D.01.001.2.

(3) Until December 14, 2022, it is not necessary that a prepackaged product meet the requirements of the following provisions of the *Food and Drug Regulations* if the prepackaged product meets all the requirements set out in subsections B.01.008.1(1), (3) and (4), paragraph B.01.008.2(2)(b), subsections B.01.010.2(1), B.01.010.3(1) and B.01.010.4(1), sections B.01.014 to B.01.017, B.01.019 to B.01.020, B.01.022 to B.01.023 and paragraph B.01.305(3)(g) of the *Food and Drug Regulations* as they read on the day before the coming into force of these Regulations or if it meets all the requirements set out in subsections B.01.010.2(1) and B.01.010.3(1), sections B.01.014 to B.01.017, B.01.019 to B.01.020 and B.01.022 to B.01.023 and paragraph B.01.305(3)(g) of the *Food and Drug Regulations* as they read before December 14, 2016:

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

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

(c) subsection B.01.010.2(1);

(d) subsection B.01.010.3(1);

(e) section B.01.010.4;

(f) section B.01.014;

(g) section B.01.023; and

(h) paragraph B.01.305(3)(g).

(4) Until December 14, 2022, it is not necessary that a prepackaged product meet the requirements of the following provisions of the *Food and Drug Regulations* if the prepackaged product meets all the requirements of those provisions, section B.01.509 and the table following section B.01.513 of the *Food and Drug Regulations* as they read on the day before the coming into force of these Regulations or if it meets all the requirements of those provisions of the *Food and Drug Regulations* as they read before December 14, 2016:

(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 and 8 of the table to section B.01.401;

(c) section B.01.467;

(d) section B.01.500;

(e) sections B.01.502 to B.01.508;

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

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

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

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

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

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

(5) Until December 14, 2022, it is not necessary that a prepackaged product meet the requirements of the following provisions of the *Food and Drug Regulations* if the prepackaged product is labelled in accordance with the requirements of the *Food and Drug Regulations* as they read before December 14, 2016:

(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);

(q) section B.08.029; and

(r) paragraph B.09.016(b).

(6) A prepackaged product that meets the requirements of the provisions listed in subsection 50(5) of these Regulations must be labelled in accordance with the *Food and Drug Regulations* as they read on the day before the coming into force of these Regulations.

Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Other Labelling Provisions and Food Colours)

51 The *Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Other Labelling Provisions and Food Colours)* (see footnote 25) **are amended by replacing subsection 76(2) that it enacts with the following:**

(2) Despite these Regulations, a prepackaged product may be labelled in accordance with the former Regulations or these Regulations until the day that is six years after the day on which these Regulations come into force.

Coming into Force

52 (1) Subject to subsection (2), these Regulations come into force on the day on which they are published in the *Canada Gazette*, Part II.

(2) Sections 25 to 41 and subsection 44(2) come into force on the 180th day after the day on which these Regulations are published in the *Canada Gazette*, Part II.

[6-1-o]

Footnotes

Footnote 1

Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Other Labelling Provisions and Food Colours) — hereby referred to as "nutrition labelling regulations."

Footnote 2

The *Regulations Amending the Food and Drug Regulations (Nutrition Labelling, Other Labelling Provisions and Food Colours)*, introduced on December 14, 2016 (SOR/2016-305), include updated requirements for the list of ingredients and the Nutrition Facts table.

Footnote 3

See references 9 and 10 from the consultation document *Toward the Prohibition of Partially Hydrogenated Oils in the Canadian Food Supply*: https://www.canada.ca/en/health-canada/programs/banning-partially-hydrogenated-oils-in-foods/consultation-document.html.

Footnote 4

A complete list of all approved sweeteners is set out in the List of Permitted Sweeteners, available on the Government of Canada's website at https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/9-sweeteners.html.

Footnote 5

https://www.canada.ca/en/health-canada/programs/consultation-front-of-package-nutrition-labelling-cgi.html

Footnote 6

Notice of Proposal: Incorporating by Reference the Table of Permitted Nutrient Content Statements and Claims (Reference No. NOP/ADP-NCC-2017-1) https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/proposal-table-permitted-nutrient-content-statements-and-claims.html.

Footnote 7

http://www.nationalacademies.org/hmd/Reports/2011/Front-of-Package-Nutrition-Rating-Systems-and-Symbols-Promoting-Healthier-Choices.aspx

Footnote 8

Project document on Front of Pack Nutrition Labelling from Costa Rica and New Zealand (item 120). 43rd session of the Codex Committee on Food Labelling (October 2016) http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCFL&session=43.

Footnote 9

Paragraphs 66 and 69, Report of the Forty-Third Session of the Codex Committee on Food Labelling [May 2016] http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-43%252FReport%252FREP16_FLe.pdf.

Footnote 10

Canadian Cost-Benefit Analysis Guide: Regulatory Proposals. https://www.tbs-sct.gc.ca/rtrap-parfa/analys/analys-eng.pdf.

Footnote 11

How Healthy are Canadians? A Trend Analysis of the Health of Canadians from a Healthy Living and Chronic Disease Perspective. https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/healthy-living/how-healthy-canadians/pub1-eng.pdf.

Footnote 12

http://www.agr.gc.ca/eng/industry-markets-and-trade/statistics-and-market-information/by-product-sector/processed-food-and-beverages-sector/overview-of-the-food-and-beverage-processing-industry/?id=1174563085690

Footnote 13

Statistics Canada. Leading causes of death, by sex. http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/hlth36a-eng.htm

Footnote 14

Becker, M.H., Radius, S.M., and Rosenstock, I.M. (1978). Compliance with a medical regimen for asthma: a test of the health belief model, *Public Health Reports*, 93, 268–77.

Footnote 15

http://ebic-femc.phac-aspc.gc.ca/custom-personnalise/national.php?clear=1

Footnote 16

Using the total figure for the five identified disease groups, $26,691,300,000 assumes a percentage reduction in total EBIC.

Footnote 17

National Farmers' Market Impact Study, 2009. Agriculture and Agri-Food Canada.

Footnote 18

https://www.canada.ca/en/health-canada/programs/consultation-front-of-package-nutrition-labelling-cgi/directory-of-nutrition-symbol-formats.html

Footnote 19
https://www.canada.ca/en/services/health/publications/food-nutrition/labelling-stakeholder-engagement-meeting-september-2017.html

Footnote 20
http://epe.lac-bac.gc.ca/100/200/301/pwgsc-tpsgc/por-ef/health/2017/060-16-e/report.pdf

Footnote 21
https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/proposal-table-permitted-nutrient-content-statements-and-claims.html

Footnote 22
Notice of Proposal: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods (Ref. No. NOP/ADP-C-2017-3) http://www.hc-sc.gc.ca/fn-an/consult/nop-adp-c-2017-3/index-eng.php.

Footnote 23
Notice of Modification: Prohibiting the Use of Partially Hydrogenated Oils (PHOs) in Foods (Ref. No. NOM/ADM-C-2017-3) https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/modification-prohibiting-use-partially-hydrogenated-oils-in-foods.html.

Footnote 24
C.R.C., c. 870

Footnote 25
SOR/2016-305

Footnote a
S.C. 2016, c. 9, s. 8

Footnote b
S.C. 2014, c. 24, s. 7

Footnote c
R.S., c. F-27