

## Canada Gazette



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## Vol. 149, No. 24 — June 13, 2015 **Regulations Amending the Food and Drug Regulations — Nutrition Labelling, Other Labelling Provisions and Food Colours**

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:** The Government of Canada is proposing to revise and strengthen the nutrition labelling sections of the *Food and Drug Regulations* (FDR, or the Regulations) in order to enable consumers to make informed food choices about the food they consume to maintain or improve their health.

The FDR set out requirements for the Nutrition Facts table (NFt), the list of ingredients on the labels of prepackaged products, the specifications for food colours, and the certification of synthetic food colours. However, the current nutritional information on labels of prepackaged products does not reflect the latest science, and the way the information is presented does not enable consumers to easily compare products at the point of sale. Moreover, despite scientific evidence of the health benefits associated with a reduced risk of heart disease resulting from the consumption of adequate quantities of fruits and vegetables, the current Regulations do not allow this health claim to be made or any nutrient content or health claim to be made on the label of fresh fruits and vegetables without triggering the requirement to provide a NFt. Additionally, the current labelling Regulations provide food manufacturers with the choice of declaring added food colours by either their common name or simply as "colours," which means consumers have difficulties avoiding food colours to which they may have sensitivities. Further, the current requirement that every lot (batch) of synthetic food colour be certified by Health Canada (the Department) provides a level of regulatory oversight that is more stringent than that which is in place for other food additives and more stringent than the requirements in many other countries. Finally, many of the specifications for food colours contained in the FDR are out of date and do not allow for the application of more up-to-date, internationally accepted food-grade specifications that are, in practice, used by the industry.

**Description:** This proposal consists of regulatory amendments that would make the information in labels on prepackaged products (i) more useful and easier to read and (ii) based on the latest science, so that Canadians are better able to maintain or improve their health. The proposed amendments also introduce changes that would help Health Canada achieve efficiencies as a regulator by removing the requirement for the certification of every lot of synthetic food colour, and enable the Department to align with other jurisdictions by relying on internationally recognized food-grade specifications for food colours. Finally, the proposed amendments would allow the claim that fruits and vegetables reduce the risk of heart disease, thereby allowing Canadians to be informed of the health benefits of eating fresh fruits and vegetables.

**Cost-benefit statement:** Costs were estimated based on the inclusion of all regulatory options that were presented during consultations (i.e. the U.S. approach for added sugar, mandatory inclusion of vitamin D in the NFt). Stakeholders indicated that the cost would be a maximum of \$727.1 million and with the removal of outliers, \$598 million. However, the decision to use a Daily Value approach for sugars instead of added sugars would significantly

lower these costs. Using estimates from the U.S. FDA adjusted for the Canadian market would yield costs as low as \$232 million, while using the EU estimates would yield a total one-time cost of \$560 million. The one-time cost to industry based on the \$727.1 million estimates represents 0.8% of the total annual revenues of approximately \$88 billion that the food manufacturing industry generates in Canada. The quantified benefits are estimated to be \$2.753 billion over 10 years, assuming a 1% reduction (compounded annually) in direct and indirect health costs in five chronic diseases (i.e. cardiovascular disease, malignant neoplasm, diabetes mellitus, musculoskeletal disease and nutritional deficiency). It is assumed that consumers, when given the necessary information to make healthy food choices, would experience reductions in negative health outcomes. The anticipated net benefit to Canadians is therefore anticipated to be \$2.026 billion over 10 years. The coming-into-force period of 5 years was chosen to minimize the cost of implementing the proposed amendments. The industry identified a life cycle for labels of between 6 months and a maximum 5 years.

**"One-for-One" Rule and small business lens:** The proposed amendments would not add any new administrative burden to industry; the "One-for-One" Rule would therefore not apply. There are approximately 22 000 small- and medium-sized businesses within the food manufacturing and retail sector that would be impacted by the proposed amendments. Given that the cost impact is greater than \$1 million, the small business lens would apply. Three provisions were included in the proposed amendments and are anticipated to reduce the cost burden on both small- and medium-sized business: a longer coming-into-force period (five years), to allow for associated label changes to be managed with internal company resources and to deplete current label stock, an exemption for products sold at local markets or farms, and an exemption from requiring bullets between items on the ingredient list for businesses in the food retail sector using scale labels. These three provisions are anticipated to void approximately \$754,935,000 in costs for small businesses.

**Domestic and international coordination and cooperation:** Food labels on prepackaged products in Canada will always differ from those used in the U.S. because of Canada's dual language requirements. Despite these differences, the health objective in both countries remains essentially the same, and many elements of the proposed Canadian amendments and U.S. Nutritional Facts label (which was consulted on in March 2014), are aligned. These include updates to the NFt as follows: provisions that relate to updates based on science, the requirement to declare potassium, increasing the prominence of calories, mandating how serving size amounts are determined for multiple-serving packages, and the approach to food colouring labelling.

## Background

#### Nutrition labelling

In 2003, the Government of Canada made regulatory amendments to the FDR related to the labelling of food, with the goal of providing information to help Canadians make informed food choices and to help improve their health. These Regulations made it mandatory for an NFt to appear on the label of most prepackaged foods. These Regulations detailed what information had to be included in the NFt and prescribed the format of the table. Regulations for nutrient content claims were also expanded and clarified, and new provisions related to diet-related health claims were introduced. The regulatory amendments came into force fully in late 2007.

The introduction of a standardized NFt on prepackaged products in Canada was heralded as a highly successful measure. However, since 2003, advances in science, changing Canadian consumption patterns, the increasing incidence and economic burden of chronic diseases, changing consumer expectations, and recent international actions (i.e. proposed nutrition labelling changes in the U.S.) have necessitated updates to the Canadian nutrition labelling Regulations.

In the 2013 Speech from the Throne, the Government of Canada made a commitment to consult with Canadian parents about how the nutrition information on food labels could be improved. As described in greater detail below, two rounds of consultations were held in 2014 with consumers. Parents in particular and stakeholders, including health organizations, health professionals, consumer advocacy groups, scientific experts and academics, provincial and territorial governments (P/Ts) and industry were asked to provide feedback by filling out online surveys, attending face-to-face consultation sessions and/or commenting on a series of technical documents posted on the Health Canada Web site. The first round of consultations led to the publication of a *What We Heard* report (http://www.hc-sc.gc.ca/fn-an/label-etiquet /modernize-report-moderniser-rapport-eng.php) that helped shape the scope and direction of this proposal. The second round of consultations was intended to address issues raised in earlier consultations. Since the conclusion of these consultations, the Department has evaluated the feedback received and adjusted the

proposed amendments to reflect stakeholder comments.

#### Efficiency measures

With the enactment of the *Jobs, Growth and Long-term Prosperity Act*, in 2012, the *Food and Drugs Act* (FDA) was amended to give the Minister of Health (the Minister) the authority to incorporate by reference public documents directly into the FDR.

These amendments were intended to enable the Minister to act rapidly on certain science and safety decisions, and to improve efficiency in the food regulatory system, ultimately making it more responsive to emerging health and safety issues.

#### Fruit and vegetable health claim

The scientific evidence linking the consumption of sufficient quantities of fruits and vegetables to a decreased incidence of heart disease is well-established. Because heart disease is the second leading cause of death in Canada (approximately 69 000 deaths annually), efforts to further inform Canadians on the benefits of eating more fruits and vegetables could lead to a significant improvement in health outcomes.

The FDR prohibits the use of a health claim unless it is specified in the Regulations; however, a health claim associated to the reduced risk of cancer is currently allowed for fruits and vegetables. Additionally, when a health or nutrient content claim is made on a prepackaged product, that food is required to carry an NFt. However, for fresh fruits and vegetables, it is difficult to generate the accurate values required for an NFt because their nutritional content is highly variable, depending on a number of factors such as the variety, region of origin, growing season and soil conditions. Because of this inherent variability, the current Regulations provide an exemption from the NFt requirement for prepackaged fresh fruits and vegetables.

#### Food colours

In general, a food additive must be declared by its common name in the list of ingredients on food labels. Food colours, however, are unique among food additives in that current labelling Regulations provide food manufacturers with the choice of declaring added food colours by either their common name (i.e. Citrus Red No. 2) or simply as "colours." When the term "colours" is used, this non-specific descriptor does not provide sufficient information to those with sensitivities to certain food colours.

These proposed amendments aim to mitigate that risk and to align food colour labelling requirements with those of other food additives by mandating that food colours be identified using their common names in the ingredient list.

The Department is also proposing to modernize its approach to food colour regulation by addressing differences between the oversight of food colours and other food additives. Currently, the FDR require the lot-by-lot certification of synthetic food colours, but not of natural or inorganic colours. Nor is certification required for any other type of food additive. The certification requirements for synthetic food colours were established more than 30 years ago and are no longer considered necessary from a food safety perspective. The requirement for lot-by-lot certification of synthetic food colours is more burdensome than the requirements for other food additives.

#### Issues

The proposed amendments would address several issues including the following:

- The way in which the nutritional information is currently presented with respect to serving size does not allow consumers to easily compare different products at the point of purchase, nor does the information reflect the latest scientific knowledge. In addition, consumers have expressed difficulty in reading the list of ingredients. Consequently, the fall 2013 Speech from the Throne included a commitment to determine ways to provide Canadian families with improved information on food labels to enable them to make healthier food choices.
- Despite scientific evidence of the health benefits associated with a reduced risk in heart disease with the consumption of adequate quantities of fruits and vegetables, current regulations do not allow this health claim to be made. Also, current Regulations do not allow for any nutrient content or health claim to be made on the prepackaged fresh fruits and vegetables without triggering additional labelling requirements.
- Consumers have difficulties avoiding food colours to which they may have sensitivities because current labelling Regulations do not require specific naming of food colours in the ingredient list as there is an option to simply indicate "colour."
- The requirement of lot-by-lot certification of synthetic food colours is not required from a food safety perspective. Additionally, food additives other than food colours are not required to be certified by Health Canada. The current requirement that every lot of synthetic food colour be certified by Health

Canada therefore provides a level of regulatory oversight more stringent than that which is in place for other food additives and the requirements in many other countries. This places unnecessary burden on both industry and the Department.

• Many of the specifications for food colours contained in the FDR are out of date, and they do not allow for the application of up-to-date internationally accepted food-grade specifications which are, in practice, used by industry.

## **Objectives**

The proposed amendments to the FDR aim to

- modernize and improve food labelling to reflect the latest science (e.g. updates to the Daily Values (DV) for nutrients to be based on the most recent dietary recommendations), and to enable Canadians to make informed choices about their food in order to maintain or improve their health;
- introduce new requirements such as a note at the bottom of the NFt explaining the % DV, serving sizes based on the amount of food typically consumed in one sitting, and improved legibility in the list of ingredients;
- provide information on the content of sugar and other sugars-based ingredients of prepackaged foods, with the goal of supporting the reduction in sugar intake, as excess sugar intake may lead to overconsumption of calories, and thus to obesity and associated chronic diseases;
- expand the use of health claims on fruits and vegetables to allow a disease reduction health claim linking their consumption to a reduction in heart disease;
- allow for approved nutrient content and health claims to be made on prepackaged fresh fruits and vegetables without additional labelling requirements;
- remove the requirement for certification prior to the sale of each individual lot of synthetic food colours; and
- allow for the application of internationally accepted food-grade specifications for food colours.

## Description

### Nutrition labelling

Health Canada developed the proposed changes to the label to

- focus on nutrients of public health concern;
- align with existing federal dietary guidance and education campaigns;
- address the needs of Canadians as heard through stakeholder feedback;
- reduce the burden on industry;
- improve international alignment in areas such as DVs;
- reflect the latest science and Canadian eating patterns; and
- use the new "incorporation by reference" authority to ensure that future updates can be made more efficiently.

## Serving size

Currently, the serving of stated size (SSS) used to calculate the nutritional content of multi-serving prepackaged foods is not mandated in regulation, so the values can vary. For example, one bag of crackers might have an SSS of 10 medium-sized crackers, while another could have an SSS of 8 small crackers that differ in weight, making it difficult for consumers to choose between two similar products when trying to reduce their sodium intake. In addition, these SSS may not reflect amounts typically consumed in one sitting. The proposed amendments regarding the SSS for foods sold in multiple-serving prepackaged products would make the SSS more realistic by aligning them more closely with the regulated reference amounts (i.e. the amount that is typically consumed in one sitting), and would allow consumers to compare various products more easily at the point of purchase. For example, foods such as crackers, which come in pieces, would have to use an SSS as close to 20 g as possible; the serving size on the label would be shown in units (number of crackers) along with the corresponding weight (in grams), making it easier for consumers to choose between two similar products.

Reference amounts for SSS calculations would be updated to reflect current consumption patterns (e.g. the consumption of 175 g or three quarters of a cup of yogourt) and marketing trends (e.g. larger "supersized" prepackaged products) so that on-label information would more closely align with what Canadians actually eat.

## Daily values

The actual information contained in the NFt would be updated so that Canadians are able to make food choices based on the most recent scientific knowledge. Using information from internationally recognized

bodies such as the U.S. Institute of Medicine (IOM) and from Canadian sources such as the Canadian Community Health Survey, adjustments have been made to (*a*) the list of nutrients that must be declared in the NFt (i.e. the core nutrients); and (*b*) the DVs for both core and non-core nutrients. These changes reflect the latest dietary recommendations and findings from surveillance data.

The proposed amendments would also account for the differences in nutritional needs of infants (seven months or older but less than one year) and children (one year or older but less than four years). Thus, the % DVs in the NFt on food sold specifically for these infants and children would be derived from the DVs established for their respective age groups.

A rule of thumb footnote would be added to the bottom of the NFt to help educate consumers about the meaning of % DV and how to use this information to make dietary choices. The % DV is provided in the NFt to help consumers assess the relative contribution of that food to a daily amount of the various nutrients. The text would read as follows: "5% or less is a little, 15% or more is a lot." The % DV has been at the core of the Nutrition Facts Education Campaign since 2010. Although many consumers have learned how to use the % DVs, others still struggle with the concept behind the % DV. The educational message on how to use the % DV is intended to increase consumers' awareness and understanding of this concept, ultimately helping Canadians make healthier choices.

### Sugar labelling

In recent years, there has been growing concern over the amount of sugar consumed by North Americans, with some findings linking excessive sugar intake to an overconsumption of calories, which in turn could lead to obesity and associated chronic diseases. The proposed amendments introduce provisions aimed at providing information and educating consumers on the content of sugar and other sugars-based ingredients (i.e. ingredients containing mostly sugar as a nutrient) in the foods they consume, with the intention of supporting the reduction in sugar intake in a manner consistent with the recommendations of Canada's Food Guide.

The proposed amendments include two elements aimed at enhancing sugar labelling: establishing a DV for sugar and grouping sugars-based ingredients in the list of ingredients. Comments received from consumers during earlier consultations supported these proposed amendments. Canadians found the % DV approach easy to understand and useful when trying to manage their sugar consumption.

A DV of 100 g is being proposed for sugar, and the declaration of the % DV for sugar in the NFt would be mandated for all foods. Consumers would be able to use the % DV to determine whether a food contains a lot or a little sugar (as indicated by the rule of thumb footnote), and as a result adjust or limit their sugar intake.

Further, the requirement to group all sugars-based ingredients in the ingredients list is intended to provide greater transparency regarding the sugar that is added to foods. Ingredients with common names such as fancy molasses, malted barley, isomaltose and pear juice concentrate may not be recognized by most Canadians as sugars-based ingredients. The grouping requirement would, in cases where a product contains a large proportion of sugar, move the sugars-based ingredients closer to the beginning of the ingredient list, indicating more clearly the relative proportion of sugars-based ingredients in the product. Thus, the proposed approach would help consumers identify unfamiliar sources of sugar in their foods.

## List of ingredients

Currently, most prepackaged product labels include a list of ingredients that consumers have indicated is challenging to read. This has been attributed to poor colour contrast and uppercase print. The proposed amendments would improve legibility by requiring the following text formatting: uppercase and lowercase letters, bullets to separate individual ingredients, and good contrast of colour (black text on a white or other uniform, neutral colour background), with a border around the list or one or more lines above, below or at the sides of the list. Other changes include the use of the mandatory title of "Ingredients" to head the list as well as a standardized format indicating the components of an ingredient (e.g. chocolate chips [sugars (dried cane syrup), unsweetened chocolate, cocoa butter, soy lecithin, vanilla extract]). Collectively, these changes would give the ingredient list a standard look and feel so consumers would be able to find and read it on the package more easily.

The requirement to use bullets in the ingredient list would not apply to prepackaged products with labels applied at retail establishments, in order to reduce costs. This sector, which consists of a significant number of small businesses, would be allowed to continue to use commas, as per current practice.

The proposed amendments address concerns raised by industry about the challenges associated with printing the NFt on smaller packages. Currently, in most cases, no NFt is required when the product has less than 100 cm<sup>2</sup> of available display surface on the label (e.g. spice jars), but the use of intense sweeteners

(e.g. aspartame) or sugar alcohols, the addition of vitamins and/or minerals and/or nutrient content claims (e.g. sugar-free claims) triggers the requirement for an NFt. The proposed amendments would address industry concerns by providing exemptions for all products with an available display surface of less than 15 cm<sup>2</sup> on the label (e.g. a very small package of gum containing two to four small pieces).

## Allergen labelling

Consumers with food allergies or sensitivities rely heavily on information provided on the labels of foods to know whether they are safe to consume. Food allergens, gluten sources and added sulphites must always be identified on the label of prepackaged foods, either in the list of ingredients or in a separate statement with the title "Contains." The proposed amendments would introduce a new requirement stating that the "Contains" statement must appear right after the list of ingredients and follow the same proposed legibility requirements as those for the list of ingredients. Additionally, if the list of ingredients is bound by a border or lines, the "Contains" statement must also be inside the border or lines.

Although the current Regulations do not require the declaration of potential allergens or potential sources of gluten or sulphites that result from cross-contamination, manufacturers may choose to declare these (as is often done under the existing Regulations using "May Contain" statements). Under the proposed amendments, any precautionary statements would also have to appear immediately after the "Contains" statement or, in cases where there is no "Contains" statement, the precautionary statement would have to appear right after the list of ingredients. Additionally, any precautionary statement would also need to appear in the same font size as the ingredients in the list. This would ensure that the information consumers require to avoid these specific ingredients due to food allergies or sensitivities is always grouped together in the same place on the label.

#### Efficiency measures

In keeping with the legislative authorities of the *Jobs, Growth, and Long-term Prosperity Act* of 2012, and to achieve efficiency gains, more timely updates to scientific information could be achieved by moving information from the Regulations into documents that could be incorporated by reference and updated administratively by the Minister. These include tables of information that set rules for labelling requirements (DVs and reference amounts) and a schedule that includes figures (graphics and descriptions) that represent all possible acceptable formats of the NFt. Health Canada is proposing amendments to move these tables and figures into documents that would be incorporated by reference in order to allow for updates and additions to the tabulated scientific information and to provide for some flexibility in the formatting of the NFt. The three proposed documents to be incorporated by reference would be

- Nutrition Labelling Table of Reference Amounts for Food (formerly Schedule M to the FDR);
- Nutrition Labelling Table of Daily Values (this would be a new document replacing recommended daily intakes found in Table I to Division 1 and Table I to Division 2 of Part D of the FDR); and
- Nutrition Labelling Directory of Nutrition Facts Table Formats (formerly Schedule L to the FDR).

These documents would be available to all stakeholders through the Health Canada Web site. The Department would keep stakeholders advised of potential changes to these incorporated documents through consultation and notification processes.

#### Fruit and vegetable health claim

The proposed amendments introduce measures that would make it easier to let Canadians know of the health benefits of eating fruits and vegetables. The claim "A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of heart disease" would be allowed on fruits and vegetables as specified in the Regulations.

The current Regulations require that prepackaged products carry an NFt on the label whenever a health claim is made for that food, unless the product is a one-bite confectionary product or milk in glass bottles. The proposed amendments would also allow nutrient content and health claims to be made for prepackaged fresh fruits or vegetables without an NFt being required.

#### Food colours

The proposed amendments would require that manufacturers list all food colours by their common name (as specified in the Regulations) within the list of ingredients on the food label. This would enable consumers who have sensitivities to specific food colours to avoid those ingredients when shopping for food. It would also align the labelling requirements for food colours with those of other food additives.

The outdated specifications, set out as standards for food colours in the FDR, would be removed and replaced by internationally recognized food-grade quality specifications to reflect current scientific

standards where they are available. Companies would therefore not have to meet the current FDR requirements for food colour specifications.

Health Canada is proposing to eliminate the current lot-by-lot certification of synthetic colours as it is no longer considered necessary from a food safety perspective. This would align oversight for food colours with regulatory requirements for other food additives, and with many other jurisdictions, in addition to reducing burden on both industry and the Department.

### Coming into force

The Department has engaged various stakeholders from the food industry during the development of these proposed amendments and has tried to minimize burden, especially to small businesses, wherever possible. A five-year coming-into-force period is being proposed, which would allow sufficient time for industry to make the necessary changes to their labels and also to use up any existing stocks of labels already printed to comply with current requirements.

### Regulatory and non-regulatory options considered

### Option 1: Status quo

The status quo is not viewed as a viable option since current nutritional labelling is confusing for Canadians for several reasons: (i) they cannot compare products easily as serving sizes are not standardized; (ii) labels need to be updated to reflect current scientific knowledge; (iii) labels do not currently provide sufficient information on sugars, to help assess whether there is a little or a lot of sugar in prepackaged food; and (iv) they find it difficult to read the list of ingredients on some prepackaged products, which is of particular concern to those who have allergies, food colour sensitivities or other concerns about ingredients.

Additionally, a claim to inform Canadians about the health benefits of eating fruits or vegetables to reduce the risk of heart disease is currently not allowed. Finally, the current Regulations contain outdated specifications for various food colours and certification requirements for synthetic food colours that are not in line with Health Canada's approach to other food additives.

#### Option 2: Voluntary approach

Health Canada considered a voluntary approach to setting serving sizes, the list of ingredients and sugar labelling, but it was determined that this information needs to be standardized in a format that would alleviate confusion and maximize usefulness for consumers. A voluntary approach to the heart disease health claim mentioned above is not possible as the Regulations currently prohibit its use. Similarly, a voluntary approach to the certification of synthetic colours and standards for various food colours was not considered as the Regulations need to be amended in order to modernize the requirements.

#### Option 3: Full alignment with the U.S.

With respect to labelling, full alignment with the U.S. is not possible due to Canada's bilingual requirements, which necessitate a Canadian-specific label. The U.S. proposed rule does not include changes to the requirements for the list of ingredients nor any requirements for allergen labelling. However, a number of proposed amendments would align with the U.S. proposed rule. For example, the health-related claims that the U.S. allows to be made for fruits and vegetables are similar to those contained in Canada's proposed amendments. Furthermore, the Canadian proposed amendments would reference the same internationally accepted standards for food colours that are currently used by industry in the U.S.

The U.S. is proposing to mandate the declaration of the total amount of sugar on their label, along with the amount of added sugar in a line just below. These amounts would be provided in grams because the U.S. does not have a DV for sugars. While both the U.S. and Canadian proposals on sugar have the same overall objective (to provide consumers with information they need to enable them to lower their sugar intake, if they so choose), somewhat different methods of achieving this goal have been chosen. The Canadian proposed amendments include two elements aimed at enhancing sugar labelling: establishing a DV for sugar in the NFt and the grouping of sugars-based ingredients in the list of ingredients (see below). The added sugar approach (in the U.S. proposed rule) and the % DV approach (in the Canadian proposed amendments) were both presented to Canadian consumers during consultations in 2014, and the feedback results indicated that Canadians found the % DV approach easier to understand and more useful than the U.S. approach.

## Option 4: Proposed regulatory approach (recommended option)

The proposed amendments would represent significant improvements in the quality of information

provided in nutritional labelling. For example, they would make it easier for Canadians to read labels and make comparisons between prepackaged foods. Furthermore, the new sugar DV would help Canadians make food choices aligned with Canada's Food Guide. In addition, the outdated standards for food colours would be replaced by internationally recognized specifications that reflect current scientific standards where they are available. Furthermore, the requirement for the certification of synthetic food colours would be removed, so that regulatory oversight would be in line with that applied to other food additives. Finally, the proposed amendments would allow the use of the claim that fruits and vegetables reduce the risk of heart disease, thereby allowing Canadians to be better informed of the health benefits of eating fresh fruits and vegetables.

In the spirit of regulatory cooperation, changes are aligned with the U.S. proposed rule to the extent possible (updates to DVs, serving sizes, increased visibility of calories). Differences between the proposals would not be expected to cause significant burden to industry. Health Canada will continue to monitor developments in the U.S. proposed rule and give consideration to any changes made to it.

### **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 foods sold in Canada. The amendments propose changes to the presentation and content of the NFt, the listing and format of the ingredients list, the listing of food colours by their common name, and the use of claims on prepackaged fruits and vegetables. The analysis identified two groups that would be directly impacted by the amendments: Canadian consumers and the Canadian food manufacturing and retail industry.

Nutrition is an important component of health, which in turn has a direct impact on the Canadian economy. For example, employees with poor nutritional health were found to take an estimated 21% more sick days and were 11% less productive than their counterparts who ate a healthy diet. Sick days and lost productivity due to ill health represent indirect health costs, leading to lost economic production. Furthermore, the health of the population is of importance to policy-makers, 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; this represents 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 7 000 food manufacturing firms operating in Canada directly affected by the proposed amendments, representing close to \$88 billion in yearly revenues and injecting approximately \$21 billion into the Canadian economy. When the entire Canadian food manufacturing and retail supply chain is considered, there are approximately 26 000 small and medium enterprises (SMEs) representing 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, confectionary produced abroad and imported into Canada); the baking and milling industry; and large manufacturers of processed foods. Approximately 80 000 products, measured as stock keeping units (SKUs), should be impacted by the proposed amendments.

The CBA examined whether health outcomes, and therefore health spending, could be reduced for five different chronic diseases that were most linked to diet and nutrition. The selected diseases were cardiovascular disease, malignant neoplasms, diabetes mellitus, nutritional deficiency and musculoskeletal disease. These five diseases accounted for approximately \$26 billion annually in both direct and indirect health expenses.

The proposed amendments are based on the assertion that by enabling Canadians to compare products more easily and make more informed choices of the foods they consumed, their overall health would improve. A conservative approach of a small (1%) improvement in health outcomes was applied to estimate the anticipated benefits for the five chronic diseases; the approach taken in the U.S. used a 3% benefit measure. The improvement in health outcomes was compounded annually over 10 years. Anticipated savings were calculated to be approximately \$275.3 million in annual cost savings over a 10-year period. It is anticipated that total benefits would amount to \$2.75 billion.

Canadian 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 the design of their product label. These estimates were based on input that they received from Health Canada during the July 2014 consultation period. Since that time, a number of changes were made to the proposed amendments, as regulatory elements were refined to reflect the intended goals of the Regulations and the

feasibility of undertaking particular policy directions. The industry estimates therefore included a large number of proposed amendments that will not be reflected in what is currently being proposed. The removal of the requirement to list vitamin D and added sugar in the NFt is one example of where feasibility was reassessed; however, industry estimates continue to include these two elements.

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. A number of industry groups were uncomfortable with providing estimates without fully being aware of the final proposed amendments. By allowing the option of providing the highest cost scenario, industry stakeholder groups were able to provide costing data, as one of their greatest concerns was an underestimation of costs in an area that would directly affect their membership. This approach also ensured that industry impacts would not be understated.

A concerted effort was made to include all industry input. Due to the variability of figures provided and the need to include all industry input, an adjusted weighted figure was used to account for all estimates. The adjusted weighted figure applies more weight to the average (or mean) of the sum of each cost-per-SKU value, while applying a reduced weight to estimate outliers (i.e. a number that is outside the normal range). Using a cost-per-SKU estimate that applies an adjusted weight, the cost per SKU would be \$9,725 or \$727.1 million in present value (PV) as a one-time compliance cost to industry. If the median (which represents where the majority of cost per SKU values fall) is used, the one-time cost to industry decreases to \$8,000/SKU or \$598 million in present value.

Using a one-time compliance cost that applies a weight-adjusted average cost per SKU would provide the most accurate estimate of total industry costs based upon all input received by industry, while a median figure would provide the most common cost per SKU figure provided by industry. If the weight-adjusted and median estimates are extrapolated to a cost per company, estimates would be between \$22,820 and \$27,746 (including manufacturers and impacted retailers).

	Base Year	Final Year	Total (PV)	Annual Average
	Year 1	Year 10		Average
Benefits				
Indirect cost savings				
<ul> <li>Cardiovascular disease</li> </ul>	\$3.62M	\$3.9M	\$37.9M	\$3.79M
<ul> <li>Malignant neoplasms</li> </ul>	\$5.86M	\$6.47M	\$61.3M	\$6.13M
<ul> <li>Diabetes mellitus</li> </ul>	\$1.45M	\$1.6M	\$15.2M	\$1.52M
<ul> <li>Nutritional deficiency</li> </ul>	\$0.01M	\$0.01M	\$0.31M	\$3,100
<ul> <li>Musculoskeletal disease</li> </ul>	\$14.0M	\$15.3M	\$146.3M	\$14.6M
Total indirect savings	\$24.9M	\$27.3M	\$261.0M	\$26.1M
Direct cost savings: hospital and				
pharmaceutical costs	\$238.3M	\$260.5M	\$2.492B	\$249.2M
Total benefits	\$263.2M	\$287.8M	\$2.753B	\$275.3M
Cost				
Industry — one-time compliance				
— Minor	\$211.4M	\$0	\$197.6M	
— Medium	\$578.7M	\$0	\$540.8M	
— Major	\$946.0M	\$0	\$884.1M	
Total cost				
— \$9,725/SKU	\$778M	\$0	\$727.1M	
Net benefit	-\$514.8M	\$287.8M	\$2.026B	

## Table 1: Cost-benefit analysis, weight-adjusted average

## **B.** Qualitative impacts

- Increased potential for product reformulation with improved nutrient profiles.

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

- Trickle-down effects of healthy family eating habits into healthy adult eating habits.

- Positive vital health indicators.

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

The estimated costs and benefits of the proposed Regulations are shown in Table 1 (above), with a net health benefit of \$2.026 billion over a 10-year period. Estimated costs to industry amount to a present value of \$727.1 million, while total estimated benefits amount to \$2.753 billion. While the costs to industry are high, the anticipated benefits to consumers are nearly four times greater.

#### <u>Costs</u>

With an estimated total of 80 000 prepackaged food products, almost all of which would require changes to their product labels due to the proposed amendments, the costs to industry are anticipated to be significant.

Costing estimates were provided by industry organizations, and relied heavily on the cost-benefit analysis undertaken by the U.S. Food and Drug Administration (U.S. FDA) on their proposed nutrition labelling regulation amendments, as well as case studies from an extensive literature review. 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.

Within the cost estimates, which are presented as costs per SKU (\$/SKU), industry stakeholder organizations identified the following two factors as implications on costs due to the proposed amendments:

#### 1. Adjusting serving sizes and nutrient analysis

The proposed amendments require serving sizes to better reflect the amounts typically consumed in a single sitting. An adjustment to the recommended serving size would require industry to complete new analyses of the nutrient content. In some instances these changes could mean that health and content claims made on the front of the package no longer apply. Conversely, these adjustments could also increase the amount of specific nutrients per serving, such as fibre, which would enable claims. Costing figures were not provided for adjustments being made to serving sizes; however, it was assumed that these costs would be included in the cost of label printing and nutrient analysis.

Changes are to be made to the list of core nutrients. The proposed amendments would remove the mandatory inclusion of vitamin A and vitamin C and specify that potassium must now be listed. Prepackaged products would require a new nutrient analysis in order to accurately specify nutrient content in the NFt. Estimated costs to conduct the nutritional analysis were provided by industry. These ranged from \$750/SKU to \$3,200/SKU; the majority of estimates fell close to \$1,700/SKU.

Based on the cost estimates and survey responses provided by Canadian industry, it is assumed that the majority of nutrient content analysis would be carried out through product analysis and not from recipes.

#### 2. Design and printing of new packaging

The reformatting of the NFt is the highest cost faced by industry. In the Regulatory Impact Analysis done by the U.S. FDA, it was determined that, across product categories, the cost of changing product labels ranged from \$1,100 to \$2,600 (in 2003 U.S. dollars) per SKU. Results provided by Canadian industry were significantly higher and detailed responses were provided to Health Canada as a means of explaining the variability.

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. A number of respondents indicated that a longer coming-into-force period could significantly reduce these costs. Design costs ranged from \$700/SKU to \$12,000/SKU; the majority of costs were close to \$4,000/SKU.

There are multitudes of ways in 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. However, the current regulatory provision stating that the NFt does not have to exceed 15% of the available label display surface would not change and industry would have many different formats to choose from. The estimated costs of the creation of new printing plates ranged from as low as \$2,000/SKU to as high as \$8,000/SKU; the majority of costs were estimated to be \$3,000/SKU.

The physical label cost, as well as the packaging that it must be printed on, was 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.

#### Labour

Labour costs would be associated with all aspects of the label design and 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 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 Web site. These costs ranged from \$400/SKU to \$2,500/SKU.

It should be noted that this CBA assumes that the calculated labour costs would only include incremental one-time costs to meet the requirements of the proposed amendments. Therefore, it is assumed that no new administrative burden would be placed on industry in regard to reporting and compliance.

• Coming into force

The coming-into-force (CIF) period has been identified by the food manufacturing industry as a major determinant of cost.

In consultations with the food manufacturer stakeholder groups, it was noted that a longer CIF 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 labour costs and the amounts of waste associated with paper stock would be extremely high with an 18-month to three-year CIF period; one respondent indicated that estimated costs to industry could double if the CIF were less than five years.

#### Cost to consumers

The analysis acknowledges that Canadian consumers may be faced with increased food costs as manufacturers and retailers recover their compliance costs associated with the proposed amendments.

Based on input from industry, calculations were done for three different scenarios: a minor, medium, and major label change. In the majority of instances, industry groups were able to provide a sample of anticipated costs based on estimates of the cost components of a label change (i.e. the ingredient list and NFt). An outline of these costs is provided in Table 3. 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).

Level of change	Cost of label production (per SKU)	Total
Minor	\$2,500	\$200,000,000
Medium	\$7,500	\$600,000,000
Major	\$10,500	\$840,000,000

#### Table 2: Sample of label costs

The majority of cost-per-SKU estimates were close to \$8,000; this figure represented the median of all provided estimates during the consultation and survey period. It should be noted that industry was encouraged to provide their highest cost or "worst-case scenario" estimates as a means of facilitating the gathering of comprehensive label cost estimates. It was determined that the best method to account for all costs was to perform an adjusted-weight average calculation, which accounts for all provided cost-per-SKU estimates; this method also allowed for the inclusion of outliers. Using an adjusted-weight cost estimate, it was determined that the average cost-per-SKU would be \$9,725 or a total one-time compliance cost of \$778 million (\$727.1 million present value) for 80 000 SKUs.

## Comparison to international jurisdictions

As a means of testing the validity of the estimates provided by Canadian industry, a comparison was performed to the analysis provided by the U.S. FDA and by the European Commission (EC). The cost estimates provided by Canadian industry were higher and not in line with estimates reported by the U.S. FDA and the EC; however, these differences in cost could be based on the removal of added sugar and vitamin D from the NFt requirements. The U.S. FDA reported a one-time cost to industry of \$2 billion with a three- year coming-into-force period; when this is adjusted for the Canadian market (i.e. the number of SKU in Canada), the costs are estimated to be approximately \$232 million or \$2,900/SKU. The EC estimates were close to \$1.6 billion (in Canadian dollars), and the figure included a coming-into-force period of three and five years that yielded identical costs. The adjusted EC total cost per SKU in Canada would be approximately \$7,000, or \$560 million. The U.S. FDA and EC cost estimates would place Canada closer to

the minor and medium cost estimates provided by industry in reference to Table 3.

Differences in cost estimates between Canada, the U.S. FDA and the EC illustrate how larger economies of scale can greatly reduce the nutrition label compliance burden on industry. Therefore, any alignment opportunities could help to reduce some of the burden for Canada's food manufacturing and retail industry (i.e. nutrient analysis that applies to both Canada and the U.S., versus two separate analyses), assuming these products are sold in the same jurisdictions.

The estimated one-time compliance cost to Canadian industry would range from \$200,000,000 to \$840,000,000. The average cost per SKU, using an adjusted weighted average, would be \$9,725, which would lead to a total one-time cost of \$778 million, or \$727.1 million in present value dollars. This estimated one-time cost would represent 0.8% of the total \$88 billion in revenues for the Canadian food manufacturing industry.

#### **Reformulation**

A number of industry groups identified reformulation as being a major cost implication. Reformulation occurs when the product ingredients or the amount of certain nutrients are changed in order to comply with regulatory changes, to address public health concerns (e.g. trans fat, sodium and sugar), and to address consumer concerns or for cost-effective purposes. However, while the proposed amendments could instigate a change in the consumer preference of certain foods, the amendments do not require that industry reformulate its products. Companies may choose to reformulate their foods, but this would be a business decision.

Based on figures from the U.S. FDA, adjusted to Canada, the total industry-wide cost for industry to reformulate its products would range from \$11.4 million to \$106.0 million.

#### **Benefits**

The proposed amendments are based on the assertion that equipping Canadians to compare products more easily and make more informed choices about the foods they consume would improve their overall health. An extensive literature review using peer-reviewed journal sources, academic position papers, government publications and stakeholder consultations yielded few articles that directly linked the use of a nutrition label to measurable outcomes outside of a laboratory setting. Consequently, a number of assumptions were made as a means to address this knowledge gap, while providing clear benefit estimates.

The indicated use of the NFt ranges from approximately 44% to as high as 88%. This estimate is based upon a variety of demographic variables. The majority of studies found in the literature review indicated an NFt and list of ingredients usage rate of between 60% and 75%; these two percentages were used in the benefit calculations of the CBA. The literature indicated a number of common characteristics of individuals who would most likely use an NFt and ingredient list. Individuals who were female, university-educated, with a middle income or greater, the primary food purchaser, the primary food preparer, and a parent/guardian of younger children; people with specific dietary requirements (i.e. related to their health); and people who were aware of the diet-disease relationship were most likely to use on-pack nutrition information. However, a number of studies examined targeted nutrition labelling interventions, and regardless of socio-economic status, disease status or whether targeted education campaigns occurred, all members of Canadian society have an equal opportunity of benefiting from the proposed amendments.

The second assumption is related to what prompts individuals to behave in a manner that is either beneficial or detrimental to their health. The health belief model is a tool used to gauge the compliance of individuals with healthy behaviour and is based upon whether the individual perceives a threat to his or her health and whether this perceived threat is great enough to change behaviour. A series of educational campaigns coordinated by Health Canada relating to the NFt are anticipated to run in parallel with the proposed amendments. It is anticipated that future campaigns would not only educate consumers about using the NFt and ingredient list, but also raise awareness about how their food decisions using the % DV can impact their health. Label use compliance is usually high during the beginning of educational campaigns among label users, then gradually decreases over time. The analysis for this CBA assumes that the NFt compliance rate is 50% for individuals who refer to the NFt and ingredient list and observe the daily recommendations.

The benefit calculation in the CBA assumed that a modest 1% improvement in health outcomes for cardiovascular disease, diabetes mellitus, malignant neoplasms, musculoskeletal disease and nutritional deficiencies would amount to savings in indirect and direct costs based on nutrition label use. Therefore, the benefit calculation in the CBA only accounts for Canadians diagnosed with one of the five chronic diseases most linked to diet. The 1% improvement was applied to the economic burden of illness calculations by the Public Health Agency of Canada. These five diseases account for approximately \$26.3 billion in yearly indirect and direct costs; this is described below in Table 3.

Table 3: Cost o	f nutrition-linked	diseases in	Canada, 2008	(current dollars)
	I Hathered			(carrent aonaro)

		Costs (2008 dollars)	
Illness	Direct	Indirect	Total
Cardiovascular diseases	\$11,692,700,000	\$362,000,000	\$12,054,700,000
Malignant neoplasms	\$3,828,100,000	\$586,100,000	\$4,414,200,000
Diabetes mellitus	\$2,178,200,000	\$145,200,000	\$2,323,400,000
Nutritional deficiency	\$343,900,000	\$300,000	\$344,200,000
Musculoskeletal disease	\$5,780,800,000	\$1,398,000,000	\$7,178,800,000
Total	\$23,832,700,000	\$2,491,600,000	\$26,315,300,000

A sensitivity analysis using reductions in the economic burden of illness was calculated for 0.1%, 0.5%, 1% and 2%; figures are provided in Table 4 below. A 1% improvement in health due to label use would lead to an average annual reduction of \$275.3 million in health care costs. Over a 10-year period, it is anticipated that total benefits would amount to \$2.753 billion. It was determined that a 1% reduction in health burden for the five chronic diseases would be the most appropriate and conservative measure when calculating the benefits of the proposed regulatory amendments.

Table 4: Estimated benefits using economic burden of illness (EBIC) for 0.1%, 0.5%, 1% and 2% reduction compounded annually (see footnote 1)

Percentage Benefit					
Year	0.1%	0.5%	1%	2%	
1	\$26,315,000	\$131,577,000	263,153,000	\$526,306,000	
2	\$26,341,000	\$132,235,000	265,785,000	\$536,832,000	
3	\$26,367,000	\$132,896,000	268,443,000	\$547,569,000	
4	\$26,393,000	\$133,561,000	271,127,000	\$558,520,000	
5	\$26,419,000	\$134,229,000	273,838,000	\$569,690,000	
6	\$26,445,000	\$134,900,000	276,576,000	\$581,084,000	
7	\$26,472,000	\$135,575,000	279,342,000	\$592,706,000	
8	\$26,499,000	\$136,253,000	282,135,000	\$604,560,000	
9	\$26,526,000	\$136,934,000	284,956,000	\$616,651,000	
10	\$26,553,000	\$137,619,000	287,806,000	\$628,984,000	
Total over					
10 years	\$264,330,000	\$1,345,779,000	\$2,753,161,000	\$5,762,902,000	

This assumption was tested for validity using two tests.

#### 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 nutritional deficiency or 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 usage rate of 50%, these values were tested against the economic burden of illness calculations by disease group. The tests demonstrated similar results to the estimated 1% reduction in illness for both the 60% and 75% label use that were equivalent to a 0.8% and a 0.9% reduction in health costs.

## Test 2 — Estimate welfare gain 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 five 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; this equates to a \$25 to 40\$ gain annually. Given that the proposed amendments for the revised nutrition labelling are in fact amendments, the full estimate of the welfare gain would most likely not be realized to the full extent. The revised calculation would reduce the benefits by 50%, with the underlying assumption being that the proposed 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 would 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 were similar to the initial 1% reduction in the

economic burden of illness estimate used as the principal benefit calculation.

A detailed summary of each test and the corresponding data are available in the CBA (the full CBA is available upon request).

Over a 10-year period, it is anticipated that total benefits would amount to \$2.753 billion in direct and indirect cost savings to the health system and, by further extension, to the Canadian economy.

### "One-for-One" Rule

The proposed amendments would modify the existing Regulations under the FDA. While it is anticipated that there will be changes to labelling and a one-time nutrient analysis of products, these changes would ordinarily occur over the product life cycle. Industry stakeholders have identified this cycle as being as low as six months to upwards of five years. A majority of those affected in the industry would have opportunities to change their label within the natural product life cycle due to the longer CIF of five years.

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

#### Small business lens

The small business lens applies to regulatory proposals that affect small business and that would impose a nationwide cost over \$1 million annually. The Treasury Board Secretariat defines a small business as any business, including its affiliates, that have fewer than 100 employees or between \$30,000 and \$5 million in annual gross revenues.

There are approximately 26 205 small enterprises in Canada that could be affected by the proposed amendments, representing close to 96% of all food manufacturers and retailers in Canada: 23% are food manufacturers (including retail and commercial bakeries); 2% are soft-drink manufacturers; 29% are food and beverage wholesaler-distributors; and 46% are retail stores. Due to the often restricted access to capital that small businesses have, three provisions have been specifically designed to lessen the impact on small businesses.

NAICS(see			All	% Micro
reference *)	Industry Sector	Small	Enterprises	and Small
311	Food manufacturing	6 086	6 422	94.7%
	Beverage and tobacco product	295	305	96.7%
312	manufacturing			
	Food, beverage and tobacco	7 631	7 714	98.9%
413	wholesaler-distributor			
445	Food and beverage stores	12 181	12 702	95.9%
452	General merchandise store	12	13	92.3%

#### Reference \*

North American Industry Classification System

#### 1. Coming into force

In consultations with industry, a longer coming-into-force (CIF) period was identified as having the largest impact on reducing label costs. Due to the longer product turnover and the longer life cycle of labels produced by the majority of small businesses, a CIF of five years has been proposed. A five-year CIF period would allow small businesses to use up existing label stocks, plan and gather capital for the label change, and allow them to use in-house resources rather than have to hire external people to design new labels if necessary. Many industry groups highlighted the latter as a large financial burden, although they did not quantify the exact burden.

#### 2. Exemption for micro firms processing and selling

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 are currently exempt from the Regulations. While it is difficult to identify precisely the number of such firms operating in any 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 2) The average market has 25 vendors, and each vendor in turn averages 1–5 employees. Total annual sales from vendors at these markets are estimated to be \$1.03 billion. The proposed amendments would maintain this exemption for these 12 700 firms.

## 3. Exemption for retail from using bullets in the list of ingredients

In order to improve the legibility of the list of ingredients, the proposed amendments would require the use of a bulleted list of ingredients instead of commas, as is the current practice to separate ingredients. Businesses that use retail or scale labels, particularly small businesses, indicated this would create a substantial cost as the existing machines are incapable of printing a bulleted list of ingredients.

Retail and grocery stores in general indicated that the cost of replacement for each store could reach well over \$10,000. The cost of even a simple retail scale that produces labels would be in excess of \$2,000. It would be safe to assume a cost of \$5,000 per retail store to replace the existing scales, imposing a cost of over \$60 million on the 12 193 retail stores that may produce products that would fall under the proposed amendments.

It is proposed, therefore, that grocery retailers be exempt from the proposed requirement to use bullets.

#### Flexibility analysis

	Initial Option		Chosen Option		
Coming into					
force	3-Ye	ar CIF	5-Ye	ar CIF	
Number of					
firms	26	26 205		205	
	Annualized	Present value	Annualized	Present value	
	average		average		
Compliance					
cost	\$149,376,000	\$1,396,037,383	\$74,688,000	\$698,018,692	
Administrative					
cost	\$0	\$0	\$0	\$0	
Total costs	\$149,376,000	\$1,396,037,383	\$74,688,000	\$698,018,692	

Farmers' market exemption	Remove Exc	emption	Maintain Ex	emption
Number of firms	12 70	0	12 70	0
	Annualized Present		Annualized	Present
	average value		average	value
Compliance cost	Unknown	Unknown	Unknown	Unknown
Administrative cost	\$0	\$0	\$0	\$0
Total costs	Unknown	Unknown	Unknown	Unknown

Ingredient list format	Bulleted Ingredients Allow Co		Bulleted Ingredients Allow Commas	
Number of firms		12 193		193
	Annualized	Present value	Annualized	Present
	average		average	value
Compliance cost	\$6,090,000	\$56,915,888	\$0	\$0
Administrative cost	\$0	\$0	\$0	\$0
Total costs	\$6,090,000	\$56,915,888	\$0	\$0

Total costs of				
all options	\$155,466,000	\$1,452,953,271	\$74,688,000	\$698,018,692
	•	•		

Using the flexible option, it is anticipated that \$754,935,000 in costs could be avoided for small business. This figure is based on the \$778 million industry one-time cost estimate and on the assumption that a shorter CIF period of less than five years will double all costs, and on the avoided cost of having to procure new scale label printers.

## Consultation

#### Nutrition labelling

The following stakeholders participated in the consultation processes undertaken in the development of these proposed amendments: Canadian consumers, food industry, retailers, health organizations, health professionals, consumer advocacy groups, scientific experts and academics, and provincial and territorial governments.

The comments highlighted below are separated into two broad groups: consumers, and other stakeholders (including industry, health professionals, non-governmental organizations [NGOs], provincial and territorial governments [P/Ts], and academic experts).

A two-pronged consultation campaign was conducted from January to April 2014, consisting of in-person round table discussions with parents and an online consultation to solicit feedback from other interested consumers. In June 2014, Health Canada published the *What We Heard* report (http://www.hc-sc.gc.ca /fnan/label-etiquet/modernize-report-moderniser-rapport-eng.php) to provide an overview of the feedback. Through their input, Canadians confirmed that they find the current food labels helpful for making healthier choices and suggested ways to improve the labels to maximize consumer usability.

In July 2014, Health Canada launched the second phase of nutrition labelling consultations. The themed technical documents incorporated advances in science and the feedback obtained in the first phase and outlined the Department's proposed changes to the appearance of the NFt and the list of ingredients; the core (i.e. mandatory) nutrients in the NFt; the DVs; and the reference amounts used to determine serving size, particularly for single-serving containers, and for assessing whether a prepackaged product meets the compositional criteria for nutrient content and health claims. Health Canada posted these technical documents on its Web site (http://www.hc-sc.gc.ca/fn-an/label-etiquet/consultation/index-eng. php) and solicited comments from interested stakeholders. An online questionnaire was launched at the same time, and both these consultations closed in mid-September 2014. Consumer engagement workshops were also conducted in various Canadian cities throughout the month of September in order to give consumers an opportunity to share their thoughts on the proposed changes in a more in-depth manner than is possible via the online consultation. The feedback from the latest round of consultations helped refine and fill in the details for the proposed amendments.

The feedback from the latest round of consultations included the following:

- consumers and all other stakeholders, including industry, were in favour of making serving sizes more consistent among similar foods. Some industry stakeholders preferred to keep how serving sizes are determined at the voluntary guideline level while other stakeholders such as health professionals, NGOs and academic experts called for a regulatory approach to ensure the use of consistent serving sizes.
- feedback on sugar-related proposals (added sugar declaration, % DV declaration and grouping of sugar-based ingredients in the list of ingredients) was mixed. The proposal to declare the amount of added sugars in the NFt was popular among consumers and health stakeholders (including health professionals, NGOs and P/Ts). However, industry stakeholders questioned the scientific basis of requiring the declaration of added sugar in the NFt given that the body metabolizes naturally occurring and added sugars in the same way. Similarly, the inability of analytical methods to distinguish between naturally occurring and added sugars would contribute to significant compliance and enforcement challenges. In addition, industry indicated that research done in the U.S. concluded that consumers have a limited understanding of the "added sugar" declaration in the NFt.
- consumers were in favour of DVs for sugars, but industry questioned their basis and health stakeholders were concerned that it might discourage the consumption of healthy sources of sugars, such as whole fruits and vegetables and plain dairy products.
- most consumers and health stakeholders believed that the grouping of sources of sugars in the list of ingredients would be useful for consumers, whereas industry was concerned that it would disrupt the conventional practice of listing the ingredients in decreasing order of their weight.
- consumers and stakeholders provided mixed feedback on the proposal to change the order of nutrients in the NFt in order to reflect what Canadians should aim to limit and what they should get sufficient amounts of.
- the % DV footnote (i.e. 5% or less is a little, 15% or more is a lot) was well received by consumers and health stakeholders. Most industry stakeholders expressed reservations about this proposal, particularly about the effect it would have on the size of the NFt.
- consumers and stakeholders (such as provincial and territorial governments, health organizations, health professionals, and consumer advocacy groups) were in support of the proposal to the format of the list of ingredients (i.e. the use of uppercase and lowercase letters, good contrast of colour, and use of bullets). Comments from industry expressed concerns about the space requirements for the new format.
- consumers and all other stakeholders, including industry, provided mixed feedback regarding proposed changes to the list of nutrients that must appear in the NFt. There was general support to include potassium and remove vitamin A and vitamin C from the list, although consumers questioned the reason behind removing these two vitamins. There was less support for the proposal to declare vitamin D, specifically among some health professionals and academic experts, mainly because this vitamin occurs naturally in very few foods, such as fatty fish, and that a "0" declaration may give the impression that a food is not nutritious. Consequently, as a result of stakeholder feedback, the requirement to declare vitamin D has been removed from this proposal.

Industry was surveyed from late 2014 through early 2015 to gather information to support the CBA for these proposed amendments. Health Canada was able to learn more about some of the activities that would be necessary to comply with the proposed changes such as redesign and printing of new labels (and possibly discarding old stock if the coming-into-force [CIF] period was too short), and nutrient analysis for newly designated core nutrients in the NFt. Compliance costs were provided for three- and five-year CIF periods.

In summary, there was an overall support for updating the nutrition label. Proposed changes to serving sizes, sugar information, and the legibility of the list of ingredients addressed major consumers concerns expressed in the *What We Heard* report (http://www.hc-sc.gc.ca/fn-an/label-etiquet/modernize-report-moderniserrapport-eng.php) and were supported by stakeholders such as health professionals and NGOs. Industry stakeholders were supportive of the updates to scientific information, but were concerned with some of the proposed changes, particularly those related to sugar labelling and format changes that would have an impact on label space requirements.

### Fruit and vegetable health claim

The Department, in forming the approach for health claims and labelling requirements for fruits and vegetables, has taken into account feedback from various stakeholders active in the marketing (from farm gate to the dinner plate) of fresh fruits and vegetables. The proposed amendments address the concerns that were raised and make it easier for industry to promote the health benefits of eating fruits and vegetables. These stakeholders strongly support these proposed amendments as the inability to make nutrient content and health claims on prepackaged fruits and vegetables has been an irritant to them.

### Food colours

A consultation document (http://www.hc-sc.gc.ca/fn-an/ consult/\_feb2010-food-aliments-col/indexeng.php) was posted online in 2010 outlining the Department's proposed approach to improving food colour labelling requirements, with direct notification of the consultation sent to select stakeholders including members of the food industry, food associations and specific citizen groups. Most of the comments received during this process were in support of Health Canada's initiatives. Some industry stakeholders expressed concern about space on the label for prepackaged products whose ingredients lists might need to declare more than one added food colour. However, the industry stakeholders also expressed their preference that food colour labelling amendments align with those in the U.S. Further, in September 2014, Health Canada engaged in targeted consultation with specific stakeholders on food colour specifications. The information received through these consultations is the basis of the changes in the proposed amendments.

#### **Regulatory cooperation**

The proposed updates to the nutrition information on prepackaged food product labels in Canada are for the most part aligned with the U.S. proposed rule. Both countries require an NFt on most prepackaged products and the NFt is considered to be the gold standard internationally. The policy objectives in both countries are very similar, but the specific proposals present different approaches to achieve similar health objectives. The differences between both countries are outlined below. Health Canada will continue to monitor developments regarding the U.S. proposed rule and give consideration to any changes made to it.

#### Key difference: format

- Health Canada is proposing to adjust the order in which nutrients are listed in the NFt in order to group energy-providing nutrients together, followed by cholesterol and sodium. This format supports Health Canada's messaging in its public education campaigns on nutrition.
- The proposed U.S. label has a greater visual emphasis on the caloric content of the food. Health Canada is proposing an increased font size and bolding for calories, but not to the extent proposed in the U.S. The Department and Canadian health stakeholders are concerned that too great a focus on calories could detract from other important factors in choosing healthy foods.

#### Key difference: note at the bottom of the NFt

- The U.S. proposed rule does not specify the exact wording of the footnote that would appear in their final rule, but instead requests feedback from stakeholders.
- The "5% or less is a little, 15% or more is a lot" footnote is part of a successful consumer education campaign on % DVs in Canada, and an easily remembered rule of thumb.

#### Key difference: vitamin D

• The U.S. is adding vitamin D to the list, but Health Canada is not. This is because vitamin D occurs

naturally in so few foods that it would often be a "0" declaration. This will also limit costs to industry (laboratory analysis for vitamin D can be very complicated and costly). However, if vitamin D is added to a product, it must be included in the Canadian NFt (e.g. milk, fortified plant-based beverages, margarine).

### Key difference: declaration of sugar in the NFt

• While both the U.S. and Canadian proposals regarding sugar have the same overall objective (to provide consumers with the information they need to lower their sugar intake, if they so choose), different methods of achieving this goal have been chosen. The Canadian proposed amendments include two elements aimed at enhancing sugar labelling: establishing a DV for sugar in the NFt, and grouping sugar-based ingredients together in the list of ingredients (see below). The added sugars approach (in the U.S. proposed rule) and the % DV approach (in the Canadian proposed amendments) were both presented to Canadian consumers during the consultation in 2014. The feedback received indicate that, while both approaches were popular, Canadians found the information about carbohydrates and total sugars confusing when there were added sugars, and they found the % DV approach easy to understand and useful, particularly in association with the footnote. It is important to note that most foods that exceed the 15% DV threshold for "a lot" are foods that contain added sugars.

### Key difference (ingredient list): grouping of sugar-based ingredients

• The proposed requirement to have all sugar-based ingredients grouped together is not part of the U.S. proposed rule. However, Canadian consumers showed strong support for the proposed amendments because they increase the transparency regarding the sources of sugar added to food and provide a better estimate of the proportion of added sugar compared to other ingredients in the food.

## Rationale

The proposed amendments are intended to improve food labels, making the information more useful and easier to understand, so Canadians are able to make informed choices about the food they consume in order to maintain or improve their health. This objective would be met by

(i) modernizing and enhancing the labelling of foods with respect to nutrition information;

(ii) enabling a new health claim linking the consumption of fruits and vegetables to a decreased risk of heart disease; and

(iii) identifying food colours by their specific name in the ingredient list.

Health Canada has consulted widely with consumers, key partners and health stakeholders, who have expressed support for the approach.

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

(i) extending the coming-into-force period to minimize the cost of complying with new labelling requirements and allowing time to deplete current label stock;

(ii) exempting products that are packaged and labelled at a retail establishment from the requirement to separate each ingredient with a bullet; and

(iii) continuing to exempt products sold at a roadside stand, craft show, flea market, farmers' market or sugar bush by the individual who processed the product from the requirement to display an NFt.

Other options have been considered, and analysis has determined that implementation of the proposed amendments, while advancing alignment with the U.S. approach to the maximum extent possible, is the best way to proceed.

## Implementation, enforcement and service standards

#### **Implementation**

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. These include a continuation of the education campaign on % DV, and a soon-to-be-launched campaign on NFt serving sizes.

The proposed five-year coming-into-force period would allow sufficient time for industry to make the necessary changes to their labels and to use up any existing stocks of labels already printed to comply with

current requirements.

### **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 would be monitored as part of the ongoing domestic and import inspection programs, while respecting the resources that the CFIA has for enforcement and compliance verification. Appropriate enforcement action would be taken based on risk. Health Canada would provide guidance to the CFIA on health risk assessments and implementation of these 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. During the transition period, when manufacturers may apply both the former Regulations and the new Regulations, the CFIA would train its staff across Canada, update inspection and compliance promotion tools (for example the Nutrition Labelling Compliance Test, the Industry Labelling Tool, training material), and carry out compliance promotion activities.

#### Performance measurement and evaluation

Health Canada is currently developing a Performance Measurement and Evaluation Plan (PMEP) to measure the performance and conduct an evaluation of these proposed amendments to the Regulations. This plan would specify the methods selected for ongoing monitoring of these proposed amendments, performance targets, indicators and data sources. These would be comprehensively tracked as part of the performance measurement strategy outlined in the PMEP. This PMEP would be available upon final publication of the Regulations in the *Canada Gazette*, Part II.

### Contact

Dana Wang Policy, Planning and International Affairs Directorate Health Products and Food Branch Health Canada Holland Cross, Tower B, 5th Floor 1600 Scott Street Ottawa, Ontario K1A 0K9 Address locator: 3105A Fax: 613-941-7104 Email: LRM\_MLR\_consultations@hc-sc.gc.ca

#### **Small Business Lens Checklist**

1. Name of the sponsoring regulatory organization:

Department of Health

2. Title of the regulatory proposal:

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

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

Ι	Communication and transparency	Yes	No	N/A
1.	Are the proposed Regulations or requirements easily	$\mathbf{\nabla}$		
	understandable in everyday language?			
In 20	003, the Government of Canada made regulatory amendments to the F	DR rela	ted to	the
label	ling of food. The proposed amendments are written in a language tha	t is sim	ilar to	what
curre	ently exists in the FDR. Manufacturers and importers are familiar with	the lang	guage	used
in th	e Regulations.			
2.	Is there a clear connection between the requirements and the	N		
	purpose (or intent) of the proposed Regulations?			

format of the Nutrition would allow Canadian improving the legibilit ingredients. The propo- recommended daily va	nents would make changes to the presentation and n Facts table (NFt) and list of ingredients. This consumers to make healthier choices by cy, ease of use and content of the NFt and list of posed amendments include updates to the alues and the suggested serving size, in atest available science.			
communications informs small b on how to comp	i implementation plan that includes s and compliance promotion activities, that usinesses of a regulatory change and guides them oly with it (e.g. information sessions, sample olkits, Web sites)?	N		
with stakeholders, in o	nning a webinar shortly after publication in the <i>Cana</i> order to help explain the regulatory changes. Additio cy (CFIA) will continue to consult stakeholders throu	nally, tl	ne Can	adian
	with respect to enforcement.	gir then	ungu	ing
4. If new forms, re consistent in ap	eports or processes are introduced, are they pearance and format with other relevant ms, reports or processes?			Ŋ
No new forms or proc	esses would be introduced. All reporting, compliance n the current Regulations.	e and er	nforcer	nent
	and streamlining	Yes	No	N/A
1. Will streamlined Canada Border information from	d processes be put in place (e.g. through BizPaL, Services Agency single window) to collect m small businesses where possible?			N
	ot collect information from small businesses.	_		
businesses by fe	ties to align with other obligations imposed on ederal, provincial, municipal or international or gulatory bodies been assessed?	Ø		
regulations for food la	d Drug Administration (FDA) and members of the Eu abelling. At the time of writing, both Canada and the bod labels, specifically to the NFt. Many of the propo	U.S. ar	e prop	osing
the NFt are anticipated	d to be aligned. Changes to the listing of food colour gn with internationally recognized standards.			
3. Has the impact	of the proposed Regulations on international or rade been assessed?	$\checkmark$		
partners such as the U bilingual labels in Can that international tradi	een given to align the proposed amendments with in J.S. to the maximum extent possible. Current require ada would remain and would not be a change from t ing partners are currently following. Member countrie (TO) have been notified of this proposal as per the W	ments f he reques of th	o have iireme e Worl	e nts
	formation, other than personal information,		V	
required to com collected by and information be instead of reque or other stakend and disposal of requirements of compliance with	apply with the proposed Regulations is already other department or jurisdiction, will this obtained from that department or jurisdiction esting the same information from small businesses olders? (The collection, retention, use, disclosure personal information are all subject to the the <i>Privacy Act</i> . Any questions with respect to the <i>Privacy Act</i> should be referred to the agency's ATIP office or legal services unit.)			
There are no new requ	irements for submitting data or information to comp	ly with	the	
<ul> <li>proposed Regulations.</li> <li>5. Will forms be proposed for the proposed of the proposed for the proposed f</li></ul>	re-populated with information or data already			$\checkmark$
available to the to complete the online application name, the system applicant's pers	department to reduce the time and cost necessary m? (Example: When a business completes an on for a licence, upon entering an identifier or a em pre-populates the application with the onal particulars such as contact information, date, nformation is already available to the			Ы
All existing record-kee	eping requirements of industry to comply with CFIA r the exception of the certification of synthetic food			buld

6.	Will electronic reporting and data collection be used, including electronic validation and confirmation of receipt of reports where appropriate?			V
	xisting record-keeping requirements of industry to comply with CFIA in a number of synthetic food with the exception of the certification of synthetic food set in the set of the certification of synthetic food set in the set of the			ould
7.	Will reporting, if required by the proposed Regulations, be aligned with generally used business processes or international standards if possible?			Ø
No a	dditional reporting would be required as part of the proposed amendr	nents.		
8.	If additional forms are required, can they be streamlined with existing forms that must be completed for other government information requirements?			Ø
<u>No a</u>	dditional 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?	V		
Cons	Has consideration been given to small businesses in remote areas, with special consideration to those that do not have access	as beer	deter	
Cons	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? sideration has been given to small businesses in remote areas and it h	as beer		
Cons that 2. No r	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? sideration has been given to small businesses in remote areas and it h these businesses would not be affected by the proposed amendments 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	as beer		mined
Cons that 2. No r	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? sideration has been given to small businesses in remote areas and it h these businesses would not be affected by the proposed amendments 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? egulatory authorizations are being introduced with this proposal. A rem	as beer		mined

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:	V		
	<ul> <li>Longer time periods to comply with the requirements, longer transition periods or temporary exemptions;</li> <li>Performance-based standards;</li> <li>Partial or complete exemptions from compliance, especially for firms that have good track records (legal advice should be sought when considering such an option);</li> <li>Reduced compliance costs;</li> <li>Reduced fees or other charges or penalties;</li> <li>Use of market incentives;</li> <li>A range of options to comply with requirements, including lower-cost options;</li> <li>Simplified and less frequent reporting obligations and inspections; and</li> <li>Licences granted on a permanent basis or renewed less frequently.</li> </ul>			
	<ul> <li>ee options were proposed in the flexible analysis as means to reduce b iness:</li> <li>A longer coming-into-force period of five years would allow small b</li> </ul>			

- A longer coming-into-force period of five years would allow small business to exhaust their existing product and label stock, without having to throw away product.
   An exemption for products that are cold at formers' markets, forms, and readside
- An exemption for products that are sold at farmers' markets, farms, and roadside stands. These products would not be required to have an NFt or list of ingredients.
- An exemption for small business retailers that use scale labels from having to separate each item in the list of ingredients with a bullet; they may continue to use commas.

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?	Ø					
The	RIAS includes a breakdown of how the flexible options provide a num	ber of a	avoideo	ł			
	ts for small business. Each of the three options is monetized and demo						
•	ions would avoid a number of financial burdens for small business. The	e cost a	voidan	ce of			
	oming-into-force period of five years would apply to all business.	-					
3.	Does the RIAS include, as part of the Regulatory Flexibility	$\checkmark$					
	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.)	 + a_+ a_a_a					
	e most commonly identified risk raised by stakeholders is associated wi p-force period. The five-year coming-into-force period would apply to a		-				
	period must remain the same for all businesses regardless of size.	iii Dusii	lesses,	as			
4.	Does the RIAS include a summary of feedback provided by small			M			
	business during consultations?			Ŀ			
No	individual small businesses were identified during the consultation per	iod 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			N			
	business in terms of administrative or compliance costs, is a						
	reasonable justification provided in the RIAS?						
	e flexible options are the lowest-cost option and are recommended to le	essen th	e ecor	nomic			
imp	act 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 the Food and Drug Regulations — Nutrition Labelling, Other Labelling Provisions and Food Colours.

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 Dino Covone, Senior Policy Analyst, Office of Legislative and Regulatory Modernization, Policy, Planning and International Affairs Directorate, Health Canada, Holland Cross, 1600 Scott Street, Tower B, 5th Floor, Address Locator: 3105A, Ottawa, Ontario K1A 0K9 (fax: 613-941-7104; email: LRM\_MLR\_consultations@hc-sc.gc.ca).

Ottawa, June 4, 2015

JURICA ČAPKUN Assistant Clerk of the Privy Council

# REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS — NUTRITION LABELLING, OTHER LABELLING PROVISIONS AND FOOD COLOURS

## **1. (1)** The definitions "recommended daily intake" and "reference standard" in subsection **B.01.001(1)** of the *Food and Drug Regulations* (see footnote 3) are repealed.

## (2) The definitions "daily value", "food colour", "reference amount" and "sweetener" in subsection B.01.001(1) of the Regulations are replaced by the following:

"daily value" means, in respect of a nutrient, the quantity applicable to the nutrient according to subsection B.01.001.1(2); (*valeur quotidienne*)

"food colour" means any colouring agent that is subject to section 2 of the *Marketing Authorization for Food* Additives That May Be Used as Colouring Agents; (colorant alimentaire)

"reference amount" means, in respect of a food set out in column 1 of the Table of Reference Amounts, the amount of that food set out in column 2; (quantité de référence)

"sweetener" means any sweetener that is subject to section 2 of the *Marketing Authorization for Food* Additives That May Be Used as Sweeteners; (édulcorant)

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

"Directory of NFT Formats" means the document entitled *Nutrition Labelling – Directory of Nutrition Facts Table Formats* published by the Department of Health on its website, as amended from time to time; (*Répertoire des modèles de TVN*)

"functional substitute for a sweetening agent" means, in respect of a prepackaged product, a food — other than any sweetener or sweetening agent, including any sugars — that replaces a sweetening agent and that has one or more of the functions of the sweetening agent including, sweetening, thickening, texturing or browning. (*substitut fonctionnel d'un agent édulcorant*)

"marketing authorization" means a marketing authorization issued by the Minister under subsection 30.3(1) of the Act; (*autorisation de mise en marché*)

"mutiple-serving prepackaged product" means a prepackaged product other than a single-serving prepackaged product; (*produit préemballé à portions multiples*)

"point" means the unit of measurement for type size that is known as an Anglo-American point and is equal to 0.3527777778 mm; (*point*)

"single-serving prepackaged product" means a prepackaged product in respect of which the net quantity of food in the package is the serving of stated size for the food as set out in paragraph B.01.002A(1)(b); (produit préemballé à portion individuelle)

"sugars-based ingredient" means, in respect of a prepackaged product,

- (a) an ingredient that is a monosaccharide or disaccharide or a combination of these;
- (b) an ingredient that is a sweetening agent other than one referred to in paragraph (a); and

(*c*) any other ingredient that contains one or more sugars and that is added to the product as a functional substitute for a sweetening agent; (*ingrédient à base de sucres*)

"Table of Daily Values" means the document entitled *Nutrition Labelling – Table of Daily Values* published by the Department of Health on its website, as amended from time to time; (*Tableau des valeurs quotidiennes*)

"Table of Reference Amounts" means the document entitled *Nutrition Labelling – Table of Reference Amounts for Food* published by the Department of Health on its website, as amended from time to time; (*Tableau des quantités de référence*)

## 2. Section B.01.001.1 of the Regulations is replaced by the following:

**B.01.001.1** (1) For the purpose of subsection (2), the term "fat" used in the Table of Daily Values means all fatty acids expressed as triglycerides.

- (2) The daily value for a nutrient in a food is
  - (a) in the case of a nutrient set out in column 1 of Part 1 of the Table of Daily Values, the quantity

(i) set out in column 2, if the food is intended solely for children one year of age or older but less than four years of age, and

(ii) set out in column 3, in any other case; and

(b) in the case of a vitamin or mineral nutrient set out in column 1 of Part 2 of the Table of Daily Values, the quantity

(i) set out in column 2, if the food is intended solely for infants seven months of age or older but less than one year of age,

(ii) set out in column 3, if the food is intended solely for children one year of age or older but less than four years of age, and

(iii) set out in column 4, in any other case.

## 3. Section B.01.002A of the Regulations is replaced by the following:

B.01.002A. (1) For the purposes of this Part, a serving of stated size of a food shall be

- (a) based on the food as offered for sale;
- (*b*) in either of the following cases, the net quantity of the food in the package:

(i) if the quantity of food in the package can reasonably be consumed by one person at a single eating occasion, or

(ii) if the package contains less than 200% of the reference amount for the food; and

(c) in all other cases, the amount indicated for the food according to the criteria set out in column 3A of the Table of Reference Amounts.

(2) A serving of stated size shall be expressed as follows:

(a) in the case of a single-serving prepackaged product referred to in paragraph (1)(b), per package and using the following units:

(i) in grams, if the net quantity of the food is shown on the label by weight or by count, and (ii) in milliliters, if the net quantity of the food is shown on the label by volume; and

(b) in the case of a multiple-serving prepackaged product referred to in paragraph (1)(c), according to the following units of measure set out in column 3B of the Table of Reference Amounts and according to the manner set out in that column:

(i) the household measure that applies to the product, and

(ii) the metric measure that applies to the product.

#### 4. Subsections B.01.008(3) to (10) of the Regulations are replaced by the following:

(3) Despite paragraph (1)(b), the following items are not required to be shown on the label of a prepackaged product:

(*a*) wax coating compounds and their components, used as an ingredient or component of prepackaged fresh fruit or vegetables;

(b) sausage casings, used as an ingredient or component of prepackaged sausages;

(c) hydrogen, used as an ingredient or component of a prepackaged product if used for hydrogenation purposes; and

(*d*) components of ingredients of a sandwich, if the sandwich is made with bread.

#### 5. The Regulations are amended by adding the following after section B.01.008:

**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 shall be shown

(*a*) in a single colour of type that is a visual equivalent of 100% solid black type and that is shown on a white background or a uniform neutral background having a maximum 5% tint of colour;

(*b*) in a single standard sans serif font that is not decorative and in such a manner that the characters never touch each other or any differentiating feature under subsection B.01.008.2(2);

(c) in type having normal or condensed width except that if a nutrition facts table appears on the label the width of type must be the same as that required for nutrients that appear in the nutrition facts table; and

(d) in regular type, subject to paragraph B.01.010.3(1)(c); and

(e) in a type size of at least 6 points with leading of at least 7 points, except that if a nutrition facts table appears on the label, the type size and leading must be at least the same as those required for nutrients that appear in the nutrition facts table.

(2) Characters may be displayed in larger type size than that referred to in paragraph (1)(d) if all characters are enlarged in a uniform manner.

**B.01.008.2** (1) The list of ingredients shall be introduced by a title that shall be shown

- (a) by the term
  - (i) "Ingredients" or "Ingredients:" in the English version of the list, and
  - (ii) "Ingrédients" or "Ingrédients :" in the French version of the list;

(b) despite paragraph B.01.008.1(1)(d), in bold type;

(c) despite paragraph B.01.008.1(1)(e), in a type size that is 2 points larger than the type size used to show ingredients in the list, except that if the available display surface of the prepackaged product is less than 100 cm<sup>2</sup>, the title may be shown in type that is at least the same size as the type size used to show ingredients in the list; and

(d) without any intervening printed, written or graphic material appearing between the title and the first ingredient shown in the list.

(2) A list of ingredients shall be shown in a manner that clearly differentiates it on the label, by means of one or both of

(a) graphics in the form of a solid-line border around the list, or one or more solid lines appearing immediately above, below or at the sides of the list; and

(b) a background colour that creates a contrast between the background colour of the list and the background colour used on the adjacent area of the label, other than the area used to display a food allergen source, gluten source and added sulphites statement, as defined in subsection B.01.010.1(1), a declaration referred to in subsection B.01.010.4(1) and a nutrition facts table.

(3) In a list of ingredients, ingredients shall be shown

(*a*) in descending order of their proportion of the prepackaged product or as a percentage of the prepackaged product, and the order or percentage shall be the order or percentage of the ingredients before they are combined to form the product;

(b) in lower case letters, except that upper case letters shall be used to show

(i) the first letter of each ingredient or in the case of a food additive shown by an acronym, the entire acronym, and

(ii) the alpha-descriptor for vitamins; and

(c) separated by a bullet point, unless the product is sold only in the retail establishment where it is packaged and is labelled by means of a sticker, in which case ingredients may be separated by a comma.

(4) Despite paragraph (3)(a), the following ingredients may be shown immediately after the other ingredients, in any order:

- (a) spices, seasonings and herbs, except salt;
- (b) natural flavours and artificial flavours;
- (c) flavour enhancers;

(*d*) food additives, except ingredients of food additive preparations or mixtures of substances for use as a food additive;

- (e) vitamins;
- (f) salts or derivatives of vitamins;
- (g) mineral nutrients; and
- (*h*) salts of mineral nutrients.

(5) In a list of ingredients, the components of an ingredient shall be shown

(*a*) in parentheses, immediately after the ingredient, unless the source of a food allergen or gluten is shown immediately after the ingredient, in which case components of the ingredient shall be shown immediately after that source;

(*b*) in descending order of their proportion of the ingredient determined before the components are combined to form the ingredient;

- (c) entirely in lower case letters except that upper case letters shall be used to show
  - (i) the acronym for a food additive, and
  - (ii) the alpha-descriptor for vitamins; and
- (d) separated by a comma.

(6) Despite paragraph B.01.008(1)(*b*) and paragraphs (5)(*a*) and (*b*), but subject to section B.01.009, if one or more components of an ingredient are required by these Regulations to be shown in a list of ingredients, the ingredient is not required to be shown in the list if all components of the ingredient are shown in the list by their common names and in accordance with subsection (3) as if they were ingredients.

(7) In a list of ingredients, the source of a food allergen or gluten shall be shown

(*a*) immediately after the ingredient or component to which it applies in accordance with subsections B.01.010.1(8) and (10);

(b) entirely in lower case letters; and

(c) separated by a comma from any other source of a food allergen or gluten that is shown for the same ingredient or component.

(8) If the English and French versions of a list of ingredients appear on the same continuous surface of the label, the version that follows the other version must not begin on the same line on which the other version ends.

**B.01.008.3** (1) If a prepackaged product contains one or more sugars-based ingredients, despite the order of presentation referred to in paragraph B.01.008.2(3)(*a*), the sugars-based ingredient or ingredients shall be shown in the list of ingredients, in parentheses, immediately following the term "Sugars".

(2) The term "Sugars" referred to in subsection (1) shall be shown in the list of ingredients

(*a*) in descending order of its proportion in the product, basing that proportion on the total quantity of all sugars-based ingredients in the product; and

(*b*) separated from other ingredients by a bullet point, unless the product is sold only in the retail establishment where it is packaged and is labelled by means of a sticker, in which case the term may be separated from other ingredients by a comma.

(3) Each sugars-based ingredient mentioned immediately following the term "Sugars" shall be shown

- (a) by its common name according to section B.01.010;
- (b) despite paragraph B.01.008.2(3)(b), entirely in lower case letters; and
- (c) in the case of more than one sugars-based ingredient, each ingredient shall be shown

(i) in descending order of its proportion in the product as prescribed by subsection  $B.01.008.2(3),\,and$ 

(ii) separated by a comma.

(4) Subsections (1) to (3) do not apply to the following prepackaged products:

(a) a sweetening agent;

(*b*) fruit or vegetable juice or vegetable drink that does not contain any sweetening agent, as well as any mixture of those juices and drinks, including any of those juices and drinks

(i) to which fruit or vegetable purée or any mixture of those purées has been added,

- (ii) that are reconstituted, or
- (iii) that are a concentrate intended for dilution and consumption as juice or drink; and

(c) fruit or vegetable purée that does not contain any sweetening agent as well as any mixture of those purées.

## 6. (1) Item 3 of the table to paragraph B.01.010(3)(b) of the Regulations is repealed.

## (2) The portion of subsection B.01.010(4) of the Regulations before paragraph (a) is replaced by the following:

(4) Despite subsection (2) and subsection B.01.008.2(5), if a food contains ingredients of the same class, those ingredients may be shown by a class name if

## 7. (1) The portion of subsection B.01.010.1(1) of the Regulations before the definition of "food allergen" is replaced by the following:

**B.01.010.1** (1) The following definitions apply in this section and in sections B.01.010.2 to B.01.010.4.

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

"food allergen source, gluten source and added sulphites statement" means a statement appearing on the label of a prepackaged product that indicates the source of a food allergen or gluten that is present in the product or the presence in the product of added sulphites in a total amount of 10 p.p.m. or more. (*mention des sources d'allergènes alimentaires ou de gluten et des sulfites ajoutés*)

## (3) Paragraph B.01.010.1(2)(b) of the Regulations is replaced by the following:

(b) in a food allergen source, gluten source and added sulphites statement.

## 8. (1) 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 and B.01.010.4, "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.

## (2) Paragraph B.01.010.2(3)(b) of the Regulations is replaced by the following:

(*b*) the food allergen source, gluten source and added sulphites statement that complies with the requirements of subsection B.01.010.3(1).

### (3) Paragraphs B.01.010.2(7)(a) and (b) of the Regulations are replaced by the following:

(*a*) sulphites that are a component of an ingredient that is shown in the list of ingredients must be shown either in parentheses immediately after the ingredient or at the end of that list where they may be shown in any order with the other ingredients that are shown at the end of that list in accordance with subsection B.01.008.2(4); and

(*b*) in all other cases, the sulphites must be shown at the end of the list of ingredients where they may be shown in any order with the other ingredients that are shown at the end of that list in accordance with subsection B.01.008.2(4).

## 9. (1) The portion of subsection B.01.010.3(1) of the Regulations before paragraph (b) is replaced by the following:

**B.01.010.3** (1) A food allergen source, gluten source and added sulphites statement on the label of a prepackaged product shall

(a) be introduced by a title that shall be shown

(i) by the term

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

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

(ii) despite paragraph B.01.008.1(1)(d), in bold type,

(iii) despite paragraph B.01.008.1(1)(e), in a type size that is 2 points larger than the type size required to show the information in the statement, unless the available display surface of the prepackaged product is less than 100 cm<sup>2</sup>, in which case the title may be shown in type that is at least the same size as the type size used for the information shown in the statement, and

(iv) without any intervening printed, written or graphic material appearing between the title and the rest of the statement;

(*a.1*) appear, in respect of each linguistic version, after the list of ingredients appearing in the same language, without any intervening printed, written or graphic material;

(a.2) appear on the same continuous surface as the list of ingredients

(i) against the same background colour as the list;

(ii) if the list of ingredients is differentiated by means of a solid-line border or lines in accordance with paragraph B.01.008.2(2)(a), the statement shall appear within the border or the lines;

## (2) The portion of paragraph B.01.010.3(1)(b) of the French version of the Regulations before subparagraph (i) is amended by the following:

(*b*) elle inclut tous les renseignements ci-après, que l'un ou plusieurs d'entre eux figurent ou non dans la liste des ingrédients du produit :

## (3) Subsection B.01.010.3(1) of the Regulations is amended by adding "and" at the end of paragraph (b) and by adding the following after paragraph (b):

(c) show information entries in regular or bold type, using lower case letters except for the first letter of each entry, which shall be an upper case letter, and shall use a bullet point to separate each entry.

## (4) Section B.01.010.3 of the Regulations is amended by adding the following after subsection (2):

(3) Despite paragraph (1)(c), if the prepackaged product is sold only in the retail establishment where it is packaged and is labelled by means of a sticker, information entries may be separated by a comma.

(4) If the English and French versions of the statement appear on the same continuous surface of the label, the version that follows the other version cannot begin on the line on which the other version ends.

## 10. The Regulations are amended by adding the following after section B.01.010.3:

**B.01.010.4** (1) If the label of a prepackaged product includes a declaration alerting consumers that, due to a risk of cross- contamination, the product may contain the source of a food allergen or gluten or sulphites,

(*a*) the declaration must be shown immediately after the food allergen source, gluten source and added sulphites statement or, if there is none, after the list of ingredients, and must appear on the same continuous surface as the statement, if any, and the list of ingredients

(i) against the same background colour as the list of ingredients, and

(ii) if the list of ingredients and the statement, if any, are differentiated by means of a solid-line border or solid lines in accordance with paragraph B.01.008.2(2)(a) or B.01.010.3(1)(a.2), 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 statement that immediately precedes it, except that a solid line may appear before the declaration;

(c) the declaration must begin on a different line than the line on which the list of ingredients or the statement that immediately precedes it ends; and

(d) the declaration must appear in regular type that is the same size as the type size used to show ingredients in the list of ingredients.

(2) For the purpose of subsection (1), the source of a food allergen or gluten must be shown in accordance with subsection B.01.010.1(6) or (7), respectively.

### 11. Paragraphs B.01.045 (b) to (f) of the Regulations are replaced by the following:

(*b*) where no specifications are set out in this Part for the additive, the additive must meet the specifications for it, if any, set out in

(i) the *Food Chemicals Codex*, ninth edition, 2014, published by the United States Pharmacopeial Convention, Rockville, MD, United States of America, as that or any subsequent edition, including their supplements, may be amended from time to time; or (ii) the *Combined Compendium of Food Additive Specifications*, prepared by the Joint FAO/WHO Expert Committee on Food Additives and published by the Food and Agriculture Organization of the United Nations, on the website of the Organization, as amended from time to time; and

(c) in the case of a food colour for which no specifications exist under paragraph (a) or (b), the food colour must contain no more than

- (i) 3 parts per million of arsenic, and
- (ii) 10 parts per million of lead.

#### **12.** Section B.01.091 of the Regulations is replaced by the following:

**B.01.091.** The label of any solid cut meat or solid cut poultry meat that has had phosphate salts or water added to it, that is not cured and that is prepackaged at retail shall contain a statement of the ingredients contained in the food in accordance with subsections B.01.008.2(1) to (5) and (7).

#### 13. Paragraphs B.01.301(1)(b) and (c) of the Regulations are replaced by the following:

(*b*) in the case of a vitamin referred to in subsection D.01.002(1), in the applicable unit set out in subsection D.01.003(1);

(b.1) in the case of the following mineral nutrients:

(i) for sodium, potassium, manganese, calcium, phosphorus, magnesium, iron, zinc, copper and chloride, in milligrams, and

(ii) for iodide, selenium, chromium and molybdenum, in micrograms;

(c) in the case of cholesterol, in milligrams;

#### 14. The Regulations are amended by adding the following after section B.01.301:

**B.01.302.** (1) If the label of a multiple-serving prepackaged product indicates that the product contains or, when prepared as directed in or on the package, provides a specified number of servings or portions, that information must be based on the serving of stated size for the product set out in the nutrition facts table.

(2) Despite subsection (1), the label of the multiple-serving prepackaged product shall not include the information referred to in subsection (1) if the serving of stated size set out in the nutrition facts table for the product is expressed in cups or tablespoons.

## **15.** Section B.01.400 of the Regulations is replaced by the following:

**B.01.400.** (1) For the purpose of sections B.01.401 to B.01.603, "fat" means all fatty acids expressed as triglycerides.

(2) For the purpose of sections B.01.401 to B.01.603, the amount of vitamins shall be determined in accordance with section D.01.003.

## 16. (1) Subsection B.01.401(1) of the Regulations is replaced by the following:

**B.01.401.** (1) Except as otherwise provided in this section and sections B.01.402 to B.01.406 and sections B.01.467 to B.01.469, the label of a prepackaged product shall carry a nutrition facts table that contains only the information set out in column 1 of the table to this section expressed using a description set out in column 2 and in the unit set out in column 3 and in the manner set out in column 4.

(1.1) For the purpose of subsection (1), the amount of the serving of stated size set out in a nutrition facts table for a prepackaged product, as expressed in the metric unit, shall be used as the basis for determining the information appearing in the nutrition facts table in respect of the energy value and nutrient content of the product.

(1.2) The percentage of the daily value for a mineral nutrient shown in the nutrition facts table for a prepackaged product in accordance with subsection (1) shall be established on the basis of the amount, by weight, of the mineral nutrient in the serving of stated size for the product, rounded off in the applicable manner set out in column 4 of the table to this section.

## (2) Subparagraph B.01.401(2)(b)(ii) of the Regulations is repealed.

## (3) Subparagraph B.01.401(2)(c)(i) of the Regulations is replaced by the following:

(i) a fresh vegetable or fruit or any combination of fresh vegetables or fruits without any added ingredients, an orange with added food colour or a fresh vegetable or fruit coated with mineral oil, paraffin wax, petrolatum or any other protective coating,

## (4) The portion of subsection B.01.401(6) of the Regulations before paragraph (a) is replaced by the following:

(6) If, for a prepackaged product other than one intended solely for infants seven months of age or older but less than one year of age, the information in respect of seven or more of the energy value and nutrients referred to in column 1 of items 2 to 5 and 7 to 15 of the table to this section may be expressed as "0" in the nutrition facts table in accordance with this section, the nutrition facts table need only include the following information:

## (5) Paragraph B.01.401(6)(*i*) of the Regulations is replaced by the following:

(*i*) the amount of any nutrient referred to in column 1 of item 4, 5, 7, 8, 10 or 11 or any of items 13 to 15 of the table to this section that may not be expressed as "0" in the nutrition facts table ; and

## (6) Section B.01.401 of the Regulations is amended by adding the following after subsection (7):

(8) If the nutrition facts table on the label of a prepackaged product corresponds to figure 6.5, 6.6, 7.3, 7.4, 17.2, 24.1 to 24.6, 25.1 to 25.6, 26.1 to 26.4, 32.1 or 32.2 set out in the Directory of NFT Formats, the nutrition facts table is not required to show the interpretative statement referred to in item 16 of the table to this section.

## (7) The portion of item 1 of the table to section B.01.401 of the Regulations in columns 3 and 4 is replaced by the following:

Column 3	Column 4
Item	

	Unit	Manner of expression
1.	The size is expressed (a) in the case of a single-serving prepackaged product, (i) per package, and (ii) in grams or milliliters, in accordance with subparagraph B.01.002A(2)(a)(i) or (ii); and	<ul> <li>(1) The size expressed in a metric unit, is rounded off</li> <li>(a) if it is less than 10 g or 10 mL, to the nearest multiple of 0.1 g or 0.1 mL; and</li> <li>(b) if it is 10 g or more or 10 mL or more, to the nearest multiple of 1 g</li> </ul>
	<ul> <li>(b) in the case of a multiple-serving prepackaged product, in the following units of measure set out in column 3B of the Table of Reference Amounts: <ul> <li>(i) the household measure that applies to the product, and</li> <li>(ii) the metric measure that applies to the product.</li> </ul> </li> </ul>	or 1 mL. (2) The size, when expressed as a fraction, is represented by a numerator and a denominator separated by a line. (3) The size shall include the word "assorted" if the information in the nutrition facts table of a prepackaged product that contains an assortment of foods is set out as a composite value.

## (8) The portion of item 7 of the table to section B.01.401 of the Regulations in column 3 is replaced by the following:

	Column 3
Item	Unit
7.	The amount
	(a) is expressed in milligrams per serving of stated size; and
	(b) may also be expressed as a percentage of the daily value per serving of stated size.

## (9) Items 9 to 13 of the table to section B.01.401 of the Regulations are replaced by the following:

	Column 1	Column 2	Column 3	Column 4
Item	Information	Description	Unit	Manner of expression
9.	Amount of carbohydrate	"Carbohydrate", "Total Carbohydrate" or "Carbohydrate, Total"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
10.	Amount of fibre	"Fibre", "Fiber", "Dietary Fibre" or "Dietary Fiber"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to "0 g"; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.

11.	Amount of sugars	"Sugars"	The amount is expressed (a) in grams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	<ul> <li>(1) The amount is rounded off <ul> <li>(a) if it is less than</li> <li>0.5 g, to "0 g"; and</li> <li>(b) if it is 0.5 g or more, to the nearest multiple of 1 g.</li> </ul> </li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as "0 g", to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> </ul>
12.	Amount of protein	"Protein"	The amount is expressed in grams per serving of stated size.	The amount is rounded off (a) if it is less than 0.5 g, to the nearest multiple of 0.1 g; and (b) if it is 0.5 g or more, to the nearest multiple of 1 g.
13.	Amount of potassium	"Potassium"	The amount is expressed (a) in milligrams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 5 mg, to "0 mg";</li> <li>(b) if it is 5 mg or more and less than 50 mg, to the nearest multiple of 10 mg;</li> <li>(c) if it is 50 mg or more and less than 250 mg, to the nearest multiple of 25 mg; and</li> <li>(d) if it is 250 mg or more, to the nearest multiple of 50 mg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>

14.	Amount of calcium	"Calcium"	The amount is expressed (a) in milligrams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 5 mg, to "0 mg";</li> <li>(b) if it is 5 mg or more and less than 50 mg, to the nearest multiple of 10 mg;</li> <li>(c) if it is 50 mg or more and less than 250 mg, to the nearest multiple of 25 mg; and</li> <li>(d) if it is 250 mg or more, to the nearest multiple of 50 mg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of</li> </ul>
15.	Amount of iron	"Iron"	The amount is expressed (a) in milligrams per serving of stated size; and (b) as a percentage of the daily value per serving of stated size.	<ul> <li>1%.</li> <li>(1) The amount is rounded off <ul> <li>(a) if it is less than 0.05 mg, to "0 mg";</li> <li>(b) if it is 0.05 mg or more and less than 0.5 mg, to the nearest multiple of 0.1 mg;</li> <li>(c) if it is 0.5 mg or more and less than 2.5 mg, to the nearest multiple of 0.25 mg; and</li> <li>(d) if it is 2.5 mg or more, to the nearest multiple of 0.5 mg.</li> </ul> </li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> </ul>

16.	% Daily Value interpretative statement	"5% or less is a little, 15% or more is a lot"	[not applicable]	The "% Daily Value" or "% DV" statement is followed by an asterisk in order to reference the % Daily Value interpretative statement shown in the nutrition facts table.
	statement	is a lot"		in order to reference the % Daily Value
				shown in the nutrition

## 17. (1) Section B.01.402 of the Regulations is amended by adding the following after subsection (2):

(2.1) For the purpose of subsection (2), the serving of stated size set out in a nutrition facts table for a prepackaged product, expressed in the metric unit, shall be used as the basis for determining the information appearing in the nutrition facts table in respect of the energy value and nutrient content of the product.

(2.2) The percentage of the daily value for a vitamin or mineral nutrient shown in the nutrition facts table for a prepackaged product in accordance with subsection (2) shall be established on the basis of the amount, by weight, of the vitamin or mineral nutrient per serving of stated size for the product, rounded off in the applicable manner set out in column 4 of the table to this section.

### (2) Subsection B.01.402(5) of the Regulations is repealed.

### (3) Subsection B.01.402(8) of the Regulations is replaced by the following:

(8) Despite subsection (1) and item 1 of the table to this section, the nutrition facts table shall not include information on the number of servings per package if the serving of stated size is expressed in cups or tablespoons.

## (4) The portion of item 1 of the table to section B.01.402 of the Regulations in columns 1 and 2 is replaced by the following:

	Column 1	Column 2
Item	Information	Description
1.	Servings per package	"Servings per Container", "(number of units) per Container", "Servings per Package", "(number of units) per Package", "Servings per (naming the package type)", or "(number of units) per (naming the package type)"

(5) Items 3 and 4 of the table to section B.01.402 of the Regulations are repealed.

(6) Item 9 of the table to section B.01.402 of the Regulations is repealed.

(7) Items 14 to 16 of the table to section B.01.402 of the Regulations are replaced by the following:

				Column 4
	Column 1	Column 2	Column 3	
Item	Information	Description	Unit	Manner of Expression
14.	Amount of vitamin A	"Vitamin A" or "Vit A"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 5 μg, to "0 μg";</li> <li>(b) if it is 5 μg or more but less than 50 μg, to the nearest multiple of 10 μg;</li> <li>(c) if it is 50 μg or more but less than 250 μg, to</li> </ul>

				<ul> <li>the nearest multiple of 50 µg; and</li> <li>(<i>d</i>) if it is 250 µg or more, to the nearest multiple of 100 µg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> </ul>
15.	Amount of vitamin C	« Vitamin C » or « Vit C »	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.1 mg, to "0 mg";</li> <li>(b) if it is 0.1 mg or more but less than 1 mg, to the nearest multiple of 0.2 mg;</li> <li>(c) if it is 1 mg or more but less than 5 mg, to the nearest multiple of 0.5 mg; and</li> <li>(d) if it is 5 mg or more, to the nearest multiple of 1 mg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> </ul>
16.	Amount of vitamin D	« Vitamin D » or « Vit D »	The amount ( <i>a</i> ) is expressed as a percentage of the daily value per serving of stated size; and ( <i>b</i> ) may also be	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.1 μg, to "0 μg";</li> <li>(b) if it is 0.1 μg</li> </ul>

			expressed in micrograms per serving of stated size.	or more but less than 1 $\mu$ g, to the nearest multiple of 0.2 $\mu$ g; ( <i>c</i> ) if it is 1 $\mu$ g or more but less than 5 $\mu$ g, to the nearest multiple of 0.5 $\mu$ g; and ( <i>d</i> ) if it is 5 $\mu$ g or more, to the nearest multiple of 1 $\mu$ g.
				(2) The percentage is rounded off
				<ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
17.	Amount of vitamin E	« Vitamin E » or « Vit E »	The amount	(1) The amount is
			( <i>a</i> ) is expressed as a percentage of the daily value per serving of stated size; and ( <i>b</i> ) may also be expressed in milligrams per serving of stated size.	rounded off (a) if it is less than 0.05 mg, to "0 mg"; (b) if it is 0.05 mg or more but less than 0.5 mg, to the nearest multiple of 0.1 mg; (c) if it is 0.5 mg or more but less than 2.5 mg, to the nearest multiple of 0.25 mg; and (d) if it is 2.5 mg or more, to the nearest multiple of 0.5 mg. (2) The percentage is rounded off (a) if the amount is
				declared as 0 mg, to "0%"; and (b) in all other cases, to the nearest multiple of 1%.

18.	Amount of vitamin K	« Vitamin K » or « Vit K »	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.05 μg, to "0 μg";</li> <li>(b) if it is 0.05 μg or more but less than 0.5 μg, to the nearest multiple of 0.1 μg;</li> <li>(c) if it is 0.5 μg or more but less than 2.5 μg, to the nearest multiple of 0.25 μg; and</li> <li>(d) if it is 2.5 μg or more, to the nearest multiple of 0.5 μg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the</li> </ul>
19.	Amount of thiamine	"Thiamine", "Thiamin", "Thiamine (Vitamin B <sub>1</sub> )", "Thiamine (Vit B <sub>1</sub> )", "Thiamin (Vitamin B <sub>1</sub> )" or "Thiamin (Vit B <sub>1</sub> )"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	nearest multiple of 1%. (1) The amount is rounded off (a) if it is less than 0.005 mg, to "0 mg"; (b) if it is 0.005 mg or more but less than 0.05 mg, to the nearest multiple of 0.01 mg; (c) if it is 0.05 mg or more but less than 0.25 mg, to the nearest multiple of 0.025 mg; and (d) if it is 0.25 mg or more, to the nearest multiple of 0.05 mg. (2) The percentage is rounded off

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20				<ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
20.	Amount of riboflavin	"Riboflavin", "Riboflavin B <sub>2</sub> )" or "Riboflavin (Vit B <sub>2</sub> )"	The amount ( <i>a</i> ) is expressed as a percentage of the daily value per serving of stated size; and ( <i>b</i> ) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.005 mg, to "0 mg";</li> <li>(b) if it is 0.005 mg or more but less than 0.05 mg, to the nearest multiple of 0.01 mg;</li> <li>(c) if it is 0.05 mg or more but less than 0.25 mg, to the nearest multiple of 0.025 mg; and</li> <li>(d) if it is 0.25 mg or more, to the nearest multiple of 0.025 mg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
21.	Amount of niacin	"Niacin"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.05 mg, to "0 mg";</li> <li>(b) if it is 0.05 mg or more but less than 0.5 mg, to the nearest multiple of 0.1 mg;</li> <li>(c) if it is 0.5 mg or more but less than 2.5 mg, to the</li> </ul>

22.	Amount of vitamin B <sub>6</sub>	"Vitamin B6" or "Vit B6"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>nearest multiple of 0.25 mg; and (d) if it is 2.5 mg or more, to the nearest multiple of 0.5 mg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> <li>(1) The amount is rounded off <ul> <li>(a) if it is less than 0.005 mg, to "0 mg";</li> <li>(b) if it is 0.005 mg or more but less than 0.05 mg, to the nearest multiple of 0.01 mg;</li> <li>(c) if it is 0.05 mg or more but less than 0.25 mg, to the nearest multiple of 0.025 mg; and</li> <li>(d) if it is 0.25 mg or more, to the nearest multiple of 0.05 mg.</li> </ul> </li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other</li> </ul> </li> </ul>
23.	Amount of folate	"Folate"	The amount ( <i>a</i> ) is expressed as a percentage of the daily value per serving of	<ul> <li>cases, to the nearest multiple of 1%.</li> <li>(1) The amount is rounded off <ul> <li>(a) if it is less than 1 µg DFE,</li> </ul> </li> </ul>

			stated size; and (b) may also be expressed in micrograms dietary folate equivalents (DFE) per serving of stated size.	to "0 µg DFE"; (b) if it is 1 µg DFE or more but less than 10 µg DFE, to the nearest multiple of 2 µg DFE; (c) if it is 10 µg DFE or more but less than 50 µg DFE, to the nearest multiple of 5 µg DFE; and (d) if it is 50 µg DFE or more, to the nearest multiple of 10 µg DFE.
				(2) The percentage is rounded off
				<ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
24.	Amount of vitamin $B_{12}$	"Vitamin $B_{12}$ " or "Vit $B_{12}$ "	The amount (a) is expressed	(1) The amount is rounded off
			as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>(a) if it is less than 0.005 μg, to "0 μg";</li> <li>(b) if it is 0.005 μg or more but less than 0.05 μg, to the nearest multiple of 0.01 μg;</li> <li>(c) if it is 0.05 μg or more but less than 0.25 μg, to the nearest multiple of 0.025 μg; and (d) if it is 0.25 μg or more, to the nearest multiple of 0.05 μg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> </ul> </li> </ul>

				(b) in all other cases, to the nearest multiple of 1%.
25.	Amount of biotin	"Biotin"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.05 μg, to "0 μg";</li> <li>(b) if it is 0.05 μg or more but less than 0.5 μg or more but less than 0.5 μg, to the nearest multiple of 0.1 μg;</li> <li>(c) if it is 0.5 μg or more but less than 2.5 μg, to the nearest multiple of 0.25 μg; and</li> <li>(d) if it is 2.5 μg or more, to the nearest multiple of 0.5 μg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> </ul>
26.	Amount of pantothenic acid	"Pantothenic Acid" or "Pantothenate"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.01 mg, to "0 mg";</li> <li>(b) if it is 0.01 mg or more but less than 0.1 mg or more but less than 0.1 mg, to the nearest multiple of 0.02 mg;</li> <li>(c) if it is 0.1 mg or more but less than 0.5 mg, to the nearest multiple of 0.05 mg; and</li> <li>(d) if it is 0.5 mg or more, to the nearest multiple of 0.1 mg.</li> </ul>

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			<ul> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
Amount of choline	"Choline"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 1 mg, to "0 mg";</li> <li>(b) if it is 1 mg or more but less than 10 mg, to the nearest multiple of 2 mg;</li> <li>(c) if it is 10 mg or more but less than 50 mg, to the nearest multiple of 5 mg; and</li> <li>(d) if it is 50 mg or more, to the nearest multiple of 10 mg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the</li> </ul>
Amount of phosphorous	"Phosphorus"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	nearest multiple of 1%. (1) The amount is rounded off (a) if it is less than 5 mg, to "0 mg"; (b) if it is 5 mg or more but less than 50 mg, to the nearest multiple of 10 mg; (c) if it is 50 mg or more but less than 250 mg, to the nearest

28.

29.	Amount of iodide	"Iodide" or "Iodine"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>multiple of 25 mg; and</li> <li>(d) if it is 250 mg or more, to the nearest multiple of 50 mg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> <li>(1) The amount is rounded off <ul> <li>(a) if it is less than 1 µg, to "0 µg";</li> <li>(b) if it is 1 µg or more but less than 10 µg, to the nearest multiple of 2 µg;</li> <li>(c) if it is 10 µg or more but less than 50 µg, to the nearest multiple of 5 µg; and</li> <li>(d) if it is 50 µg or more, to the nearest multiple of 5 µg; and</li> <li>(d) if it is 50 µg or more, to the nearest multiple of 5 µg; and</li> <li>(d) if it is 50 µg or more, to the nearest multiple of 5 µg; and</li> <li>(d) if it is 50 µg or more, to the nearest multiple of 5 µg; and</li> <li>(d) if it is 50 µg or more, to the nearest multiple of 5 µg; and</li> <li>(d) if it is 50 µg or more, to the nearest multiple of 5 µg; and</li> <li>(b) in all other the amount is declared as 0 mg, to "0%"; and</li> </ul> </li> </ul>
				and (b) in all other cases, to the nearest multiple of 1%.
30.	Amount of magnesium	"Magnesium"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 1 mg, to "0 mg";</li> <li>(b) if it is 1 mg or more but less than 10 mg, to</li> </ul>

			serving of stated size.	the nearest multiple of 2 mg; (c) if it is 10 mg or more but less than 50 mg, to the nearest multiple of 5 mg; and (d) if it is 50 mg or more, to the nearest multiple of 10 mg.
				(2) The percentage is rounded off
				<ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
	mount f zinc	"Zinc"	The amount	(1) The amount is
O	ι ΖΠC		( <i>a</i> ) is expressed as a percentage of the daily value per serving of stated size; and ( <i>b</i> ) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.05 mg, to "0 mg";</li> <li>(b) if it is 0.05 mg or more but less than 0.5 mg, to the nearest multiple of 0.1 mg;</li> <li>(c) if it is 0.5 mg or more but less than 2.5 mg, to the nearest multiple of 0.25 mg; and</li> <li>(d) if it is 2.5 mg or more, to the nearest multiple of 0.5 mg.</li> <li>(2) The percentage is rounded off <ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul> </li> </ul>

32.	Amount of selenium	"Selenium"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.1 µg, to "0 µg";</li> <li>(b) if it is 0.1 µg or more but less than 1 µg, to the nearest multiple of 0.2 µg;</li> <li>(c) if it is 1 µg or more but less than 5 µg, to the nearest multiple of 0.5 µg; and</li> <li>(d) if it is 5 µg or more, to the nearest multiple of 1 µg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
33.	Amount of copper	"Copper"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.0015 mg, to "0 mg";</li> <li>(b) if it is 0.0015 mg or more but less than 0.025 mg, to the nearest multiple of 0.002 mg;</li> <li>(c) if it is 0.025 mg or more but less than 0.05 mg, to the nearest multiple of 0.005 mg; and</li> <li>(d) if it is 0.05 mg or more, to the nearest multiple of 0.01 mg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the</li> </ul>

				amount is declared as 0 mg, to "0%"; and (b) in all other cases, to the nearest multiple of 1%.
34.	Amount of manganese	"Manganese"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.005 mg, to "0 mg";</li> <li>(b) if it is 0.005 mg or more but less than 0.05 mg, to the nearest multiple of 0.01 mg;</li> <li>(c) if it is 0.05 mg or more but less than 0.25 mg or more but less than 0.25 mg, to the nearest multiple of 0.025 mg; and</li> <li>(d) if it is 0.25 mg or more, to the nearest multiple of 0.05 mg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple</li> </ul>
35.	Amount of chromium	"Chromium"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	of 1%. (1) The amount is rounded off (a) if it is less than 0.05 µg, to "0 µg"; (b) if it is 0.05 µg or more but less than 0.5 µg, to the nearest multiple of 0.1 µg; (c) if it is 0.5 µg or more but less than 2.5 µg, to the nearest

				<ul> <li>multiple of</li> <li>0.25 μg; and</li> <li>(<i>d</i>) if it is 2.5 μg</li> <li>or more, to the</li> <li>nearest multiple</li> <li>of 0.5 μg.</li> </ul> (2) The percentage <ul> <li>is rounded off</li> </ul>
				<ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
36.	Amount of molybdenum	"Molybdenum"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in micrograms per serving of stated size.	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 0.05 µg, to "0 µg";</li> <li>(b) if it is 0.05 µg or more but less than 0.5 µg, to the nearest multiple of 0.1 µg;</li> <li>(c) if it is 0.5 µg or more but less than 2.5 µg, to the nearest multiple of 0.25 µg; and</li> <li>(d) if it is 2.5 µg or more, to the nearest multiple of 0.5 µg.</li> <li>(2) The percentage is rounded off</li> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>
37.	Amount of chloride	"Chloride"	The amount (a) is expressed as a percentage of the daily value per serving of stated size; and (b) may also be expressed in milligrams per	<ul> <li>(1) The amount is rounded off</li> <li>(a) if it is less than 5 mg, to "0 mg";</li> <li>(b) if it is 5 mg or more but less than 50 mg, to</li> </ul>

serving of stated size.	the nearest multiple of 10 mg; (c) if it is 50 mg or more but less than 250 mg, to the nearest multiple of 25 mg; and (d) if it is 250 mg or more, to the nearest multiple of 50 mg.
	(2) The percentage is rounded off
	<ul> <li>(a) if the amount is declared as 0 mg, to "0%"; and</li> <li>(b) in all other cases, to the nearest multiple of 1%.</li> </ul>

### **18.** The heading before section **B.01.403** of the Regulations is replaced by the following:

Foods for Infants Seven Months of Age or Older but Less Than One Year of Age

### **19.** (1) Subsections B.01.403(1) and (2) of the Regulations are replaced by the following:

**B.01.403.** (1) This section applies in respect of a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age.

(2) The nutrition facts table of the prepackaged product shall not contain the percentage of the daily value of fat, sugars, cholesterol or sodium or of the sum of saturated fatty acids and *trans* fatty acids.

### (2) The portion of subsection B.01.403(5) of the Regulations before paragraph (a) is replaced by the following:

(5) If the information in respect of six or more of the energy value and nutrients referred to in column 1 of items 2, 3 and 8 to 15 of the table to section B.01.401 may be expressed as "0" in the nutrition facts table of the prepackaged product in accordance with that section, the nutrition facts table need only include the following information:

### (3) Paragraph B.01.403(5)(*i*) of the Regulations is replaced by the following:

(*i*) the amount of any nutrient referred to in column 1 of item 8, 10 or 11 or any of items 13 to 15 of the table to section B.01.401 that may not be expressed as "0" in the nutrition facts table;

# 20. The portion of subparagraph B.01.404(3)(c)(i) of the Regulations before clause (A) is replaced by the following:

(i) information for vitamins referred to in subsection D.01.002(1) shall be expressed in the applicable unit referred to in subsection D.01.003(1), and information for mineral nutrients referred to in paragraphs D.02.001(1)(*a*) to (*j*), (*l*) to (*n*) and (*p*) shall be expressed in milligrams for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, chloride and manganese and in micrograms for iodide, selenium, chromium and molybdenum,

# 21. (1) Subparagraphs B.01.406(5)(a)(i) and (ii) of the Regulations are replaced by the following:

(i) except in the case described in subparagraph (ii), the amount of the food expressed using the unit referred to in column 3 of subitem (1)(b)(i) of the table to section B.01.401 as "about (naming the

serving size)" or "about (naming the serving size) prepared" and, if applicable, in the manner specified in column 4 of subitems 1(1) and (2), and

(ii) if the food is commonly served combined with another food, the amount of the other food expressed using the unit referred to in column 3 of subitem 1(b)(i) of the table to section B.01.401,

# (2) Paragraph B.01.406(5)(a) of the Regulations is amended by adding "and" at the end of subparagraph (iii) and by replacing subparagraphs (iv) and (v) with the following:

(iv) the information set out in column 1 of items 3, 6 to 8, 11 and 13 to 15 of the table to section B.01.401 and in column 1 of items 14 to 37 of the table to section B.01.402 that is declared as a percentage of the daily value in the nutrition facts table for the food as sold, expressed using a description set out in column 2, as a percentage of the daily value per serving of stated size and in the manner specified in column 4; and

# (3) Subparagraphs B.01.406(5)(b)(i) and (ii) of the Regulations are replaced by the following:

(i) the information set out in column 1 of items 3 to 5 and 7 to 12 of the table to section B.01.401, expressed using a description set out in column 2, in milligrams for the information set out in column 1 of items 7 and 8 and in grams for the information set out in column 1 of items 3 to 5 and 9 to 12 and in the manner specified in column 4,

(ii) the information set out in column 1 of items 5 to 8 and 10 to 13 of the table to section B.01.402, expressed using a description set out in column 2, in grams, and in the manner specified in column 4; and

(iii) the information set out in column 1 of item 2 of the table to section B.01.401, expressed using a description set out in column 2, in the unit set out in column 3, per serving of stated size of the food as prepared, and in the manner specified in column 4.

### (4) Subsection B.01.406(6) of the Regulations is replaced by the following:

(6) Subsection (5) does not apply in respect of a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age.

### (5) Subparagraph B.01.406(7)(a)(i) of the Regulations is replaced by the following:

(i) the amount of the food expressed in the units specified in column 3 of subitem 1(b) of the table to section B.01.401 and in the manner specified in column 4 of subitems 1(1) and (2),

# (6) Paragraph B.01.406(7)(*a*) of the Regulations is amended by adding "and" at the end of subparagraph (ii) and by replacing subparagraphs (iii) and (iv) with the following:

(iii) the information set out in column 1 of items 3, 6 to 8, 11 and 13 to 15 of the table to section B.01.401 and in column 1 of items 14 to 37 of the table to section B.01.402 that is declared as a percentage of the daily value in the nutrition facts table for the first amount of food for which information is declared, expressed using a description set out in column 2, as a percentage of the daily value per serving of stated size and in the manner specified in column 4;

### (7) Subparagraph B.01.406(7)(c)(i) of the Regulations is replaced by the following:

(i) the amount of the food expressed in the units specified in column 3 of subitem 1(b) of the table to section B.01.401 and in the manner specified in column 4 of subitem 1(1),

### (8) Subparagraph B.01.406(7)(c)(iii) of the Regulations is replaced by the following:

(iii) the information set out in column 1 of items 5 to 8 and 10 to 13 of the table to section B.01.402, expressed using a description set out in column 2, in grams and in the manner specified in column 4.

### (9) Subsection B.01.406(8) of the Regulations is replaced by the following:

(8) If the nutrition facts table of a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age sets out information in accordance with subsection (7), it shall set out the information referred to in paragraphs (7)(a) and (c).

# 22. Section B.01.450 of the Regulations is amended by adding the following after subsection (3):

(3.1) The type size shown in parentheses for a version referred to in a table to sections B.01.454 to B.01.459 or sections B.01.461 to B.01.464 is the minimum type size that may be used in a nutrition facts table to show nutrients set out in the tables to sections B.01.401 and B.01.402 in accordance with that

version.

### 23. Section B.01.453 of the Regulations is replaced by the following:

**B.01.453.** (1) Sections B.01.454 to B.01.460 apply to prepackaged products other than those that are intended solely for infants seven months of age or older but less than one year of age.

(2) Sections B.01.461 to B.01.465 apply to prepackaged products that are intended solely for infants seven months of age or older but less than one year of age.

### 24. (1) The heading of column 1 to Part 1 of the table to section B.01.454 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (2) The portion of items 1 to 6 of Part 1 of the table to section B.01.454 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	1.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	1.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	1.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	1.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	1.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	1.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

(3) The heading of column 1 to Part 2 of the table to section B.01.454 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(4) The portion of items 1 to 4 of Part 2 of the table to section B.01.454 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	2.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	2.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	2.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	2.4(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

(5) The heading of column 1 to Part 3 of the table to section B.01.454 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(6) The portion of items 1 to 4 of Part 3 of the table to section B.01.454 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	3.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	3.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	3.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	3.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

(7) The heading of column 1 to Part 4 of the table to section B.01.454 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(8) The portion of items 1 and 2 of Part 4 of the table to section B.01.454 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	4.1(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
2.	4.2(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# 25. (1) The heading of column 1 to Part 1 of the table to section B.01.455 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (2) The portion of items 1 to 6 of Part 1 of the table to section B.01.455 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	5.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	5.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	5.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	5.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	5.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	5.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

### (3) The heading of column 1 to Part 2 of the table to section B.01.455 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 4 of Part 2 of the table to section B.01.455 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	6.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	6.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	6.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	6.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

(5) The heading of column 1 to Part 3 of the table to section B.01.455 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(6) The portion of items 1 and 2 of Part 3 of the table to section B.01.455 of the Regulations in column 1 is replaced by the following:

Column 1
Figure in Directory of NFT Formats (Version)
7.1(B)
(nutrients to be shown in a type size of not less than 7 points (condensed))
7.2(B)
(nutrients to be shown in a type size of not less than 6 points (condensed))

26. (1) The heading of column 1 to Part 1 of the table to section B.01.456 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (2) The portion of items 1 to 6 of Part 1 of the table to section B.01.456 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	8.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	8.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	8.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	8.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	8.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	8.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

(3) The heading of column 1 to Part 2 of the table to section B.01.456 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 4 of Part 2 of the table to section B.01.456 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	9.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	9.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	9.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	9.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

27. (1) The heading of column 1 to Part 1 of the table to section B.01.457 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(2) The portion of items 1 to 6 of Part 1 of the table to section B.01.457 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	10.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	10.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	10.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	10.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	10.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	10.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (3) The heading of column 1 to Part 2 of the table to section B.01.457 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(4) The portion of items 1 to 4 of Part 2 of the table to section B.01.457 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	11.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	11.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	11.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	11.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# 28. (1) The heading of column 1 to Part 1 of the table to section B.01.458 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (2) The portion of items 1 to 6 of Part 1 of the table to section B.01.458 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	12.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	12.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	12.3(E) and (F)
_	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	12.4(E) and (F)
_	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	12.5(E) and (F)
_	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	12.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (3) The heading of column 1 to Part 2 of the table to section B.01.458 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 4 of Part 2 of the table to section B.01.458 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	13.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	13.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	13.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	13.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

29. (1) The heading of column 1 to Part 1 of the table to section B.01.459 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(2) The portion of items 1 to 6 of Part 1 of the table to section B.01.459 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	14.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	14.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	14.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))

4.	14.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	14.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	14.6(E) and (F)

(nutrients to be shown in a type size of not less than 6 points (condensed))

# (3) The heading of column 1 to Part 2 of the table to section B.01.459 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 4 of Part 2 of the table to section B.01.459 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	15.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	15.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	15.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	15.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

### **30.** The heading before section **B.01.461** of the Regulations is replaced by the following;

Standard and Horizontal Formats — Infants Seven Months of Age or Older but Less Than One Year of Age

### **31.** (1) Subsection B.01.461(1) of the Regulations is replaced by the following:

**B.01.461.** (1) This section applies to a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age unless section B.01.462, B.01.463 or B.01.464 applies to the product.

# (2) The heading of Part 1 of the table to section B.01.461 of the Regulations is replaced by the following:

STANDARD FORMAT - INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

### (3) The heading of column 1 to Part 1 of the table to section B.01.461 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 6 of Part 1 of the table to section B.01.461 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	20.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	20.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	20.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	20.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	20.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	20.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (5) The heading of Part 2 of the table to section B.01.461 of the Regulations is replaced by the following:

NARROW STANDARD FORMAT — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

## (6) The heading of column 1 to Part 2 of the table to section B.01.461 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (7) The portion of items 1 to 4 of Part 2 of the table to section B.01.461 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	21.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	21.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	21.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	21.4(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

(8) The heading of Part 3 of the table to section B.01.461 of the Regulations is replaced by the following:

BILINGUAL STANDARD FORMAT — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

# (9) The heading of column 1 to Part 3 of the table to section B.01.461 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (10) The portion of items 1 to 4 of Part 3 of the table to section B.01.461 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	22.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	22.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	22.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	22.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (11) The heading of Part 4 of the table to section B.01.461 of the Regulations is replaced by the following:

BILINGUAL HORIZONTAL FORMAT — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

### (12) The heading of column 1 to Part 4 of the table to section B.01.461 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (13) The portion of items 1 and 2 of Part 4 of the table to section B.01.461 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	23.1(B)
2.	(nutrients to be shown in a type size of not less than 7 points (condensed)) 23.2(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

### 32. The heading before section B.01.462 of the Regulations is replaced by the following:

Simplified Formats — Infants Seven Months of Age or Older but Less Than One Year of Age

### 33. (1) Subsection B.01.462(1) of the Regulations is replaced by the following:

**B.01.462.** (1) This section applies to a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age if it satisfies the condition set out in subsection B.01.403(5) and its nutrition facts table includes only the information referred to in paragraphs B.01.403(5)(a) to (k).

# (2) The heading of Part 1 of the table to section B.01.462 of the Regulations is replaced by the following:

SIMPLIFIED STANDARD FORMAT — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

### (3) The heading of column 1 to Part 1 of the table to section B.01.462 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 6 of Part 1 of the table to section B.01.462 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	24.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	24.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	24.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	24.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	24.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	24.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (5) The heading of Part 2 of the table to section B.01.462 of the Regulations is replaced by the following:

BILINGUAL SIMPLIFIED STANDARD FORMAT — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

# (6) The heading of column 1 to Part 2 of the table to section B.01.462 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (7) The portion of items 1 to 4 of Part 2 of the table to section B.01.462 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	25.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	25.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	25.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	25.4(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (8) The heading of Part 3 of the table to section B.01.462 of the Regulations is replaced by the following:

BILINGUAL SIMPLIFIED HORIZONTAL FORMAT — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

# (9) The heading of column 1 to Part 3 of the table to section B.01.462 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

(10) The portion of items 1 and 2 of Part 3 of the table to section B.01.462 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	26.1(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
2.	26.2(B)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

### 34. The heading before section B.01.463 of the Regulations is replaced by the following:

Aggregate Format — Different Kinds of Foods — Infants Seven Months of Age or Older but Less Than One Year of Age

### 35. (1) Subsection B.01.463(1) of the Regulations is replaced by the following:

**B.01.463.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age includes separate information for each food or ingredient as provided in subsection B.01.406(2), paragraph B.01.406(3)(*a*) or subsection B.01.406(4), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

### (2) The heading of Part 1 of the table to section B.01.463 of the Regulations is replaced by the following:

### (3) The heading of column 1 to Part 1 of the table to section B.01.463 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (4) The portion of items 1 to 6 of Part 1 of the table to section B.01.463 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	27.1(E) and (F)
	(nutrients to be shown in a type size of not less than 8 points)
2.	27.2(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points)
3.	27.3(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
4.	27.4(E) and (F)
	(nutrients to be shown in a type size of not less than 7 points (condensed))
5.	27.5(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))
6.	27.6(E) and (F)
	(nutrients to be shown in a type size of not less than 6 points (condensed))

# (5) The heading of Part 2 of the table to section B.01.463 of the Regulations is replaced by the following:

BILINGUAL AGGREGATE FORMAT — DIFFERENT KINDS OF FOODS — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

# (6) The heading of column 1 to Part 2 of the table to section B.01.463 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (7) The portion of items 1 to 4 of Part 2 of the table to section B.01.463 of the Regulations in column 1 is replaced by the following:

	Column 1	
Item	Figure in Directory of NFT Formats (Version)	
1.	28.1(B)	
2.	(nutrients to be shown in a type size of not less than 8 points) 28.2(B)	
	(nutrients to be shown in a type size of not less than 7 points)	

3. 28.3(B) (nutrients to be shown in a type size of not less than 7 points (condensed))
4. 28.4(B)

(nutrients to be shown in a type size of not less than 6 points (condensed))

### 36. The heading before section B.01.464 of the Regulations is replaced by the following:

Aggregate Format — Different Amounts of Foods — Infants Seven Months of Age or Older but Less Than One Year of Age

### **37.** (1) Subsection B.01.464(1) of the Regulations is replaced by the following:

**B.01.464.** (1) Subject to subsection (2), if the nutrition facts table of a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age includes separate information for different amounts of the food as provided in subsection B.01.406(8), the nutrition facts table shall be set out in a version that is listed in column 1 of the table to this section and in respect of which the condition specified in column 2 is satisfied.

# (2) The heading of Part 1 of the table to section B.01.464 of the Regulations is replaced by the following:

AGGREGATE FORMAT — DIFFERENT AMOUNTS OF FOODS — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

### (3) The heading of column 1 to Part 1 of the table to section B.01.464 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

### (4) The portion of items 1 to 6 of Part 1 of the table to section B.01.464 of the Regulations in column 1 is replaced by the following:

	Column 1				
Item	Figure in Directory of NFT Formats (Version)				
1.	29.1(E) and (F)				
	(nutrients to be shown in a type size of not less than 8 points)				
2.	29.2(E) and (F)				
	(nutrients to be shown in a type size of not less than 7 points)				
3.	29.3(E) and (F)				
	(nutrients to be shown in a type size of not less than 7 points (condensed))				
4.	29.4(E) and (F)				
	(nutrients to be shown in a type size of not less than 7 points (condensed))				
5.	29.5(E) and (F)				
	(nutrients to be shown in a type size of not less than 6 points (condensed))				
6.	29.6(E) and (F)				
	(nutrients to be shown in a type size of not less than 6 points (condensed))				

# (5) The heading of Part 2 of the table to section B.01.464 of the Regulations is replaced by the following:

BILINGUAL AGGREGATE FORMAT — DIFFERENT AMOUNTS OF FOODS — INFANTS SEVEN MONTHS OF AGE OR OLDER BUT LESS THAN ONE YEAR OF AGE

# (6) The heading of column 1 to Part 2 of the table to section B.01.464 of the Regulations is replaced by "Figure in Directory of NFT Formats (Version)".

# (7) The portion of items 1 to 4 of Part 2 of the table to section B.01.464 of the Regulations in column 1 is replaced by the following:

	Column 1
Item	Figure in Directory of NFT Formats (Version)
1.	30.1(B)
	(nutrients to be shown in a type size of not less than 8 points)
2.	30.2(B)
	(nutrients to be shown in a type size of not less than 7 points)
3.	30.3(B)
	(nutrients to be shown in a type size of not less than 7 points (condensed))

### **4.** 30.4(B)

(nutrients to be shown in a type size of not less than 6 points (condensed))

### 38. The heading before section B.01.465 of the Regulations is replaced by the following:

Presentation of Additional Information — Infants Seven Months of Age or Older but Less Than One Year of Age

### **39.** Subsection B.01.465(1) of the Regulations is replaced by the following:

**B.01.465.** (1) This section applies to a prepackaged product that is intended solely for infants seven months of age or older but less than one year of age.

### 40. The Regulations are amended by adding the following after section B.01.467:

**B.01.468.** (1) Subject to subsection (2), if a prepackaged product has an available display surface of less than  $100 \text{ cm}^2$  and has a nutrition facts table, the nutrition facts table need only include

(a) the serving of stated size;

(b) the energy value and, subject to subsection (2), the amount of nutrients referred to in column 1 of items 2 to 15 of the table to section B.01.401 if the amount shown in the nutrition facts table is not "0" according to the manner set out in column 4; and

(c) the amount of any sugar alcohol, vitamin or mineral nutrient added to the prepackaged product.

(2) If the label of a prepackaged product, or any advertisement for the product that is made or placed by or on the direction of the manufacturer of the product, contains a representation, express or implied, that includes information that is set out in column 1 of the table to section B.01.401 or B.01.402, that information shall also be in the nutrition facts table.

**B.01.469.** Despite subsection B.01.401(1), the label of a prepackaged product that has an available display surface of less than 15 cm<sup>2</sup> need not carry a nutrition facts table.

# 41. (1) The portion of subitems 1(1) and (2) of the table following section B.01.603 of the Regulations in column 3 is replaced by the following:

### Column 3

Item Conditions – Label or Advertisement

**1.** If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of sodium and potassium per serving of stated size, in accordance with section B.01.602 if applicable.

(2) The portion of paragraph 4(a) of the table following section B.01.603 of the Regulations before subparagraph (i) in column 2 is replaced by the following:

	Column 2				
Item	Conditions — Food				
4.	( <i>a</i> ) is one of the following vegetables, fruits or juices and may contain only food additives that are subject to section 2 of a marketing authorization, sweetening agents, salt, herbs, spices, seasonings and water:				

# (3) The table following section B.01.603 of the Regulations is amended by adding the following after item 4:

	Column 1	Column 2	Column 3
Item	Statement or Claim	Conditions — Food	Conditions — Label or Advertisement

4.1 The food "A healthy diet rich in a variety of (a) is one of the following vegetables and vegetables or fruits and may fruit may help contain only food additives that reduce the risk of are subject to section 2 of a heart disease." marketing authorization, salt, herbs, spices, seasonings and water: (i) a fresh, frozen, canned or dried vegetable, (ii) a fresh, frozen, canned or dried fruit, or (iii) a combination of the foods set out in subparagraphs (i) and (ii); (b) is not one of the following: (i) potatoes, yams, cassava, plantain, corn, mature legumes and their juices, (ii) vegetables or fruit used as condiments, garnishes or flavourings, including maraschino cherries, glacé fruit, candied fruit and onion flakes, (iii) jams or jam-type spreads, marmalades, preserves and jellies, (iv) olives, (v) a fruit or vegetable juice, a fruit or vegetable drink or any mixture of these foods, or (vi) powdered vegetables or fruit; (c) contains 0.5% or less alcohol; and (d) contains less than 15% of the Daily Value of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less.

42. (1) The definitions "official method FO-7", "official method FO-8", "official method FO-9", "official method FO-10", "official method FO-11", "official method FO-12", "official method FO-13", "official method FO-14" and "official method FO-15" in section B.06.001 of the Regulations are repealed.

### (2) The definition "synthetic colour" in section B.06.001 of the Regulations is replaced by the following:

"synthetic colour" means any organic food colour, other than caramel, that is produced by chemical synthesis and that has no counterpart in nature. (*colorant synthétique*)

### 43. Sections B.06.003 to B.06.006 of the Regulations are repealed.

44. Section B.06.008 of the Regulations is repealed.

45. The heading before section B.06.021 and sections B.06.021 to B.06.033 of the

### Regulations are repealed.

# 46. The heading before section B.06.041 and sections B.06.041 and B.06.042 of the Regulations are repealed.

### 47. Sections B.06.043 to B.06.051 of the Regulations are replaced by the following:

**B.06.043. [S].** Ponceau SX shall be the disodium salt of 2-(5-sulpho-2,4-xylylazo)-1-naphthol-4-sulphonic acid, shall contain not less than 85 per cent dye, and may contain not more than

- (a) 0.2% water insoluble matter;
- (b) 0.2% combined ether extracts;
- (c) 1.0% subsidiary dyes;
- (d) 0.5% intermediates;
- (e) 3 parts per million of arsenic; and
- (f) 10 parts per million of lead.

### 48. Section B.06.053 of the Regulations is replaced by the following:

**B.06.053. [S].** Citrus Red. No. 2 shall be 1-(2,5- dimethoxyphenylazo)-2-naphthol and shall contain not less than 98 per cent dye and may contain not more than

- (a) 0.5% volatile matter (at 100°C);
- (b) 0.3% sulphated ash;
- (c) 0.3% water soluble matter;
- (d) 0.5% carbon tetrachloride insoluble matter;
- (e) 0.05% uncombined intermediates;
- (f) 2.0% subsidiary dyes;
- (g) 1 part per million of arsenic; and
- (*h*) 10 parts per million of lead.

#### 49. Section B.06.061 of the Regulations is replaced by the following:

**B.06.061.** The lake of any water soluble synthetic colour that is subject to section 2 of the *Marketing Authorization for Food Additives That May Be Used as Colouring Agents* shall be the calcium or aluminum salt of the respective colour extended on alumina.

### **50.** Paragraph B.14.031(*i*) of the Regulations is replaced by the following:

(*i*) in the case of tocino, annatto in such amount as will result in the finished product containing not more than 0.1% annatto; and

#### **51.** Subparagraph B.14.032(*d*)(xvi) of the Regulations is replaced by the following:

(xvi) in the case of longaniza,

(A) annatto in such amount as will result in the finished product containing not more than 1000 parts per million annatto,

(B) allura red in such amount as will result in the finished product containing not more than 80 parts per million allura red, and

(C) sunset yellow FCF in such amount as will result in the finished product containing not more than 20 parts per million sunset yellow FCF,

### 52. Subparagraphs B.24.202(a)(iii) to (v) of the Regulations are replaced by the following:

(iii) the vitamin A, vitamin D, vitamin E, vitamin C, thiamin or vitamin  $B_1$ , riboflavin or vitamin  $B_2$ , niacin, vitamin  $B_6$ , vitamin  $B_{12}$ , folate and pantothenic acid or pantothenate contents of the food, expressed

(A) in the case of a meal replacement, as a percentage of the daily value specified in column 4 of Part 2 of the Table of Daily Values for that vitamin, and

(B) in the case of a nutritional supplement, in the applicable unit referred to in subsection D.01.003(1),

(iv) the calcium, phosphorus, iron, iodide, magnesium and zinc contents of the food, expressed

(A) in the case of a meal replacement, as a percentage of the daily value specified in column 4 of Part 2 of the Table of Daily Values, and

(B) in the case of a nutritional supplement, in milligrams for calcium, phosphorus, iron, magnesium and zinc and in micrograms for iodide,

- (v) the copper, potassium, sodium and manganese contents of the food expressed in milligrams, and
- (vi) the biotin, selenium, chromium and molybdenum contents of the food expressed in micrograms;

# 53. (1) The definition "recommended daily intake" in subsection D.01.001(1) of the Regulations is repealed.

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

"Table of Daily Values" has the same meaning as in subsection B.01.001(1). (*Tableau des valeurs quotidiennes*)

"Table of Reference Amounts" has the same meaning as in subsection B.01.001(1). (*Tableau des quantités de référence*)

### (3) Subsections D.01.001(2) and (3) of the Regulations are replaced by the following:

(2) For the purposes of this Part, a serving of stated size of a food shall be

- (a) based on the food as offered for sale;
- (*b*) in either of the following cases, the net quantity of the food in the package:

(i) if the quantity of food in the package can reasonably be consumed by one person at a single eating occasion, or

(ii) if the package contains less than 200% of the reference amount for the food; and

(c) in all other cases, the amount indicated for the food according to the criteria set out in column 3A of the Table of Reference Amounts.

(3) A serving of stated size shall be expressed as follows:

(a) in the case of a single-serving prepackaged product referred to in paragraph (2)(b), per package and using the following units:

- (i) in grams, if the net quantity of the food is shown on the label by weight or by count, and
- (ii) in milliliters, if the net quantity of the food is shown on the label by volume; and

(b) in the case of a multiple-serving prepackaged product referred to in paragraph (2)(c), according to the following units of measure set out in column 3B of the Table of Reference Amounts and according to the manner set out in that column:

- (i) the household measure that applies to the product, and
- (ii) the metric measure that applies to the product.

### 54. The Regulations are amended by adding the following after section D.01.001:

**D.01.001.1** The daily value of a vitamin or mineral nutrient set out in column 1 of Part 2 of the Table of Daily Values is, in respect of a food, the quantity

(a) set out in column 2, if the food is intended solely for infants seven months of age or older but less than one year of age;

(*b*) set out in column 3, if the food is intended solely for children one year of age or older but less than four years of age; and

(c) set out in column 4, in any other case.

# 55. Subsection D.01.002(1) of the Regulations is amended by striking out "and" at the end of paragraph (I), by adding "and" at the end of paragraph (m) and by adding the following after paragraph (m):

(n) choline.

### 56. (1) Paragraph D.01.003(1)(a) of the Regulations is replaced by the following:

(*a*) in the case of vitamin A, in terms of the content of retinol and its derivatives and beta-carotene, calculated on the basis of micrograms of retinol activity equivalents (RAE) and expressed in micrograms on the basis of the following relationships:

- (i) 1 RAE = 1 microgram of retinol, and
- (ii) 1 RAE = 12 micrograms of beta-carotene;

### (2) Paragraph D.01.003(1)(h) of the Regulations is replaced by the following:

(*h*) in the case of niacin, in terms of the content of niacin and its derivatives, calculated in milligrams of nicotinic acid, plus the content of tryptophan, calculated in milligrams and divided by 60, with the total niacin equivalents (NE) expressed in milligrams;

### (3) Paragraph D.01.003(1)(j) of the Regulations is replaced by the following:

(*j*) in the case of folate, in terms of the content of folic acid (pteroylmonoglutamic acid) and related compounds exhibiting the biological activity of folic acid, calculated and expressed in micrograms of dietary folate equivalents (DFE);

### (4) Subsection D.01.003(1) of the Regulations is amended by striking out "and" at the end of paragraph (I) and by replacing paragraph (m) with the following:

(m) in the case of biotin, in terms of the content of biotin, expressed in micrograms; and

(*n*) in the case of choline, in terms of the content of choline, expressed in milligrams.

### 57. (1) Paragraphs D.01.004(1)(a) and (b) of the Regulations are replaced by the following:

- (a) the vitamin is set out in column 1 of Part 2 to the Table of Daily Values;
- (b) the percentage of the daily value of the vitamin, per serving of stated size, is 5% or more; and

### (2) Subsection D.01.004(5) of the Regulations is replaced by the following:

(5) Paragraph (1)(c) does not apply in respect of a declaration of the biotin content as required by subparagraph B.24.202(*a*)(vi).

### 58. Paragraph D.01.007(1)(a) of the Regulations is replaced by the following:

(*a*) despite subsection B.01.008.2(6), the vitamin is declared by its common name, and that common name is shown in parentheses immediately after the ingredient in respect of which it is a component, except that if a source of a food allergen or gluten is required by paragraph B.01.010.1(8)(*a*) to be shown immediately after that ingredient, the common name of the vitamin is instead shown immediately after that source; and

### 59. Table I to Division 1 of Part D of the Regulations is repealed.

### 60. Paragraphs D.02.002(1)(a) and (b) of the Regulations are replaced by the following:

(a) the mineral nutrient is set out in column 1 of Part 2 of the Table of Daily Values;

(*b*) the percentage of the daily value of the mineral nutrient, per serving of stated size, is 5% or more; and

### 61. Paragraph D.02.005(1)(*a*) of the Regulations is replaced by the following:

(a) despite subsection B.01.008.2(6), the mineral nutrient is declared by its common name, and that common name is shown in parentheses immediately after the ingredient in respect of which it is a component, except that if a source of a food allergen or gluten is required by paragraph B.01.010.1(8)(a) to be shown immediately after that ingredient, the common name of the mineral nutrient is instead shown immediately after that source; and

### 62. Table I to Division 2 of Part D of the Regulations is repealed.

### 63. Schedules L and M to the Regulations are repealed.

# 64. The French version of the Regulations is amended by replacing "portion déterminée" with "portion indiquée" in the following provisions:

- (*a*) paragraph B.01.014(*d*);
- (b) paragraph B.01.015(1)(d);
- (c) paragraph B.01.016(c);

(*d*) paragraph B.01.017(1)(*c*);

(e) section B.01.018;

(f) paragraph B.01.019(c);

(g) paragraph B.01.020(1)(c);

(*h*) subsection B.01.021(1);

(*i*) paragraph B.01.022(*c*) and the portion of paragraph B.01.022(*d*) before subparagraph (i);

(j) paragraph B.01.023(c) and the portion of paragraph B.01.023(d) before subparagraph (i);

(k) the portion of section B.01.053 before paragraph (a);

(*I*) the portion of subsection B.01.301(1) before paragraph (*a*) and paragraph B.01.301(2)(c);

(*m*) paragraph B.01.305(2)(*b*);

(*n*) subsection B.01.311(4);

(o) the portion of subsection B.01.312(1) before paragraph (a);

(p) paragraphs B.01.401(2)(a) and (6)(a);

(q) the table to section B.01.401;

(r) the table to section B.01.402;

(s) paragraph B.01.403(5)(a);

(*t*) subparagraph B.01.404(3)(*c*)(iii);

(u) the portion of paragraph B.01.503(1)(c) before subparagraph (i);

(v) the table following section B.01.513:

(w) the table following section B.01.603:

(x) subsection B.08.028(2);

(y) subsection B.08.032(3);

(z) subsection B.08.074(2);

(z.1) subsection B.08.076(2);

(z.2) the portion of paragraph B.24.202(a) before subparagraph (i);

(z.3) paragraph D.01.004(1)(c), the portion of subsection D.01.004(2) before paragraph (a) and the portion of subsection D.01.004(3) before paragraph (a); and (z.4) paragraph D.02.002(1)(c), the portion of subsection D.02.002(2) before paragraph (a) and the portion of subsection D.02.002(3) before paragraph (a).

65. The Regulations are amended by replacing ""Contains" statement" with "food allergen source, gluten source and added sulphites statement" in the following provisions:

(a) the portion of subsection B.01.010.1(9) before paragraph (a) and paragraph B.01.010.1(10)(b); and

(b) paragraph B.01.010.2(6)(b), subsection B.01.010.2(9) and paragraph B.01.010.2(10)(b).

66. The Regulations are amended by replacing "Schedule L" with "Directory of NFT Formats" in the following provisions:

(a) subsection B.01.450(1), paragraph B.01.450(3)(b) and subsections B.01.450(4) and (6);

(b) paragraphs B.01.454(3)(a) to (c);

(c) paragraphs B.01.455(3)(a) to (c);

(d) paragraph B.01.456(2)(a);

- (e) subparagraphs B.01.457(2)(a)(i) and (b)(i);
- (f) paragraph B.01.458(2)(a);
- (g) paragraph B.01.459(2)(a);

(h) paragraphs B.01.460(1)(a) and (b) and (2)(a) and (b) and subsection (3);

(*i*) paragraphs B.01.461(3)(*a*) to (*c*);

- (j) paragraphs B.01.462(3)(a) to (c);
- (k) subparagraphs B.01.463(2)(a)(i) and (b)(i);
- (*I*) paragraph B.01.464(2)(*a*); and

### (m) paragraphs B.01.465(2)(a) and (b) and (3)(a) and (b) and subsection (4).

### **COMING INTO FORCE**

## 67. These Regulations come into force five years after the day on which they are published in the *Canada Gazette*, Part II.

[24-1-0]

Footnote 1

Using the total figure for the five identified disease groups, \$26,315,300,000, assumes a percentage reduction in total EBIC.

Footnote 2

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

Footnote a S.C. 2012, c. 19, s. 414 Footnote b S.C. 2012, c. 19, s. 416 Footnote c R.S., c. F-27 Footnote 3 C.R.C., c. 870

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