# Regulations Amending the Food and Drug Regulations (Beer): SOR/2019-98

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FOOD AND DRUGS ACT

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) of the *Food and Drugs Act*, makes the annexed *Regulations Amending the Food and Drug Regulations (Beer)*.

## Regulations Amending the Food and Drug Regulations (Beer)

### Amendments

**1 Subsection B.01.010.1(5) of the *Food and Drug Regulations* is repealed.**

**2 Subsection B.01.010.2(5) of the Regulations is repealed.**

**3 Section B.02.130 of the Regulations is replaced by the following:**

**B.02.130 [S]. (1) Beer**

- **(a)** shall be the product of the alcoholic fermentation by yeast, or a mixture of yeast and other micro-organisms, an infusion of barley or wheat malt and hops or hop extract in potable water;
- **(b)** shall contain at most 4% of residual sugars; and
- **(c)** may have added to it during the course of manufacture any of the following ingredients:
  - **(i)** cereal grain,
  - **(ii)** honey, maple syrup, fruit, fruit juice or any other source of carbohydrates,
  - **(iii)** herbs and spices,
  - **(iv)** salt,
  - **(v)** flavouring preparations,
  - **(vi)** pre-isomerized hop extract,
  - **(vii)** reduced isomerized hop extract, and
  - **(viii)** food additives to which a marketing authorization applies and that are set out in the *Lists of Permitted Food Additives* published on the Health Canada website.

**(2)** The name of any flavouring preparation added to a beer shall form part of the common name of the beer.

**4 Section B.02.131 of the Regulations is repealed.**

**5 Section B.02.132 of the Regulations is replaced by the following:**

**B.02.132** The qualified common name or common name set out in column II of the table to this section shall be used in any advertisement and on the label of a beer that contains the percentage of alcohol by volume set out in column I.

TABLE

| Item | Column I<br>Percentage Alcohol by Volume | Column II<br>Qualified Common Name or Common Name |
|---|---|---|
| 1 | 1.1 to 2.5 | Extra Light Beer |
| 2 | 2.6 to 4.0 | Light Beer |
| 3 | 4.1 to 5.5 | Beer |
| 4 | 5.6 to 8.5 | Strong Beer |
| 5 | 8.6 or more | Extra Strong Beer |

### Transitional Provision

**6 Despite these Regulations, beer may, until December 13, 2022, be sold in accordance with the *Food and Drug Regulations*, as they read immediately before the day on which these Regulations come into force.**

### Coming into Force

**7 These Regulations come into force on the day on which they are registered.**

## REGULATORY IMPACT ANALYSIS STATEMENT

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

### Issues

The Government of Canada is amending the compositional standards for beer and ale, stout, porter and malt liquor to allow for innovation within the beer category while still preserving product integrity and to better reflect the tastes and needs of consumers.

The beer standards, under the *Food and Drug Regulations* (FDR), had not previously undergone a major amendment for at least 30 years. The industry had recently been seeking the use of more ingredients than was permitted by the compositional standard. Language in the standard had created ambiguity over the years and needed to be clarified including the consideration of measurable criteria. Additionally, the FDR provided for one standard for beer and another one for ale, porter, stout and malt liquor that were virtually identical, potentially causing unnecessary confusion.

Beer was the only prepackaged food that was exempted from the labelling of food allergen sources, gluten sources and added sulphites. As a wider range of ingredients are now permitted in beer, the shift to the labelling of food allergen sources, gluten sources and added sulphites on beer will provide important ingredient information to consumers.

### Background

#### Food and Drug Regulations *and food compositional standards*

The *Food and Drugs Act* (FDA) and the *Food and Drug Regulations* (FDR) set out requirements regarding health and safety, composition, labelling, treatment, processing, sale and advertising requirements that apply to food.

There are over 300 food compositional standards prescribed under the FDR. Food compositional standards are a set of established requirements, including technical specifications and other criteria (such as ingredients, strength, potency, purity and quality), that define a particular food, often with its associated common name.

Food compositional standards provide consumers with predictability of composition for specific foods, for example jam, Camembert cheese, bread or beer. In addition, standards are intended to protect consumers from fraudulent products and to help them make purchasing decisions. Foods that are subject to the requirements of a standard are referred to as "standardized foods."

The non-health and safety components of food compositional standards (such as ingredients requirements) under the FDR apply to food products traded inter-provincially or imported into Canada.

#### *Beer, ale, stout, porter and malt liquor compositional standards*

Many alcoholic beverages including beer have compositional standards prescribed in Division 2 of the FDR. Those alcoholic beverages are considered standardized. For example, there is one compositional standard for beer, and previously another standard, nearly identical, for ale, stout, porter and malt liquor.

Beer will continue to be exempted from the requirement to show a list of ingredients, as are all standardized alcoholic beverages. Beer was also exempted from declaring food allergen sources, gluten sources and added sulphites on the label but will no longer be exempted under the amended beer compositional standard.

***Unstandardized alcoholic beverages***

Alcoholic beverages that are not subject to the requirements of a compositional standard are considered unstandardized alcoholic beverages, which may be labelled as "alcoholic beverages," "coolers," "malt-based alcoholic beverages" or other such names, depending on their composition.

Unstandardized alcoholic beverages are required to display a list of ingredients and must, like all other prepackaged foods, clearly identify the presence of any food allergen source, gluten source and added sulphites.

***Industry***

Over the past two decades, the Canadian brewing industry has experienced changes both in its structure and operating environment. The industry has been reorganized considerably through mergers, acquisitions and new microbrewery start-ups.

According to a report released by Statistics Canada in 2017, beer is Canada's most popular alcoholic beverage. Although average beer consumption has shown a slight decline over the last few years, the number of brewing facilities has increased from 62 in 1990 to 817 in 2017. Consumer interest in having access to a variety of alcoholic beverages has fuelled the growth of new products and, as a result, there has been a proliferation of new domestic and imported offerings.

## Objectives

The FDR are amended to modernize the compositional standards for beer and ale, stout, porter and malt liquor by

- (1) reducing duplication by having one compositional standard for all types of beers regardless of style, and one source of information for food additives relating to beer;
- (2) allowing for the use of new ingredients and flavouring preparations to enable innovation and better reflect market developments;
- (3) maintaining the integrity of beer by setting a maximum level of residual sugar; and
- (4) clarifying existing requirements to reduce inconsistencies.

Other labelling amendments apply to provisions of the FDR to protect the health of Canadians by providing them with the necessary information on the label with respect to food allergen sources, gluten sources and added sulphites to make informed purchasing decisions. These labelling amendments apply to all beer sold in Canada, including intra-provincial sales.

## Description

***Beer compositional standard***

**Maximum percentage of residual sugars**

The standard requires beer to contain no more than 4% by weight of residual sugars. Residual sugars are sugars (as defined in the FDR) that are still present in beer after the fermentation process has been completed. This provides an objective measurement to distinguish beer from malt-based beverage products (e.g. coolers), which are generally sweeter and associated with a percentage of residual sugars above the 4% by weight limit. It replaces the current element of the beer standard related to possessing "the aroma, taste and character commonly attributed to beer." It is also intended to reduce consumer confusion between beer and sweet, malt-based alcoholic beverages.

While most beers have a low level of residual sugars, the 4% limit was established to take into account various beer styles. Targeted sampling by the Canadian Food Inspection Agency (CFIA) and Beer Canada (a voluntary trade association of over 40 brewers) indicated that most beers are below the 4% limit with the exceptions being beer with juice blends and some barley wines.

Products not meeting this requirement could be reformulated to lower the residual sugars below the limit to meet the beer standard or be sold as an unstandardized beverage with an appropriate common name (e.g. "blend of beer and grapefruit juice").

**Flavouring preparations**

A flavouring preparation includes any food for which a standard is provided in Division 10 of the FDR. Flavouring preparations are used in the manufacture of foods to impart or modify an odour or taste. To facilitate innovation and increase consumer choices, the beer standard specifically allows for flavouring preparations in beer. The use of a flavouring preparation triggers an additional requirement for a mandatory declaration that a specific flavouring preparation was used as part of the common name on the label (e.g. "beer with blueberry flavour"). This clearly identifies to consumers that flavouring preparations were added to a beer while allowing product innovation for brewers.

**Food additives**

A food additive is any chemical substance that is added to food during preparation or storage and either becomes a part of the food or affects its characteristics (e.g. caramel for colouring). Health Canada has long maintained positive lists of permitted food additives, which set out the conditions of use for each specific food additive (that is the foods in which each additive may be used, the maximum concentration of each additive, and any other conditions of use). Historically, these positive lists have been set out as tables in Part B, Division 16, of the FDR. As part of efforts to more efficiently regulate food additives, these positive lists were recreated as the Lists of Permitted Food Additives (Lists) which were incorporated by reference into Marketing Authorizations for food additives in October 2012. These Lists replace the Division 16 tables, which are no longer actively used and will be repealed. Health Canada published a transition guide to help ensure that affected stakeholders are aware that the Division 16 tables are no longer being updated and that the Lists of Permitted Food Additives must be consulted. Health Canada will repeal the redundant Division 16 tables once it has completed the analysis of all of the associated consequential amendments that will be required to the FDR when the tables are repealed.

The pre-existing beer standards specifically named the food additives that were permitted in beer, ale, stout, porter and malt liquor. The full conditions of use for these food additives must be determined by consulting the Lists of Permitted Food Additives. Rather than identifying each specific food additive in the beer standard, which duplicates information already in the Lists, the standard includes a general provision that allows for the presence of permitted food additives. This aligns with the general approach that Health Canada plans to apply to other food standards in the FDR. Specific food additives permitted in beer, including ale, stout, porter, and malt liquor, and the permitted maximum levels of use will remain in the Lists. As noted above, the Lists were established in October 2012. There is a high degree of awareness of these Lists in the food industry, including beer manufacturers, as a result of proactive communication and consultation efforts by Health Canada. The food industry needs to consult the Lists for the most up-to-date information on the use of permitted food additives, including those permitted in beer.

With the amended standard, some unstandardized alcoholic beverages may now be considered beer and vice versa. The food additives permitted for unstandardized alcoholic beverages differ from those permitted for beer. Brewers of unstandardized alcoholic beverages affected by this change may no longer have the ability to use some additives in their products and may have to apply to Health Canada to have the additives assessed for use in beer. The food additives currently permitted for use in beer are not changing with these amendments.

**Processing aids**

A food processing aid is a substance used for a technical effect in food processing or in manufacture (e.g. a substance added to minimize the foaming in the kettle or fermenter during beer processing). Its use does not affect the intrinsic characteristics of the food and results in no or negligible residues of the substance or its by-products in or on the finished food. The amendments remove the listed processing aids from the standard. The FDR do not typically list processing aids in compositional standards, with the exception of wine, honey wine and pectin. Removing the listed processing aids from the beer compositional standard makes the beer standard consistent with the majority of food standards of the FDR.

**Carbohydrates**

In 2012, the CFIA developed guidance material setting out the policy intent of the FDR beer and ale, stout, porter and malt liquor standards. The guidance clarifies that the term "carbohydrate matter" is intended to mean an ingredient whose single largest component is carbohydrate and that is used to assist in fermentation, or to enhance the flavour, body, or colour of the product.

The beer standard has been drafted to reflect this policy intent in allowing for ingredients that could be used as sources of carbohydrates and providing examples in a non-exhaustive list.

**Herbs and spices**

The changes to the beer compositional standard include the allowance to use herbs and spices as part of the beer product formulation, during the course of manufacturing. Herbs and spices whose single largest component is carbohydrate, which is used to assist in fermentation or to enhance the flavour, body or colour of the product, have been permitted as "carbohydrate matter" consistent with the 2012 CFIA guidance; this change provides additional clarity in the regulations by stating that herbs and spices are permitted ingredients regardless of the carbohydrate content.

**Micro-organisms**

The amendments include an allowance for the use of other micro-organisms in addition to yeast in the fermentation starter culture. This allows brewers to take advantage of changes in manufacturing and allow for continued innovation.

***Repeal of the standard for ale, stout, porter and malt liquor***

Ale, stout, porter and malt liquor are defined by the industry as types or styles of beer. However, the number of styles or types of beers available currently in the marketplace far exceeds ale, stout, porter and malt liquor. The repeal of the standard for ale, stout, porter and malt liquor in its entirety eliminates the duplication with the beer standard, as they each provided for allowance of the same ingredients through the beer standard.

The amendments result in one standard for all beer styles or types. If an alcoholic beverage meets the requirements of the beer compositional standard, the common name "beer" must appear on the label. The common name for beer continues to depend on its alcohol content (e.g. light beer). A declaration of the beer style or type (e.g. ale, stout, porter) is optional and would be considered supplementary labelling information.

***Other labelling amendments: food allergen source, gluten source and added sulphite labelling***

Prepackaged beers, ales, stouts, porters and malt liquors were exempted from the food allergen source, gluten source and added sulphite labelling requirements of the FDR.

The changes to the beer compositional standard allow for the introduction of new ingredients not previously permitted in beer that could include food allergen sources, gluten sources or ingredients containing added sulphites. The risks associated with the potential introduction of these new ingredients, as well as those ingredients previously permitted (e.g. wheat, barley, sulphurous acid), are addressed by amending the FDR to remove the labelling exemption. This helps to ensure that consumers who must avoid these ingredients are better informed about the ingredients which may affect their health and safety. With the removal of the exemption, brewers are required to identify food allergen sources (e.g. wheat), gluten sources (e.g. barley) or added sulphites (e.g. sulphurous acid) in either their list of ingredients (i.e. in cases where such a list is voluntarily provided) or in a food allergen source, gluten source or added sulphite statement (e.g. "Contains: Sulphites").

Beers are exempted from the requirement to declare a list of ingredients on the label. If ingredients on the label of a beer are voluntarily declared, then food allergen sources, gluten sources or added sulphites could be declared as part of that list. If not, then a statement is required.

***Coming into force***

These regulations come into force once registered in the *Canada Gazette*, Part II.

***Transition period***

There is a transition period that allows brewers to follow either the former FDR requirements or the new requirements until December 13, 2022, inclusively. The transitional period provides sufficient time to make necessary labelling or formulation changes. On December 14, 2022, the new requirements must be applied.

## Benefits and costs

The cost-benefit analysis assessed the potential impacts (i.e. costs and benefits) representing the differences between the baseline and regulatory scenarios.

The baseline scenario describes the situation given the current federal regulatory framework. It also takes into account the provincial requirement in British Columbia of a 4% residual sugar limit for beer. Therefore, there is no cost to businesses to meet this provision in British Columbia.

The beer compositional standard is applicable to interprovincially traded and imported products. In some cases provincial liquor boards are using the FDR as guidelines or policy. As a result of these decisions, it is possible that some Canadian manufacturers, who do not trade any of their affected products interprovincially, may still be required to comply with the beer compositional standard. However, since these practices are external to the regulations, the analysis excluded any such costs. It is also important to note that beer sold intraprovincially may not have to be distributed through a provincial liquor board, as the distribution scheme may vary by province or territory.

The detailed methodology, assumptions and descriptions have been fully documented in a cost-benefit analysis report that is available from the CFIA upon request. The impacts are briefly reported below.

***Affected stakeholders***

The following stakeholders are impacted:

- Brewers;
- Distributors and/or retailers, including provincial liquor boards;
- Government (CFIA, Health Canada); and
- Consumers and general public.

***Qualitative benefits***

Note that the health-related benefits [(e) to (g)] below are consistent with those previously reported by Health Canada in its enhancement to labelling requirements for food allergen source declarations on prepackaged foods (2012).

(a) Product innovation

Flavouring preparations are allowed to accommodate industry innovation. The CFIA amendments allow the use of flavouring preparations in beer with a mandatory declaration on the label as part of the common name. This clearly identifies to consumers that flavouring preparations were added to a beer.

Product innovation is supported, particularly at a time when the market for flavoured products is growing.

(b) Removal of duplication of standards

The standard for ale, stout, porter and malt liquor is repealed in its entirety to eliminate the duplication with the beer compositional standard, as it allows for the same ingredients as beer. This duplication is viewed as creating unnecessary labelling complications for brewers. The amendment results in one standard for all beer styles.

(c) Provision of clearer and more objective measures of standard to maintain the integrity of beer

The current standard requires beer to "possess the aroma, taste and character commonly attributed to beer." This requirement is removed to promote innovation and flexibility to meet the changing tastes of consumers. It is replaced in part by a residual sugar limit established at 4%, by weight, as a clear and objective measure to maintain the integrity of beer versus sweeter malt-based beverages.

(d) Support of product development

Modernizing the beer compositional standard facilitates industry compliance with the regulatory requirements by providing a clearer and more objective standard. This minimizes confusion in interpreting the standard that may cause delays in product development. For businesses, it means avoiding sales losses whenever product development is delayed or if a product is pulled from the market due to non-compliance with the regulatory requirements.

(e) Enhanced protection of human health

Beers are not required to carry an ingredient list. Beer must be made from barley and/or wheat, but beer could also possibly contain other food allergen sources, gluten sources or added sulphites depending on the individual product. Given the greater varieties of beer being launched on the market because of new flavours and added ingredients, the amendments to require enhanced labelling of food allergen sources, gluten sources and added sulphites will help consumers with allergies or sensitivities in deciding which product to consume.

Scientific evidence has clearly linked certain foods and food ingredients with adverse reactions when consumed by individuals with food allergies, celiac disease or sulphite sensitivity. For individuals, these reactions can range from mild to severe and, in some cases, the reaction can progress to anaphylactic shock and death.

Food allergies, celiac disease and sulphite sensitivity affect approximately 1.75 million Canadians. The labelling changes, which apply the same enhanced food allergen source, gluten source and added sulphite labelling requirements to beer as are already applied to other prepackaged foods, will contribute to the assurance of the health and safety of these consumers and enable informed consumer decisions.

(f) Prevention of adverse reactions to product ingredients

Increased awareness related to products containing food allergen sources, gluten sources and added sulphites may prevent adverse reactions to food allergens requiring medical care. For beer consumers, increased awareness as a result of the new standard related to labelling could potentially result in reduced adverse reactions to food allergen sources, gluten sources and added sulphites following implementation of the regulatory amendment.

(g) Reduced costs and improved quality of life for individuals with food sensitivities

Adults with food sensitivities need to know whether or not the ingredient they should avoid is in the food or beverage they are considering purchasing or consuming. Specialists in treating food sensitivities advise not purchasing products that do not have a list of ingredients (unless there is label information provided on priority food allergen sources, gluten sources, or added sulphites), to read the product label every time they make a purchase and to verify the label of a product at least three times (when they purchase it, when they unpack and store it, and when they consume or serve it). Whenever they feel that the information provided on the label is incomplete or unclear, consumers are advised to call the manufacturer or importer to obtain additional information.

There are costs savings associated with the time saved by individuals with ingredient sensitivities in identifying and verifying information about the products that they purchase and consume.

Increased awareness from food allergen source, gluten source, and added sulphite labelling on products also contributes to an improved quality of life by reducing uncertainty and fear among food-sensitive individuals and their families and enabling an increased opportunity for socializing. Although those with allergies, celiac disease and sensitivities only represent a small proportion of Canadians (approximately 5%), some of these are beer consumers who will be provided with the opportunity to identify and select the most appropriate products prior to their consumption.

***Monetized costs***

(a) Labelling (labour and capital)

The enhanced mandatory labelling fully applies to the declaration of food allergen sources, gluten sources and added sulphites, and any added flavour is required to appear as part of the common name. These amendments require businesses to relabel their products (recognizing, however, that products that are currently considered unstandardized are already subject to the enhanced food allergen source, gluten source and added sulphite labelling requirements). In addition, beverages that exceed the 4% residual sugar limit may not be sold as beer or use beer as a common name, and therefore have to be relabelled. Also, some existing beer could be reformulated to meet the 4% residual sugar limit and therefore might also need to be relabelled to reflect the changes in the formulation. For brewers that need to relabel their products, there are additional labour (e.g. redesign of label) and capital (e.g. printing plates) costs.

(b) Product reformulation (labour, other)

Some breweries that manufacture beer with more than 4% residual sugar may decide to reformulate their products by changing the recipe to meet the requirement in order to continue selling their product as beer. This decision will largely depend on a number of factors including the potential price and demand, and on the tax structure. There will be additional labour and other costs (including testing) depending on the complexity of the reformulation, the distribution of the product and the implications for relisting with provincial liquor boards.

(c) Testing of residual sugar (labour, other)

Some breweries will conduct tests on select products to determine if the level of residual sugar of their products is in compliance with the requirement. For breweries and provincial liquor boards, the tests may be conducted in-house or outsourced to a third party.

(d) Familiarization of new regulatory requirements (labour)

The amendments change the requirements for how a beer is defined (e.g. sugar content, which is measurable) and impose administrative reporting requirements for some stakeholders. Therefore, all stakeholders will need to take some time to become familiar with the new regulatory requirements.

(e) Labour cost of submitting an application to Health Canada on use of food additives

The updated beer compositional standard allows some products that are currently unstandardized to be marketed as a beer. This may result in the need for some stakeholders to apply to Health Canada for the use of certain food additives in their beer. The application process requires that information be submitted to Health Canada.

***Methodology***

An industry survey was the primary data source used by the CFIA to determine the impacts of the regulatory changes. The survey was distributed to 800 beer industry stakeholders (associations, manufacturers and importers) in July 2017. In total, 37 responses were received and breweries who responded account for 89% of domestic beer production in Canada.

(a) Overarching assumptions

- Monetized costs were estimated over 10 years.
- Costs are reported in 2012 prices and discounted to 2019 (year of registration) using a 7% discount rate.
- There is a transition period that allows brewers to follow either the former FDR requirements or the new requirements until December 13, 2022, inclusively. Therefore, it was assumed that monetized costs will be incurred starting in 2022.
- The standard cost model was used to estimate costs related to impacts on labour (time). The model reflects the time required for individuals to perform a task, the individuals' wage rate and how often the task must be performed. The cost estimate was made for a single unit, and then the total cost estimate results were calculated by multiplying the estimated cost per unit by the total number of units.
- There are 580 beer manufacturers and 12 provincial liquor boards.
- The wage rate per hour is $31.50 (including overhead).

Table 1 presents the number of impacted businesses, the average number of labour hours per product, and the average number of products affected per impacted business. The estimates from the survey (by business size) were extrapolated to the entire industry to determine total estimated costs. The numbers in parentheses in the third and fourth columns are for small (s), medium/large (m/l) and big (b) businesses.

Table 1: Number of impacted businesses, number of labour hours and number of affected products

| | Number of Impacted Businesses | Average Number of Labour Hours per Product | Average Number of Products Affected per Impacted Business |
|---|---|---|---|
| **Labelling** | 255 (44%) table 2 note * | 19<br>(s: 4.6; m/l: 1.8; b: 51) | 32<br>(s: 16; m/l: 13; b: 112) |
| **Testing** | 77 (13%) | 0.74<br>(s: 0.77; m/l: 0.58; b: 0.58) | 11<br>(s: 12.2; m/l: 7.8; b: 9.5) |
| **Reformulation** | 23 (4%) | 87<br>(s: 80; m/l: 100; b: 100) | 2<br>(s: 1; m/l: 3.5; b: 3.5) |
| **Learning** | 592 (100%) | 1 | NA |
| **Food additive application to Health Canada** | 8 (1.4%) | 2.5 | 9 |

**Table 2 note(s)**

Table 2 Note *

This reflects the transition period ending on December 13, 2022, inclusively and survey findings indicating that 31% of beer manufacturers are already compliant with the food allergen declaration and/or do not manufacture beer with food allergen sources, gluten sources or added sulphites.

Return to table 2 note * referrer

(b) Other specific assumptions

1. Labelling (one-time/compliance costs)

- Breweries that routinely change their labels every three years or less will not carry additional labelling costs.
- Breweries that only manufacture and sell products intra-provincially will only carry costs to meet the mandatory labelling requirement for food allergen sources, gluten sources and added sulphites.
- Breweries that sell any products inter-provincially will meet all the requirements. The same product sold intra- and inter-provincially will have the same label.
- Printing plates will cost $431 per product for small businesses and $6,250 per product for medium/large businesses.
- There will be no labelling costs for imported products as foreign breweries will carry the change in labelling costs.

2. Testing

- One in five provincial liquor boards will conduct testing.
  - On average, 500 products will be tested, with ongoing testing conducted four times per year.
- Outsourcing testing will cost $125 per test.

3. Learning costs

Refer to the "'One-for-One' Rule" section of this Regulatory Impact Analysis Statement for details.

4. Submission of a food additive application to Health Canada

Refer to the "'One-for-One' Rule" section of this Regulatory Impact Analysis Statement for details.

***Estimated results***

All monetized costs are summarized in tables 2 and 3. Benefits are presented qualitatively.

Table 2: Compliance costs (2012 prices, 2019 present value [PV] base year, 7% discount rate, 10-year period)

| | Total (PV) | Annualized Value |
|---|---|---|
| **Labelling** | $4,276,524 | $608,881 |
| **Reformulation** | $264,545 | $37,665 |
| **Testing** | $454,120 | $64,656 |
| **Total compliance cost** | $4,995,188 | $711,202 |

Table 3: Administrative costs (Can$, 2012 prices, 2019 PV base year, 7% discount rate, 10-year period)

| | Total (PV) | Annualized Value |
|---|---|---|
| **Learning new regulatory requirements** | $14,226 | $2,026 |
| **Submitting an application to Health Canada** | $496 | $71 |
| **Total administrative costs** | $14,722 | $2,096 |

**Table 4: Costs, benefits and distribution**

**A. Quantified and monetized impacts: COST (to the beer industry)**

| | Costs | | | | |
|---|---|---|---|---|---|
| **Costs, Benefits and Distribution, in Millions of Can$** | **First Year (2019)** | **Fourth Year (2022)** | **Final Year (2029)** | **Total (PV)** | **Annualized Value** |
| Labelling costs | 0 | 5.24 | 0 | 4.28 | 0.61 |
| Reformulation costs | 0 | 0.32 | 0 | 0.26 | 0.04 |
| Testing costs | 0 | 0.13 | 0.07 | 0.45 | 0.06 |
| Learning costs | 0 | 0.02 | 0 | 0.02 | 0.002 |
| Submission of food additive application | 0 | 0.0006 | 0 | 0.0005 | 0.0001 |
| **Total cost** | **0** | **$5.71** | **$0.07** | **$5.01** | **$0.71** |

**B. Qualitative impacts**

**Positive impacts**

For the beer industry:

- Accommodates product innovation.
- Provides clarity in the use of ingredients and food additives to avoid confusion.
- Provides clearer and more objective measures of standard to maintain the integrity of beer.
- Supports innovation and product development.
- Removes duplication of standards.

For Canadians:

- Enhanced labelling information to assist consumers with food allergies, celiac disease or sulphite sensitivity in making informed choices.
- Prevention of accidental ingestion of beer containing food allergen sources, gluten sources, or added sulphites by individuals with sensitivities to those substances and reduction in adverse reactions.
- Reduction of time required by beer consumers with beer ingredient sensitivities to search for information.
- Improved quality of life for beer consumers with ingredient sensitivities and their families.
- Improved confidence among consumers due to consistent application of the labelling requirements across all prepackaged foods and simplified educational messaging to consumers on enhanced labelling.
- Wider range of products available which will be considered as beer.

For the Government:

- Reduced costs in resolving interpretation of standards with industry.

### Negative impacts

For the beer industry:

- Small craft breweries may experience difficulty in complying with the requirements because of limited financial resources.
- Some products may not meet the modernized beer standard and will have to be sold as unstandardized alcoholic beverages and not be represented as beer.
- May have the potential to impact international trade with countries that do not have the same beer compositional standard.

For the Government:

- There will be an impact on government resources to process a small number of additional food additive applications.

Given that the brewing industry of Canada is dominated by three major multinational companies who control approximately 90% of retail sales, these companies carry 40% of the costs. On a geographic basis, Ontario carries the largest share of the costs (34%), followed by Quebec (26%) and British Columbia (13%). By sector, beer manufacturers carry most of the costs (91.4%), but provincial liquor boards, as the sole or largest distributors and retailers of beer in each of the provinces and territories, are also impacted (8.6%).

In 2016, per capita consumption of beer in Canada (based on legal drinking age) was 77.1 L, down 2.9% from 2015. Over 2012–2016, the average annual rate of decline was 1.6%. This decline occurred despite the number of brewing facilities increasing by over 100% over the same period, triggered by consumer interest in access to new product offerings. Therefore, although the amendments strengthen innovation and further allow for new product offerings, they are not expected to have any impact on the rate of beer consumption. Furthermore, the amendments will not have any impact on socio-economic variables that may increase the demand for alcoholic beverages (e.g. income, unemployment).

Some of the survey respondents (primarily small craft breweries) raised some concerns related to lost revenue and/or market share resulting from the amendments. However, it is expected that any potential losses will ultimately be captured/gained by other brewers in the industry. Therefore, there will be no overall cost impact to industry related to these concerns.

### “One-for-One” Rule

The “One-for-One” Rule applies, because the regulatory amendments impose incremental administrative costs associated with learning the new regulatory requirements.

Following the “One-for-One” Rule, a 7% discount rate and a 10-year forecast period for the valuation of “INs” and “OUTs” were used. The price base year is 2012 (values are in constant 2012 prices), and the present value (PV) base year for the valuation is 2012 (i.e. the impact of all “INs” and “OUTs” was discounted back to 2012).

The amendments are considered to be an “IN.” The total annualized administrative impact for all businesses is $1,305 or $2 per affected business.

The standard cost model was used, and the key assumptions are documented below.

1. Learning costs

A total of 592 industry stakeholders have to learn the regulatory requirements to determine the impact on their business. It was assumed that one employee per business needs to learn the regulatory requirements and it would take one hour to complete the task.

2. Submission of food additive application to Health Canada

Based on survey responses, only eight breweries were estimated to be impacted. Based on a review of the application form, the average time to apply to Health Canada was estimated at 2.5 hours. The time includes writing a cover letter and completing the food additive submission checklist, but excludes any potential time for gathering information that may also need to be included in the package. A follow-up information request was sent to a sample of survey respondents in an attempt to collect this information. The response indicated that the time will be highly dependent on the specific products/additives affected (which is currently unknown), and from where the information will be sourced. Therefore, due to lack of information, any potential costs for the gathering of information could not be estimated.

Table 5 presents the estimates of the administrative impacts for the “One-for-One” Rule.

Table 5: Estimated annualized values of administrative impacts for the “One-for-One” Rule (Can$, constant 2012 prices, 2012 PV base year, 7% discount rate)

| Cost/Benefit Type | Task Description | Annualized Values |
|---|---|---|

| | | |
|---|---|---|
| Learning new regulatory requirements | Familiarization with the information obligation | $1,261 |
| Complete and submit application | Complete application form | $44 |
| **Total annualized administrative impact on all businesses** | | **$1,305** |
| **Estimated number of affected businesses** | | **592** |
| **Average annualized administrative impact per affected business** | | **$2** |

*Note: Figures may not add up to the total annualized administrative impact on all businesses due to rounding.*

### Small business lens

The small business lens (SBL) has been applied. Using the Treasury Board of Canada Secretariat definition of small business (fewer than 100 employees), there will be an estimated 555 small businesses affected by the amendments, which represents 94% of total beer manufacturers and liquor boards.

The SBL requires that two regulatory options for small businesses be assessed with one of the options being chosen for regulatory implementation. The results of the SBL analysis are presented in Table 6.

1. Initial option

The initial option for the regulation is that all-sized businesses need to comply with the changes to the Regulations as soon as they come into force in 2019. The estimated total annualized costs to small businesses are $583,954 (or $1,052 per impacted business).

2. Flexible option (recommended option)

The flexible option is the option the CFIA recommends for the implementation of the amendments (i.e. it was the regulatory scenario assessed in the cost-benefit analysis). Businesses (including small businesses) are provided a transition period until December 13, 2022, inclusively, for stakeholders to make adjustments to their current business operations. The option is intended to result in a higher industry compliance rate.

The estimated total annualized costs to small businesses in the recommended option are $236,865 (or $427 per impacted business). This represents a cost savings of $347,089 (or cost savings of $625 per impacted business).

Table 6: Regulatory flexibility analysis statement (Can$, constant 2012 prices, 2019 PV base year, 7% discount rate)

| | **Initial Option** | | **Flexible Option (Recommended)** | |
|---|---|---|---|---|
| Short description | Immediate implementation | | With transition period ending on December 13, 2022, inclusively | |
| Number of small businesses impacted (administrative impact) | 555 | | 555 | |
| | **Annualized Value (2012 $)** | **Present Value (2012 $)** | **Annualized Value (2012 $)** | **Present Value (2012 $)** |
| **Compliance costs** | $581,627 | $4,085,107 | $234,966 | $1,650,300 |
| **Administrative costs** | $2,326 | $16,339 | $1,899 | $13,337 |
| **Total costs (all small businesses)** | $583,954 | $4,101,445 | $236,865 | $1,663,638 |
| **Total cost per impacted small business** | $1,052 | $7,390 | $427 | $2,998 |
| Risk considerations | Small businesses may not be ready and the possibility of non-compliance is likely to be high. | | Health-related concerns over food allergens are not immediately addressed. | |

*Note 1: Numbers may not add up to totals due to rounding.*

*Note 2: The analysis covered a 10-year time period (2019–2029).*

### Consultation

In March 2014, Beer Canada (a voluntary trade association of over 40 brewers who collectively account for 90% of the beer brewed in Canada) provided the CFIA with a draft modernized beer compositional standard, resulting from broad consultations with Beer Canada's members.

From 2014 to 2017, the CFIA conducted consultations on proposed changes to the beer and ale, stout, porter and malt liquor compositional standards. These consultations took place as an online questionnaire and as a notice of intent in the *Canada Gazette*, Part I. The intent of the consultations was to obtain an understanding of stakeholders' knowledge and views of the proposed changes, and to document the gaps, challenges and issues they identified.

A wide range of stakeholders commented during the consultations, including breweries of all sizes, national associations, provincial associations of microbreweries, provincial liquor boards, consumers, health professionals, the beverage industry and international partners. Most of the elements of the proposed beer standard were well supported by respondents, inclusive of breweries of all sizes; however, some elements received mixed support. Given that the maximum level of 4% residual sugar was a new approach for maintaining the integrity of beer, it generated considerable discussions among stakeholders. Analyses were conducted on specific styles of beer that were identified through the consultation as potentially exceeding the limit. Based on domestic and imported product testing, most styles of beer have a percentage by weight of residual sugars in the final product of less than 4%.

The CFIA consulted targeted stakeholders and determined that there was sufficient support to proceed with establishing a limit in residual sugars and concluded that this requirement achieves its purpose of characterizing beer.

On July 28, 2017, an economic survey was also distributed to over 800 industry stakeholders to assist in developing the cost-benefit analysis for the proposed amendments to the beer compositional standard.

#### *Prepublication in the* Canada Gazette*, Part I*

On June 16, 2018, the proposed regulatory changes to amend the beer compositional standard under the FDR were published in the *Canada Gazette*, Part I, for a 90-day public comment period. A World Trade Organization (WTO) notification was also issued to provide Canada's international trading partners with an opportunity to provide comments on the changes to the standard.

The CFIA received 310 submissions from a variety of stakeholders including industry, associations, consumers, a provincial liquor board, and foreign trading partners.

All comments received during the consultation were reviewed and considered by the CFIA to help inform the development of the final regulations. Comments pertaining to the proposed repeal of the food allergen source, gluten source and added sulphite labelling exemptions in particular were reviewed and considered by Health Canada to help inform their final decision on the proposed removal of these exemptions.

Of the 310 submissions, 31 comments were received on the following elements with a high level of support:

- Repealing of the standard for ale, stout, porter and malt liquor
- Permitting the use of other microorganisms for fermentation, and removing the aroma statement
- Removing the listing of food additives and processing aids
- Allowing flavouring preparations
- Clarifying allowance for source of carbohydrates, herbs and spices

Overall, there was support to proceed with changes to the beer compositional standard as presented in the *Canada Gazette*, Part I. Stakeholders were supportive of the proposed direction to modernize the current beer standard in order to reduce duplication, provide clarity and allow industry to be more innovative in developing products to meet consumer interest in having more variety, such as flavoured beers, while maintaining the characteristics of beer.

#### *Maximum level of residual sugar*

The new requirement for a 4% limit by weight of residual sugar received support from a majority of stakeholders. However, an international stakeholder and a provincial microbrewer association commented that there could be a risk that certain specialty beers might not be able to meet the 4% limit. The CFIA proceeded with additional targeted testing of fruit beers and samples were all below the 4% limit.

CFIA Response: Since the majority of brewers, including provincial microbrewer associations, provided their support for this element as a way to clearly distinguish beer from sweeter malt-based beverages, the CFIA has determined that there is sufficient support to proceed with establishing a limit in residual sugars and concluded that this requirement will achieve its purpose.

#### *Food allergen source, gluten source and added sulphite labelling*

Two hundred and ninety-five comments were received on the proposal to remove the exemption for beer from the requirement to declare food allergen sources, gluten sources and added sulphites. The majority of comments (262 of the 295) came from consumers, with the remainder being from food allergy associations, celiac associations, brewing companies, industry (brewing/beer) associations, and health care professionals. Virtually all of the comments from the public, celiac associations, allergy associations, and health care

professionals were supportive of treating beer the same as any other prepackaged food, including other standardized alcoholic beverages, and removing the labelling exemptions. These comments referred specifically to allergen and/or gluten labelling, with a few referring specifically to sulphite labelling. Comments from brewing companies and industry associations were generally supportive of removing the exemption from allergen and sulphite labelling but expressed opposition to gluten-source labelling on the basis of concerns about costs to the industry when those with celiac disease may already be expected to avoid beer. Further, brewers also indicated that the new costs come at a time when they are working to manage other new and unexpected costs, specifically increased excise duty rates that also adjust automatically by the rate of inflation each year (these changes came into force on March 23, 2017).

HC Response: Health Canada considered various scenarios in which the gluten-source labelling exemption was maintained and noted that under these scenarios, there would be inconsistent labelling among beers that could lead to consumer confusion. A consistent and equitable regulatory regime for the labelling of food allergen sources, gluten sources and added sulphites on all prepackaged foods is considered beneficial for those consumers who must avoid these ingredients. Consideration was also given to the absence of a health-based rationale supporting the treatment of beer differently than other prepackaged foods, including other alcoholic beverages.

Based on these considerations it was determined to proceed with the removal of the labelling exemptions as proposed in the *Canada Gazette*, Part I.

## Regulatory cooperation

***United States***

The requirements for malt-based beverages in the United States are not identical to the Canadian beer standard mainly because the United States does not limit residual sugars. However, the amendments are not expected to impact trade of U.S. beers imported into Canada.

The amendments to the labelling requirements partially align Canadian requirements with those proposed in the United States. While beers sold in Canada are now required to be labelled with food allergen sources, gluten sources, added sulphites and added flavouring preparations, the United States also requires labelling of flavours and added sulphites, and has proposed mandatory labelling of major food allergens. In the meantime, the United States has set out standards for voluntary allergen statements.

***International***

There is currently no international standard for beer and, as a result, the compositional standards and regulations for beer differ from country to country.

Many international trading partners, including the European Union, require food allergen labelling on beer.

With these amendments, all imported beer will be required to comply with all aspects of the regulatory requirements, including the 4% residual sugar limit and the food allergen source, gluten source and added sulphite labelling.

Statistics from 2015 indicate that imported beer from the United States (3%) and Europe (6.7%) make up a small portion of the domestic beer market. The purpose of the amendments is to allow brewers to take advantage of innovations in brewing and to better reflect market developments within the Canadian brewing industry while maintaining the characteristics of beer. While the current standards and changes differ in some respects from those of international trading partners, these changes are not expected to impact trade.

***Federal responsibilities***

Health Canada is responsible for establishing standards for the safety and nutritional quality of food under the FDA and the FDR, which are enforced by the CFIA. The CFIA is responsible for the administration and enforcement of the non-health and safety food provisions (e.g. food compositional standards) under the FDR.

***Provinces and territories***

Under the *Importation of Intoxicating Liquors Act*, provinces and territories have responsibility over the importation of alcohol into their jurisdictions, including beer. Under federal jurisdiction over the sale of imported foods, imported beers for sale have to comply with the beer standard in the FDR.

The beer compositional standard in the FDR does not apply intra-provincially, unless this is required by the province or the territory. The provinces and territories regulate beer within their jurisdictions by their applicable laws and policies. Some have their own definition for beer that applies in their jurisdiction while others reference the federal regulations.

Some of the provinces and territories (such as British Columbia, Alberta, Saskatchewan, Ontario, Quebec, New Brunswick and Prince Edward Island) refer to the FDR and other federal legislation as guidelines. In British Columbia, the Liquor Distribution Branch has implemented a policy allowing beer to contain residual sugars up to 4%, which is aligned with the federal standard.

## Rationale

The amendments to the FDR fulfill the Government of Canada's commitment to modernize the beer compositional standard. It is anticipated that the modernization of the beer compositional standard, developed in consultation with stakeholders, will bring benefits to the beer industry, impacted regulated parties, producers and consumers.

This modernization is intended to support industry innovation, and enhance consumer offerings by

- allowing for innovation;
- addressing duplication and inconsistencies in the current beer compositional standards;
- enhancing labelling information for consumers; and
- providing additional clarity to regulated parties and consumers.

A transition period allows brewers to continue using current requirements until December 13, 2022, inclusively, providing sufficient time for stakeholders to make necessary labelling/formulation changes. Regulated parties may follow either the current requirements or the new requirements during the transition period. On December 14, 2022, the new requirements must be applied.

For beer that was brewed in accordance with the new standard prior to the end of the transition period, brewers must comply with all the provisions of the new standard.

## Implementation, enforcement and service standards

These amendments come into force once they are registered in the *Canada Gazette*, Part II. Regulated parties may follow either the former requirements or the new requirements during the transition period that is ending on December 13, 2022, inclusively. At the end of the transition period, on December 14, 2022, the new requirements must be applied.

The CFIA's ongoing monitoring of the beer industry includes inspection and complaint follow-up of domestic and imported beers in the marketplace. Operational procedures will be amended to include verification of the new labelling and compositional requirements.

## Contact

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**Small Business Lens Checklist**

1. Name of the sponsoring regulatory organization:

Canadian Food Inspection Agency (CFIA)

2. Title of the regulatory proposal:

Regulations amending the Food and Drug Regulations (Beer)

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

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

A. Small business regulatory design

| I | Communication and transparency | Yes | No | N/A |
|---|---|---|---|---|
| 1. | Are the proposed Regulations or requirements easily understandable in everyday language? | ☑ | ☐ | ☐ |
| 2. | Is there a clear connection between the requirements and the purpose (or intent) of the proposed Regulations? | ☑ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 3. | Will there be an implementation plan that includes communications and compliance promotion activities, that informs small business of a regulatory change and guides them on how to comply with it (e.g. information sessions, sample assessments, toolkits, Web sites)? | ☑ | ☐ | ☐ |
| 4. | If new forms, reports or processes are introduced, are they consistent in appearance and format with other relevant government forms, reports or processes? | ☐ | ☐ | ☑ |
| **II** | **Simplification and streamlining** | **Yes** | **No** | **N/A** |
| 1. | Will streamlined processes be put in place (e.g. through BizPaL, Canada Border Services Agency single window) to collect information from small businesses where possible? | ☐ | ☐ | ☑ |
| 2. | Have opportunities to align with other obligations imposed on business by federal, provincial, municipal or international or multinational regulatory bodies been assessed? | ☑ | ☐ | ☐ |
| 3. | Has the impact of the proposed Regulations on international or interprovincial trade been assessed? | ☑ | ☐ | ☐ |
| 4. | If the data or information, other than personal information, required to comply with the proposed Regulations is already collected by another department or jurisdiction, will this information be obtained from that department or jurisdiction instead of requesting the same information from small businesses or other stakeholders? (The collection, retention, use, disclosure and disposal of personal information are all subject to the requirements of the *Privacy Act*. Any questions with respect to compliance with the *Privacy Act* should be referred to the department's or agency's ATIP office or legal services unit.) | ☐ | ☐ | ☑ |
| 5. | Will forms be pre-populated with information or data already available to the department to reduce the time and cost necessary to complete them? (Example: When a business completes an online application for a licence, upon entering an identifier or a name, the system pre-populates the application with the applicant's personal particulars such as contact information, date, etc. when that information is already available to the department.) | ☐ | ☐ | ☑ |
| 6. | Will electronic reporting and data collection be used, including electronic validation and confirmation of receipt of reports where appropriate? | ☐ | ☐ | ☑ |
| 7. | Will reporting, if required by the proposed Regulations, be aligned with generally used business processes or international standards if possible? | ☐ | ☐ | ☑ |
| 8. | If additional forms are required, can they be streamlined with existing forms that must be completed for other government information requirements? | ☐ | ☐ | ☑ |
| **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? | ☐ | ☐ | ☑ |
| 2. | If regulatory authorizations (e.g. licences, permits or certifications) are introduced, will service standards addressing timeliness of decision making be developed that are inclusive of complaints about poor service? | ☐ | ☐ | ☑ |
| 3. | Is there a clearly identified contact point or help desk 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?<br><br>Examples of flexible options to minimize costs are as follows:<br><br>• Longer time periods to comply with the requirements, longer transition periods or temporary exemptions;<br>• Performance-based standards;<br>• Partial or complete exemptions from compliance, especially for firms that have good track records (legal advice should be sought when considering such an option);<br>• Reduced compliance costs;<br>• Reduced fees or other charges or penalties;<br>• Use of market incentives;<br>• A range of options to comply with requirements, including lower-cost options;<br>• Simplified and less frequent reporting obligations and inspections; and<br>• Licences granted on a permanent basis or renewed less frequently. | ☑ | ☐ | ☐ |
| 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? | ☑ | ☐ | ☐ |
| 3. | Does the RIAS include, as part of the Regulatory Flexibility Analysis Statement, a consideration of the risks associated with the flexible option? (Minimizing administrative or compliance costs for small business cannot be at the expense of greater health, security or safety or create environmental risks for Canadians.) | ☑ | ☐ | ☐ |
| 4. | Does the RIAS include a summary of feedback provided by small business during consultations? | ☑ | ☐ | ☐ |
| **V** | **Reverse onus** | **Yes** | **No** | **N/A** |
| 1. | If the recommended option is not the lower-cost option for small business in terms of administrative or compliance costs, is a reasonable justification provided in the RIAS? | ☐ | ☐ | ☑ |