

Canada Gazette, Part 2, Volume 153, Number 11: Regulations Amending the Food and Drug Regulations (Flavoured Purified Alcohol)

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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 (Flavoured Purified Alcohol)*.

Regulations Amending the Food and Drug Regulations (Flavoured Purified Alcohol)

Amendment

1 The *Food and Drug Regulations* are amended by adding the following after section B.02.003:

B.02.004 (1) No person shall sell flavoured purified alcohol in a container with a capacity of 1,000 mL or less unless it contains 25.6 mL or less of alcohol.

(2) Subsection (1) does not apply to flavoured purified alcohol that is sold in a glass container with a capacity of at least 750 mL.

(3) For the purposes of this section, ***flavoured purified alcohol*** means an alcoholic beverage

- **(a)** that is obtained from an alcohol base that has been purified during the course of manufacture through a process other than distillation and from which most of the naturally occurring substances other than alcohol and water have been removed; and
- **(b)** to which has been added during the course of manufacture any substance or mixture of substances that imparts flavour.

Coming into Force

2 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

There is a new and growing class of flavoured alcoholic beverages in Canada that are characterized as high in alcohol and sold in large, single-serve containers. However, they do not taste like alcohol, as the alcohol base is purified, flavoured, and often highly sweetened, which masks the alcohol taste. These flavoured purified alcoholic beverages are formulated, packaged, and marketed in a manner that can appeal to a younger segment of the drinking population. The sweetened taste profile combined with the large format and high alcohol content can result in unintentional overconsumption or excessive drinking due to the multiple standard alcoholic drinks in what appears to be a single-serve container. Some of these products contain as much alcohol as 4 standard alcoholic drinks.

Available data, research studies, and reports related to these products point to an alarming trend and growing public health risk. Regulatory measures are necessary to reduce the risks associated with these products and protect Canadians — especially youth — from unintended over consumption, which can lead to alcohol-related harms, including acute alcohol poisoning.

Background

In October 2017, emergency physicians in Quebec expressed concerns after observing an increase in the number of young people admitted to hospital emergency rooms with alcohol intoxication after drinking these types of beverages. On October 26, 2017, the National Assembly of Quebec passed a motion that instructed the national public health director to examine cases of alcohol poisoning following the consumption of beverages with high sugar and alcohol content, especially among young people, and directed the provincial Minister of Public Health to report back to the Assembly with findings and recommendations. The ministère de la Santé et des Services sociaux asked the Institut national de santé publique du Québec (INSPQ) to produce a scientific study on this public health issue. The INSPQ published its report on March 13, 2018.

The researchers found that from January 1 to November 26, 2017, an average of 21 individuals aged 12 years and older were admitted to emergency rooms each day in Quebec for acute alcohol poisoning, with the rate for the 18–24-year-old age group at least two and a half times higher than other age groups. Although the researchers could not attribute emergency room visits to flavoured purified high alcohol content beverages specifically, they reported a 319% increase in the sales of high alcohol content (at least 11% alcohol by volume [alc/vol]), flavoured malt-based beverages in Quebec between 2016 and 2017 (flavoured malt-based beverages are a type of flavoured purified alcohol). The report also showed that emergency room visits for the 12–17 and 18–24 age groups fell from 2014 to 2015 and then increased annually thereafter. This timing coincides with these large format, single-serve, high alcohol content flavoured malt-based beverages first appearing in Quebec in late 2014 and increasing in sales in subsequent years.

A separate study conducted in Sherbrooke, Quebec, also found that in 2017, 17% of individuals aged 12–24 presenting at an emergency department had consumed a type of flavoured purified alcoholic beverage, whereas no medical records referred to these types of products between 2012 and 2016. There were four other cases of alcohol overdoses (e.g. poisoning) related to these products documented in the Canadian Hospitals Injury Reporting and Prevention Program in 2017.

In December 2017, one of these products was implicated in the death of a 30-year-old male in Quebec, and another was implicated in the death of a 14-year-old female in Quebec in late February 2018. The coroner's investigative report on the death of the 14-year-old female (released March 27, 2019) determined the cause of death to be drowning and possibly hypothermia after drinking approximately three 568 mL cans of a sugary alcoholic beverage in a short period of time (i.e. approximately thirty minutes). At 11.9% alcohol and 568 mL, each can contained four standard drinks of alcohol, meaning that the 110 lb, 14-year-old female could have consumed up to the equivalent of approximately 12 glasses of wine in less than thirty minutes. The incident resulted in public concern and calls from the Province of Quebec, health stakeholders, and Canadians for federal action.

On March 19, 2018, the House of Commons Standing Committee on Health (HESA or the Committee) adopted a motion to study the health and safety risks of pre-mixed drinks that are highly sweetened, high in alcohol and contain caffeine. The Committee's report was tabled in the House of Commons on June 19, 2018, and it highlighted the need to take action to reduce the health and safety risks of these types of beverages. Specifically, one of the report's recommendations was for Health Canada (the Department) to take regulatory action to restrict the alcohol content of these types of products.

Alcohol regulation in Canada

Alcohol regulation in Canada is a shared responsibility between federal, provincial and territorial governments.

At the federal level, Health Canada regulates alcohol under the regulatory framework for food. The *Food and Drug Regulations* (FDR) set out compositional standards for different categories of alcoholic beverages, including beer, cider, gin, vodka and wine, among others. A compositional standard sets out permitted ingredients and manufacturing requirements. Compositional standards are primarily for interprovincial trade purposes and provide consumers with predictability on what is contained in certain foods. Outside of these Regulations, there are no federal regulations that prescribe or otherwise limit the alcohol content of alcoholic beverages for health and safety purposes. There is also no pre-market approval required for alcoholic beverages. Like most foods, manufacturers must ensure that alcoholic beverages meet general food safety requirements.

Many of the regulatory controls on alcohol are set by provincial and territorial (PT) governments. Provinces and territories have exclusive control of alcohol sales within their jurisdiction, notably the responsibility for enacting laws and regulations regarding the sale, legal drinking age, and distribution of alcohol. Each province and territory has a liquor board or commission to oversee these activities. Some jurisdictions allow sales from private liquor stores while others operate government retail monopolies. Most jurisdictions have a mix of private and public retailers.

In response to the death in late February 2018 of a 14-year-old female in Quebec, the Government of Quebec enacted legislative changes to restrict the sale of beer blends with more than 7% alc/vol to the Société des alcools du Québec (SAQ). As a result, the sale of beer blends with more than 7% alc/vol is no longer permitted in corner stores and grocery stores. The Government of Quebec also committed to

establishing an expert group to review the advertising and promotion of alcohol in the province.

Why flavoured purified alcoholic beverages appeal to youth

A. Taste

Unlike traditional alcoholic products such as beer, wine, and spirits, flavoured alcoholic beverages lack a perceptible taste and aroma of alcohol since they take on the taste of added flavours. This difference is the result of the practices used in the manufacturing of these products.

All alcoholic beverages first undergo fermentation, where yeast converts sugars in the source material to ethanol (alcohol) and carbon dioxide. This process of fermentation imparts a distinct taste and aroma to the alcohol based on the source of sugars used (e.g. malt for beer, grapes for wine, apples for cider). Spirits are also manufactured through the fermentation process and undergo distillation as an additional processing step to increase the strength of the alcohol in the finished product.

Beverages in this new class of flavoured purified alcohol are manufactured using innovative purification methods (e.g. reverse osmosis, carbon filtration) that further process the fermented liquid, stripping it of its source taste and aroma — essentially leaving only alcohol and water. This step creates a neutral-tasting high-alcohol liquid to which flavouring and/or sweetening ingredients are added to enhance palatability. As a result, the final product is high in alcohol, subject to lower excise duties (see section “C. Price and Availability”), and takes on the taste of the added flavours and sweeteners, effectively masking the taste of alcohol.

A major reason why flavoured purified alcoholic beverages appeal to youth is that their sweet and fruity flavours make these alcoholic beverages taste more like soft drinks than alcohol. Studies show a link between age and a preference for sweetness, with children and adolescents showing a much stronger preference for sweetness than adults. The results of an experiment exploring the acceptability of a range of alcoholic and non-alcoholic beverages among youth and young adults (aged 12–30) revealed that the acceptability of traditional alcoholic beverages (e.g. beer, wine, spirits) increased with age whereas the acceptability of sweeter beverages, including mixed alcoholic drinks, decreased. [Focus groups](#) conducted with 12–17-year-olds corroborate the importance of taste as a key driver in the choice to consume a flavoured alcoholic beverage. Alcohol strength (% alc/vol), convenience and product packaging were also identified as important factors to youth.

Not only is the flavouring and sweetening more palatable for youth, many youth may not be aware they are consuming alcoholic beverages if the characteristic taste of alcohol is masked, which is what happens when flavours and sweeteners are added to a neutral-tasting alcohol base. In one study that compared beer, wine, and flavoured and sweetened spirits-based beverages, 100% of teenagers aged 18 and 19 detected the taste of alcohol in beer and wine, whereas 24% did not detect the taste of alcohol in the flavoured and sweetened beverages. Furthermore, flavoured and sweetened beverages had the most taste appeal — 60% of participants reported liking their taste compared to 38% and 25% liking the taste of beer and wine, respectively.

B. High alcohol content and container format

A number of flavoured purified alcoholic beverages are also high in alcohol and many are sold in large single-serve containers, a combination which facilitates excessive drinking and increases the risk of unintended intoxication. The size of these containers combined with most of them being non-resealable suggests that the entire contents should be consumed in a single sitting. The consumer may not be aware that a large single-serve container can contain multiple standard drinks of alcohol. Many single-serve containers of flavoured purified alcoholic beverages contain as much alcohol as 4 standard drinks.

At 4 standard drinks per container, consuming the contents of one container in under one hour would put most adults weighing 180 lbs or less over the legal limit for impaired driving (as set out in the *Criminal Code* of Canada), which is a blood alcohol concentration (BAC) of 0.08%. As the body can only metabolize a certain amount of alcohol per hour, increasing the length of time over which these products are consumed is not an effective mitigation measure. Consuming two such containers over the course of two hours more than doubles an individual's BAC (twice the legal limit) and would result in significant intoxication for adults weighing 180 lbs or less. Consuming three containers would likely result in a BAC that has been associated with hospitalization (e.g. alcohol poisoning).

The impact would be even greater for teenagers who, on average, weigh less than adults. For example, consuming a single flavoured purified alcoholic beverage containing 4 standard drinks would result in severe intoxication for a youth weighing 100 lbs (BAC greater than 0.15%); consuming two of these would result in hospitalization with a possibility of death (BAC greater than 0.3%).

According to [Canada's Low-Risk Alcohol Drinking Guidelines](#) (“Guidelines”), individuals between 25 and 64 years of age can reduce long-term alcohol-related health risks (e.g. liver disease, some cancers) by drinking no more than 10 standard drinks a week for women (with no more than 2 drinks a day most days) and 15 standard drinks a week for men (with no more than 3 drinks a day most days). To help reduce the

short-term risk of injury and harm, women should drink no more than 3 drinks and men no more than 4 on any single occasion. The alcohol content in a single container of many flavoured purified alcoholic beverages exceeds the recommended daily maximum set out in the Guidelines for men and women.

C. Price and availability

In general, alcohol is like many other products in that consumer demand is inversely related to price: when the price decreases, demand (sales) increase, if other factors such as income (consumer purchasing power) are kept constant. Cost and convenience are key factors in youth's choice of which alcoholic beverage to consume (after taste and alcohol strength), as they generally have lower incomes compared to the rest of the population.

There are no federal laws regarding the minimum retail price of alcohol. However, federal excise duties are charged on alcoholic beverages under the *Excise Act* and the *Excise Act, 2001*. Flavoured purified alcoholic beverages between 7.1 and 11.9% alc/vol currently have one of the lowest excise duty rates for that alcohol strength. Spirits and spirits-based beverages with more than 7% alc/vol have the highest excise duty rates. This results in a market incentive for manufacturers to produce spirits-based coolers with lower alcohol (i.e. 7% or less alc/vol) and flavoured purified alcohol with higher alcohol (i.e. between 7.1 and 11.9% alc/vol).

Lower excise rates also allow for lower retail prices, making high alcohol flavoured purified products cheaper and therefore more accessible to youth compared to spirits or spirits-based alcoholic beverages, which are generally priced higher. Spirits and spirits-based products are subject to higher minimum retail prices than malt-based products in many jurisdictions (Alberta and Quebec are the exceptions).

Moreover, flavoured purified alcoholic beverages are more widely accessible compared to spirits-based products. Many jurisdictions allow the sale of non-spirits alcoholic beverages (e.g. malt-based or wine-based) by grocery and/or corner stores (i.e. British Columbia, Ontario, Quebec, and Newfoundland). No jurisdiction allows widespread sale of spirits-based beverages by grocery or corner stores.

Parliamentary study

In spring 2018, HESA conducted a study titled "Pre-mixed Drinks Combining High Alcohol, Caffeine, and Sugar Content." The Committee held two meetings in April and May 2018 and heard testimony from 15 witnesses and received 7 written briefs. Government of Canada officials representing Health Canada appeared as witnesses, along with public health experts, physicians, toxicology experts and industry representatives.

The Committee's "Report on Highly Sweetened Pre-mixed Alcoholic Beverages" was tabled on June 19, 2018. It contains 15 recommendations for the Government of Canada, mostly pertaining to the broader alcohol industry (e.g. labelling, marketing, pricing, monitoring and surveillance, and the National Alcohol Strategy). Recommendations specific to flavoured purified alcoholic beverages were

- A. That Health Canada restrict the alcohol content in highly sweetened pre-mixed alcoholic beverages to that of one standard serving of alcohol in Canada, or 13.5 g or 17.05 mL of pure alcohol, through the *Food and Drug Regulations*;
- B. That Health Canada set the sweetness threshold of highly sweetened pre-mixed alcoholic beverages at 5% under the *Food and Drug Regulations* to restrict the place of sale of these products.

The recommendations above, as well as feedback received during Health Canada's consultations, were taken into consideration in the development of the *Regulations Amending the Food and Drug Regulations (Flavoured Purified Alcohol)* [the Regulations].

Caffeine

There have been media reports stating that flavoured purified alcoholic beverages contain caffeine, a combination that can increase the risk of unintentional overconsumption (caffeine masks the depressant effects of alcohol). It is important to clarify that it is illegal in Canada to sell alcoholic beverages that contain caffeine as an additive. Caffeine directly added to food and food ingredients is strictly controlled as a food additive under the FDR. Currently, caffeine is only authorized for use as a food additive in non-alcoholic carbonated soft drinks.

Caffeine may be present in some alcoholic beverages due to the use of flavouring ingredients that naturally contain caffeine (e.g. guarana seed extract, coffee, chocolate). Some alcohol products may be advertising the use of such flavourings. However, the amount of caffeine contributed to beverages by such flavourings is very low and as a result there is little to no caffeine in these types of products. For example, the amount of caffeine in the product that triggered the HESA study was less than 1 mg per 568 mL can (as confirmed through testing by the Canadian Food Inspection Agency [CFIA]). Regular coffee contains between 70 and 180 mg per 237 mL and an average cola-type carbonated soft drink can contain up to 50 mg of caffeine in a 355 mL can.

Objective

The objective of these Regulations is to reduce the health and safety risks associated with unintentional overconsumption and acute alcohol poisoning as a result of consuming flavoured purified alcoholic beverages by limiting the alcohol content in single-serve containers of these types of beverages.

Description

Division 2 (Alcoholic Beverages) of the FDR has been amended to

- 1. Define a new class of flavoured purified alcoholic beverages that meet both of the following conditions:
 - are obtained from an alcohol base that has been purified during the course of manufacturing through a process other than distillation and from which most of the naturally occurring substances other than alcohol and water have been removed; and
 - to which have been added, during the course of manufacturing, any substance, or any combination of substances, that imparts flavour.
- 2. Restrict the alcohol content in beverages in this new class. Beverages that meet the definition of the new class are limited to 25.6 mL of alcohol (representing 1.5 standard drinks) when they are packaged in containers of a volume of 1 000 mL or less. This includes both non-resealable and resealable containers. Manufacturers have flexibility in determining how to comply with the alcohol content restriction: reformulate their beverage to modify the alcohol content (% alc/vol); resize the beverage containers; or combine both measures.

For example, a flavoured purified alcoholic beverage containing 25.6 mL of alcohol could have the following percentages of alcohol based on its format:

- 7.5% alc/vol if sold in a 341 mL container;
- 7.2% alc/vol if sold in a 355 mL container;
- 5.4% alc/vol if sold in a 473 mL container;
- 4.5% alc/vol if sold in a 568 mL container;
- 3.6% alc/vol if sold in a 710 mL container;
- 3.5% alc/vol if sold in a 740 mL container; or
- 2.6% alc/vol if sold in a 1 000 mL container that is not made of glass.
- 3. Create an exemption from the alcohol content limit for beverages in the new class that are packaged in glass containers of a volume of 750 mL or more. This includes both non-resealable and resealable glass containers.

These amendments come into force on the day on which the Regulations are registered.

1. Definition

The products within the scope of these Regulations are alcoholic beverages that have been purified such that most of the naturally occurring substances other than alcohol and water, including the taste and aroma of the starting material (e.g. malt), are no longer present, and products that have subsequently been flavoured and/or sweetened so that the taste of alcohol is masked.

Other jurisdictions, such as the province of Quebec and the United States, have defined a category of products as “malt-based,” “flavoured malt” or “beer blends,” in recognition of the source material that is used. However, it is the purification process and the use of flavouring rather than the malt source itself that mask the taste of alcohol and contribute to the appeal of the products to youth. Flavoured purified alcoholic beverages can also be made from non-malt sources; however, the majority in Canada are currently malt-based.

For further clarification, the definition explicitly excludes distillation. Distillation may also be considered a form of purification; however, the end result of distillation is spirits or spirits-based products, which are not in the scope of these Regulations. As noted in the “Background” section, spirits are subject to higher excise duties and existing distribution controls by provinces and territories. Furthermore, market analysis has determined that a large number of single-serve spirits-based beverages sold in Canada are already between 1 and 1.5 standard drinks, and the majority of spirits-based coolers contain fewer than 2 standard drinks. Therefore, in recognition of an existing regulatory landscape that already mitigates the health and safety risks associated with unintentional overconsumption of spirits-based beverages, Health Canada has not included spirits-based beverages in the scope of these Regulations.

There is no objective sugar or sweetness threshold below which these products would be less appealing to youth or pose less of a health and safety risk, as sweetness is largely based on individual taste perceptions, and intense flavouring without added sweetness can also be appealing and mask the taste of alcohol.

Considering this, a sugar threshold was deemed not to be an appropriate means to address the health and safety risks, and therefore, was not used to determine the scope of alcoholic beverages affected by the amendments.

2. Restriction of the amount of alcohol

Flavoured purified alcoholic beverages are limited to a maximum alcohol content of 25.6 mL per single-serve container to reduce the risks of unintentional alcohol intoxication, particularly among youth. This limit is equivalent to 1.5 standard alcoholic drinks.

Canada's Low-Risk Alcohol Drinking Guidelines recommend consumption of no more than 2 standard drinks per day for women and no more than 3 standard drinks per day for men — applying to ages 25–64 for both genders. To help reduce the short-term risk of injury and harm, the Guidelines recommend women drink no more than 3 drinks and men no more than 4 on any single occasion. It is estimated that if all Canadians consumed alcohol within the Guidelines, alcohol-related deaths would be reduced by approximately 4 600 per year.

Alcohol generally takes at least 30 minutes to be fully absorbed into the bloodstream, so consumers may not notice any immediate effects. As the rate of alcohol absorption is higher than the rate of elimination, BAC can continue to increase hours after drinking has stopped. As noted in the “Background” section, consumption of 4 standard drinks in a short period of time would put a 180 lb adult over the legal limit for impaired driving. The taste of alcohol is masked in flavoured purified alcoholic beverages, so consumers may not be aware how much alcohol they have consumed. This increases the risk that more than one container of these products could be consumed in a single sitting.

At 1.5 standard drinks per single-serve container, a woman would be under the daily recommended maximum, and two containers of such beverages (i.e. 3 standard drinks) would still be below the recommended limit for any single occasion. The same would be true for men. One and a half standard drinks would be the upper limit. Flavoured purified alcoholic beverages will likely be sold with an alcohol content ranging between 0.8 and 1.5 standard drinks, depending on the target taste profile and market.

3. Container thresholds

The volume thresholds apply equally to resealable and non-resealable single-serve containers.

Most large single-serve flavoured purified alcoholic beverages in Canada are sold in aluminum pull-tab cans. Aluminum cans have a history and perception of being single-serve and are commonly found in sizes up to 950 mL. Currently, the vast majority of aluminum cans are non-resealable. However, technology to manufacture resealable cans exists. Simply turning a container format that has a history of being single-serve from non-resealable to resealable would not transform it into a multi-serve product. Therefore, Health Canada has set the single-serve threshold at 1 000 mL regardless of whether the container can be resealed. Furthermore, these Regulations are not specific to aluminum pull-tab cans in recognition of ongoing single-serve packaging innovation (e.g. Tetra Pak, pouches).

Glass bottles of at least 750 mL in volume are exempt. Glass bottles of 750 mL and above are a common multi-serve format for traditional alcoholic beverages, such as wine and spirits. Due to their long history of use, consumers are likely to identify these formats as containing multiple servings (standard drinks) of alcohol. The policy intent is not to capture multi-serve containers. Although alcoholic beverages sold in multi-serve containers may also present a risk of overconsumption, the consumer would be making a conscious decision to overconsume alcohol and would be more aware of the consequences.

4. Coming into force and transition period

Under the World Trade Organization (WTO) Technical Barriers to Trade Agreement (TBT), WTO members are required to provide a reasonable interval, generally at least six months, between the final publication of technical regulations and their entry into force in order to allow time for producers in exporting WTO members to adapt their products or methods of production to the new requirements (Article 2.12). However, where there are urgent problems of health and safety, a shorter coming-into-force period is permitted.

In Canada, large, single-serve flavoured purified alcoholic beverages have been implicated in numerous hospitalizations and two deaths within the past year in the province of Quebec. Their popularity and sales appear to be growing. Any delay in the coming into force of these Regulations places the health and safety of Canadians at risk.

Therefore, these Regulations come into force on the day on which they are registered, with no transition period after their coming into force.

Regulatory development

Consultation

The Regulations were finalized following extensive consultations with impacted and interested parties, including provinces and territories, regional/municipal health centres, health organizations, other federal departments, the alcohol industry, non-profit and non-governmental organizations, representatives of people with personal experience of problematic alcohol use, academia, and the general public.

The process of engaging stakeholders and other interested parties began in March 2018 with the publication of a notice of intent (NOI), followed by meetings and follow-up consultations throughout 2018. Health Canada took into consideration all feedback received during pre-consultations, as well as recommendations by HESA. Literature reviews and market research also informed the development of the proposed Regulations, which were prepublished in the *Canada Gazette*, Part I, on December 22, 2018, and were open for public comment for a period of 45 days.

Pre-consultation (NOI and stakeholder engagement prior to prepublication)

Health Canada published a NOI on its website on March 19, 2018, and in the *Canada Gazette*, Part I, on March 24, 2018, to signal the Department's intent to regulate highly sweetened alcoholic beverages. Health Canada also disseminated the notification through its stakeholder registry (Consultations and Stakeholder Information Management System [CSIMS]) on March 23, 2018, to all subscribers who expressed an interest in the topic of alcohol. Stakeholders were invited to provide feedback by May 8, 2018. Health Canada received 27 submissions in total: 7 from members of the public; 8 from government organizations (including public health units); 7 from health stakeholders (including associations and non-profit organizations); and 5 from industry stakeholders (industry associations representing alcohol manufacturers as well as individual manufacturers). The majority of the submitted comments were supportive of the federal government taking action to reduce the health risks associated with these products.

During the consultation period on the NOI, Health Canada convened a meeting with all provinces and territories to better understand the scope of this issue in their respective jurisdictions. Health Canada presented the issue and policy proposal twice to the Federal-Provincial-Territorial Problematic Substance Use and Harms Committee. In June 2018, the Department hosted a stakeholder meeting with provinces and territories, health stakeholders and major industry associations to discuss shared areas of responsibility, namely on the subject of marketing and advertising.

Based on the feedback received, on June 28, 2018, Health Canada distributed a (revised) proposed regulatory approach to government, health and industry stakeholders, who were invited to submit feedback by July 31, 2018. During this follow-up consultation period, Health Canada met with industry stakeholders on July 6 and 10, provinces and territories and other government officials on July 16, and health stakeholders on July 17 to discuss the revised approach. Health Canada received 18 submissions in total: 5 from government organizations; 7 from health stakeholders; and 6 from industry associations and manufacturers. There were no major changes in stakeholder positions between the NOI and the follow-up consultation.

Stakeholder feedback on pre-consultations

Health stakeholders were strongly supportive of the federal government taking regulatory action to restrict the amount of alcohol in single-serve containers of flavoured purified alcoholic beverages. Provinces and territories were also supportive, but many indicated that they were not aware of these types of products being sold in their jurisdictions. Most industry stakeholders expressed support for targeted regulatory measures that address the immediate health and safety risks. Impacted companies felt that Health Canada's proposed Regulations would unfairly target one product class and that measures should apply to the broader alcohol industry.

Alcohol content: Health stakeholders favoured strong restrictions, suggesting a maximum of 1 to 1.5 standard drinks per container (17.05 to 25.6 mL of alcohol). Industry stakeholders suggested a higher limit of approximately 2.2 or 3 standard drinks per container (38 to 51 mL of alcohol). Some provinces and territories voiced a preference for restricting alcohol by volume rather than by standard drink. Restricting alcohol by volume, such as setting a 7% alc/vol limit as in the case of Quebec, would permit the sale of 3 standard drinks in a single-serve 740 mL can (a common format for these beverages). Health Canada's proposal struck a balance between what was recommended by health stakeholders and HESA.

Sweetness: Many stakeholders supported a sweetness threshold to help determine the scope of beverages to which alcohol content restrictions would apply. However, there was no consensus on how a threshold would be determined or the level at which it should be set. Defining this class of beverages based on their innovative methods of purification was determined to be a more effective means to impose restrictions.

Container size: The proposal to limit alcohol content based on container type and size generated a few comments from health and industry stakeholders. Health stakeholders were concerned that companies could reduce the size of the container, but sell multiple containers in a pack. Some health stakeholders also voiced concern over low-cost 4 L boxes of flavoured purified alcoholic beverages. These concerns were

associated with multi-serve formats that were not in the scope of the policy intent (e.g. focus on single-serve formats). Industry indicated the 1 000 mL threshold was too high and pointed out that large volume glass containers are commonly perceived as multi-serve. Health Canada proposed an exemption for flavoured purified alcoholic beverages in glass containers of 750 mL or more, which was reflected in the draft regulations republished in the *Canada Gazette*, Part I.

Other: Health stakeholders also commented on topics outside the scope of the regulatory proposal. The most often cited topics included advertising restrictions, mandatory labelling (including the number of standard alcoholic drinks), caffeine content limits and higher excise duty rates. These topics may be considered under the Canadian Drugs and Substances Strategy (CDSS). In fall 2018, Health Canada launched a public consultation on the CDSS.

Consultation on the cost-benefit analysis

On June 18, 2018, Health Canada distributed a costing survey to 21 national and provincial associations representing different sectors of the alcohol industry and to manufacturers of beverages impacted by the proposed Regulations. The purpose of the survey was to collect data to further understand the current marketplace and estimate the costs and benefits associated with complying with the proposed Regulations. Stakeholders had nine weeks to provide responses to the survey. The Department received five responses.

Canada Gazette, Part I, consultation

The proposed *Regulations Amending the Food and Drug Regulations (Flavoured Purified Alcohol)* were published in the *Canada Gazette*, Part I, on December 22, 2018, for a 45-day public comment period that ended on February 5, 2019. A total of 60 submissions were received: 28 from members of the public; 17 from government organizations; 9 from health stakeholders; and 6 from industry stakeholders. Two health organizations made a single joint submission, meaning there were 61 respondents.

The majority of respondents (55 of 61, including government, health, industry and members of the public) were supportive of the Government of Canada taking regulatory action to restrict the alcohol content of this class of beverages. Twenty-nine respondents supported the regulatory text proposed by Health Canada. Twenty-six respondents supported the policy objective but had concerns with one or two elements of the proposal. Only 5 respondents (all individual members of the public) opposed any regulatory action, and one member of the public was neither in favour nor opposed. In addition to the concerns expressed over the risks posed by these beverages, especially to youth, many respondents provided additional recommendations beyond the scope of this regulatory initiative.

Key themes that emerged during the prepublication comment period are outlined below.

1. Limit on alcohol content: number of standard drinks

Approximately half of respondents did not raise any concerns with the proposed 1.5 standard drink limit. Of those who did not support this limit, most recommended either a 1 or 2 standard drink limit instead. Both numbers were recommended based on the respondents' interpretation of *Canada's Low-Risk Alcohol Drinking Guidelines*, which recommend no more than 2 standard drinks for women most days.

Respondents in favour of a 1 standard drink limit indicated that most people perceive one single-serve container of alcohol as 1 standard drink, and that this limit would be more protective, as women could consume two such containers and still be within their daily limit under the Guidelines. They also noted that flavoured purified alcoholic beverages are marketed to a younger consumer population. The Guidelines do not support alcohol consumption by underage youth, but recognize this is common in Canada and that there is an urgent need to reduce alcohol-related harm in this group. If young people decide to consume alcohol, the Guidelines recommended that they have no more than 2 standard drinks, no more than once a week, in order to minimize the risk of harmful consequences.

Respondents in favour of a 2 standard drink limit noted that women could consume one such container and still be within their daily limit under the Guidelines. Respondents supporting this higher limit indicated that the recommended limits were based on self-reported consumption data (which are known to be conservative estimates), that the amount of alcohol in a standard drink varies internationally, and that other types of single-serve alcoholic beverages are currently sold at 2 standard drinks. A few respondents suggested restricting the alcohol content of these beverages to 4–5% alc/vol or another level comparable to the majority of other single-serve alcoholic beverages on the market. This recommendation was intended to prevent the sale of miniature containers of high-strength flavoured purified alcoholic beverages (e.g. a 100 mL container at 25% alc/vol).

Response

Health Canada has maintained the 1.5 standard drink limit.

- Health Canada took into consideration a variety of factors, including the recommended limits under

the Guidelines, the prevention of unintentional overconsumption leading to acute alcohol intoxication, as well as the current and historical market landscape.

- A standard drink limit of 1.5 is a protective limit that will significantly reduce the amount of alcohol in flavoured purified alcohol beverages (e.g. from the existing 3–4 standard drinks) and at the same time is aligned with comparable single-serve ready-to-drink alcoholic beverages that are typically 1–1.5 standard drinks.
- A 1.5 standard drink limit is below the daily recommended limit for women and consuming two such containers is still within the recommended limit for special occasions, which is 3 drinks. At a 2 standard drink limit, it is recognized that women would be at their daily limit after one container, and after the consumption of two containers they would be at 4 standard drinks and exceed the limit for special occasions. Consuming two containers at 2 standard drinks each in under an hour would put a 180 lb adult over the legal limit for impaired driving.
- Although the amount of alcohol in a standard drink varies from country to country, the limits recommended by *Canada's Low-Risk Alcohol Drinking Guidelines* were developed by experts and informed by the current scientific evidence. The amount of alcohol in a standard drink in Canada is based on the consumption patterns of Canadians and the limits under the Guidelines are set to protect the health and safety of Canadians.
- A 1 standard drink limit could impact trade between the United States and Canada as the amount of alcohol in 1 standard U.S. drink is slightly higher (17.7 mL of alcohol) than in Canada (17.05 mL of alcohol). The 1.5 standard drink limit allows for the importation of flavoured purified alcoholic beverages sold at 1 standard U.S. drink. If the standard drink limit was set at 1, U.S. exporters would be required to reformulate existing low-alcohol products to conform to Canada's standard drink limit.
- Restricting the alcohol content based on the number of standard drinks provides flexibility for manufacturers to meet the requirements of these Regulations. Manufacturers have the option to reduce the alcohol by volume, the size of the container, or both, to achieve compliance with these Regulations.
- The 1.5 standard drink limit is the upper limit, not a target. Flavoured purified alcoholic beverages can be sold with a range in the number of standard drinks below 1.5. A large percentage of flavoured purified alcoholic beverages currently contain fewer than 1.5 standard drinks.

2. Sugar, flavouring and caffeine

Some respondents recommended limiting the amount of sugar and/or flavourings in flavoured purified alcoholic beverages to reduce their appeal to youth. A few respondents also expressed concern over the addition of caffeine to alcoholic beverages and recommended further restrictions on added caffeine and flavouring ingredients naturally containing caffeine, such as guarana and taurine, in these beverages.

Response

Health Canada did not add restrictions on sugars, flavourings, or additional restrictions on caffeine to these Regulations for the following reasons:

- The main health and safety risk of flavoured purified alcoholic beverages is the multiple servings of alcohol in a single-serve container. A restriction on alcohol content directly addresses this risk.
- Restrictions on sugars, sweetness and flavourings were not considered because there is no objective threshold below which these products would be less appealing to youth or pose less of a health and safety risk. Sweetness and flavours are largely based on individual taste perceptions.
- It is illegal in Canada to sell alcoholic beverages containing caffeine as an additive. Caffeinated energy drinks that contain alcohol, such as those sold in the United States between 2005 and 2010, were never allowed to be sold in Canada. The amount of caffeine imparted by flavouring ingredients such as guarana seed extract is very low, and if such ingredients are treated to concentrate their caffeine content, they are considered food additives and cannot be added to alcoholic beverages. Provincial and territorial liquor control boards have restrictions on caffeine in alcohol. Liquor control boards set a limit of 30 mg of caffeine from all sources (resulting from the use of flavouring ingredients) in all types of alcoholic beverages.

3. Container size and multi-packs

Some respondents suggested prescribing a minimum container size in these Regulations, to prevent the sale of miniature containers of high-strength flavoured purified alcoholic beverages, including in multi-packs. These respondents expressed concern that an individual could consume multiples of such containers in a single sitting. A few respondents voiced concern over the exemption for 750 mL glass containers and larger, stating that it would incentivize manufacturers to sell high-strength flavoured purified alcoholic beverages in glass containers larger than 750 mL. A few respondents suggested adding a maximum container size for flavoured purified alcoholic beverages in these Regulations, with recommendations ranging from the size of a typical bottle of beer to 750 mL.

Response

Health Canada did not prescribe additional requirements on container size and multi-packs for the following reasons:

- The objective of these Regulations is to reduce the health and safety risks from unintentional overconsumption and acute alcohol intoxication from beverages which contain as much as 4 standard drinks in a single-serve container. A 750 mL glass bottle and a multi-pack of single-serve flavoured purified alcoholic beverages at 1.5 standard drinks each are both examples of multi-serve packaging. Although alcoholic beverages sold in multi-serve packaging also carry the risk of overconsumption, the risk of unintentional overconsumption is reduced because of consumer awareness that there are multiple servings of alcohol in those products.
- Restricting the alcohol content based on the number of standard drinks rather than restricting the container size will achieve the public health and safety objectives while also providing flexibility for manufacturers with regard to compliance with these Regulations.

4. Tolerance

Two respondents commented on a need for a “tolerance” threshold to be established for flavoured purified alcoholic beverages. “Tolerance” is a technical term that represents an acceptable margin of error between the alcohol content originally declared on the label and the value measured through later laboratory testing. The alcohol content of a beverage can fluctuate after it is packaged. Tolerance thresholds are allowed for other types of alcoholic beverages (e.g. wine, beer, spirits), and are also outlined in the Health Canada guidance documents.

Response

Tolerance thresholds have been established for flavoured purified alcoholic beverages and are available in the guidance documents.

Health Canada has worked closely with the CFIA and provinces and territories to ensure compliance with the proposed restrictions of 1.5 standard drinks for flavoured purified alcoholic beverages and that the amount of alcohol in the product is reflected on the label. The Canadian Association of Liquor Jurisdictions (CALJ) has existing harmonized alcohol tolerances for various types of alcoholic beverages but does not have one specific to flavoured purified alcoholic beverages. CALJ tolerance levels were established through a process that compared existing tolerances among Canadian provinces and territories, reviewing tolerances of international associations, and factoring in analytical uncertainty in the measurement of alcohol content. CALJ’s tolerance level for Miscellaneous Products (+/–0.5% alcohol by volume), such as coolers, will be adopted for compliance purposes.

5. Transition period

Some respondents requested a transition period. Recommendations ranged from 60–180 days for the entire supply chain (e.g. manufacturers) to 180 days for retailers only. The purpose of the transition period would be to allow suppliers and retailers to liquidate existing inventory and minimize costs related to the disposal of non-compliant products that remain once these Regulations come into force.

Response

These Regulations come into force immediately upon their registration, without a subsequent transition period.

- Large, single-serve flavoured purified alcoholic beverages have been implicated in numerous hospitalizations and two deaths in the province of Quebec since December 2017. A transition period to exhaust existing inventory means allowing more of these products to be sold to Canadians, posing a risk to health and safety.
- While no transition period is provided, there has been a high level of engagement and outreach with industry throughout the majority of 2018 and early 2019 to raise awareness of the Government of Canada’s intent to limit the alcohol content in flavoured purified alcoholic beverages.

6. Issues being examined under the new Canadian Drugs and Substances Strategy

Many respondents also expressed concerns and made recommendations on issues outside the scope of this regulatory initiative, such as

- restrict packaging, marketing and advertising that appeal to youth;
- require enhanced labelling, including warning labels, standard drink labels, and nutrition information (calories, sugars);
- reduce the accessibility of these products, such as through minimum pricing or higher volumetric excise duties;
- promote public awareness, treatment, and harm reduction;
- support research and surveillance; and
- conduct a comprehensive review of all existing alcohol legislation and policies.

Response

These additional recommendations will not be addressed in these Regulations; however, they are being taken into consideration under the new Canadian Drugs and Substances Strategy (CDSS).

The Government of Canada is committed to addressing alcohol-related harms more broadly through a comprehensive, collaborative, compassionate and evidence-based public health approach. In December 2016, the Minister of Health introduced the CDSS to address illegal and legal substances, including alcohol. In September 2018, Health Canada launched public consultations on CDSS. The consultations ended on December 4, 2018. Feedback from these consultations, as well as recommendations from the HESA “Report on Highly Sweetened Pre-mixed Alcoholic Beverages,” will be considered as Health Canada develops an approach to alcohol under the CDSS in the months to come.

Modern treaty obligations and Indigenous engagement and consultation

When Health Canada published its March 19, 2018, NOI and proposed Regulations in the *Canada Gazette*, Part I, on December 22, 2018, the Department notified and sought input from all health, government, academic, and industry stakeholders registered in CSIMS. The NOI also went out to all Canadians who are registered in CSIMS and have an interest in the topic of alcohol. Although Health Canada did not specifically reach out to individual Indigenous associations and governments, the NOI was sent to a number of Indigenous organizations and Councils registered in CSIMS. Health Canada did not receive any submissions from these stakeholders on its NOI or on the regulatory proposal in the *Canada Gazette*, Part I.

Health Canada did receive feedback from several regional/municipal health units, including two regional health units that service Indigenous communities in Northern Ontario and one regional health centre that services Indigenous communities in Manitoba. All three regional health units were supportive of Health Canada taking regulatory action on these products.

Instrument choice

Addressing the public health and safety risks associated with these types of beverages requires a combination of coordinated measures at the federal, provincial and territorial (PT) levels. Below are the options that were considered.

1. Status quo — No action

Many of the regulatory controls on alcohol are set at the PT level. This extends to controls over distribution, pricing, and additional controls over marketing and advertising.

The Government of Quebec has enacted legislative changes to restrict the sale of beer blends with more than 7% alc/vol to the SAQ, its government-run liquor distributor. As a result, the sale of beer blends with more than 7% alc/vol is no longer permitted in corner stores and grocery stores. To remain eligible for sale in corner stores and grocery stores, such products need to be reformulated to contain 7% alc/vol or less.

The risks of these products have mainly been documented in Quebec. This is due to the fact that the manufacturing and distribution of these types of products were initially concentrated in Quebec and only produced by a few companies. However, market analysis indicates that these types of products have been entering markets in other provinces, in particular Ontario, and are being manufactured by more companies, including large alcohol manufacturers.

By not taking any action, flavoured purified alcoholic beverages and their associated risks could emerge on a national scale as the industry explores market opportunities in this sector.

2. Public education and awareness

In 2007, a comprehensive strategy on “Reducing Alcohol-Related Harm in Canada” was published by the National Alcohol Strategy Working Group. Members of the working group comprised a wide range of stakeholders and included representatives from federal, provincial and territorial governments, health stakeholders, and the alcohol beverage and hospitality industries. This strategy identified numerous areas for action, including recommendations under health promotion, prevention and education to

- develop and promote national alcohol drinking guidelines, including through a multi-sectoral social marketing campaign;
- support and fund local communities to develop and implement community-wide health promotion initiatives;
- regulate standardized, easily visible labels that convey the number of standard drinks in each container;
- develop and evaluate policies and programs that are appropriate to youth stages of development; and
- develop and evaluate policies and programs in schools and colleges through a national collaborative

initiative.

Following this report, *Canada's Low-Risk Alcohol Drinking Guidelines* were developed and introduced to Canadians in 2011. These Guidelines have been promoted on the websites of governments, health stakeholders and industry. Industry associations, liquor control boards, and non-profit organizations also have education and awareness programs on responsible alcohol consumption and alcohol harm reduction.

The recent trend in acute alcohol intoxication associated with this category of products has emerged despite extensive and ongoing public education and awareness. In the 2015 Chief Public Health Officer's report on alcohol consumption in Canada, it was noted that alcohol is one of the few health-related topics where mass media campaigns are rarely effective and they have not yet changed drinking behaviour or the intention to drink. Although educational campaigns can increase knowledge and shift attitudes, building awareness is a much slower process and not effective in addressing the urgent health and safety risks of these products.

3. Voluntary measures by industry

On March 19, 2018, when Health Canada issued its NOI, the Department also called on industry to come forward with voluntary actions.

Although one manufacturer has ceased production of the beverage implicated in one of two deaths, similar products containing as many as 4 standard drinks in a single-serve container continue to be sold in Canada. Market analysis shows that other companies are entering the market with these types of products in Canada.

In subsequent meetings with industry associations and individual companies, Health Canada learned that all major alcohol associations have voluntary advertising standards to protect youth and promote responsible consumption.

Market analysis has determined that the vast majority of spirits-based beverages contain fewer than 2 standard drinks.

4. Regulations under the *Food and Drug Regulations* (recommended option)

Public awareness and voluntary measures have not been effective in stopping the proliferation of flavoured purified alcoholic beverages in large single-serve containers. Although the Government of Quebec has taken action to restrict the distribution of these products, they continue to be sold in other jurisdictions. Market analysis suggests that products that can no longer be sold in grocery and corner stores in Quebec as the result of the new provincial legislation (i.e. beer blends with an alcohol content above 7% alc/vol) are entering stores in Ontario where there are no such restrictions. Therefore, regulatory action has been taken to (1) address the immediate issue; and (2) prevent these products from increasing market share in other PT jurisdictions.

These Regulations have been designed to mitigate the risks associated with the high alcohol content of these products while providing industry with flexibility on how to modify their products to be in compliance with these Regulations. Manufacturers can reformulate their products, change the size of containers, or use a combination of both measures.

Regulatory analysis

Costs and benefits

The cost-benefit analysis (CBA) seeks to explain the qualitative and quantitative costs and benefits of these Regulations. A conservative approach to the costs has been taken whereby Health Canada is of the view that the costs are overstated. The data used to complete the analysis was collected through costing surveys distributed to alcoholic beverage industry stakeholders, a literature review, and expert opinions. All costs and benefits have been calculated over a 10-year period, and the present value (PV) figures have been discounted by 7% as required by the Treasury Board Secretariat.

The estimated one-time incremental costs for the affected industry to comply with these Regulations are \$7,200,180 (PV). This translates to an annualized average cost of \$1,025,144.

It is anticipated that the Regulations will reduce the health and safety risks associated with unintentional overconsumption and acute alcohol intoxication as a result of consuming flavoured purified alcoholic beverages.

Table 1: Cost-benefit statement (2018 dollars)

Quantitative impacts				
Stakeholder	Year 1	Year 10	Total (PV)	Annualized Average

Cost of resizing and relabelling**Industry****\$7,704,193 \$0****\$7,200,180 \$1,025,144****Qualitative impacts****Benefits**

Reducing the health and safety risks associated with unintentional overconsumption and acute alcohol poisoning.

Preventive efforts in reducing short- and long-term risks of alcohol harm to young people.

Determining the baseline

Health Canada distributed a costing survey to 21 national and provincial associations representing different sectors of the alcohol industry and to the main, known manufacturers and distributors of beverages impacted by these Regulations. The purpose of the survey was to collect data to further understand the current marketplace and estimate the costs and benefits associated with complying with the proposed Regulations. Health Canada received responses from five stakeholders; however, only one provided cost data (some respondents indicated that none of their products would be subject to the proposed Regulations; therefore, they would not incur any costs as a result of these amendments).

These Regulations are designed to mitigate the risks associated with the high alcohol content of flavoured purified alcoholic beverages while providing industry the flexibility on how they would modify their products to be compliant with the Regulations. Manufacturers could choose to reduce the alcohol content of their products by reformulation, to change the container size of their products, or to combine both measures. The CBA was developed on the assumption that industry would choose the least-cost option to comply with the proposed Regulations. Based on the data available, the least-cost option was assumed to be resizing and relabelling containers. Nevertheless, a range of costs associated with resizing and reformulating is presented in the “Sensitivity analysis” section.

The baseline of the analysis took into account the fact that (1) the Government of Quebec enacted legislative changes to restrict the sale of beer blends with more than 7% alcohol to the SAQ, meaning that the sale of beer blends with more than 7% alc/vol is no longer permitted in corner stores and grocery stores; and (2) the manufacturer of a popular flavoured purified alcoholic beverage announced that it suspended sales of the product in Quebec until further notice. During consultations, the manufacturer confirmed that it ceased production and distribution of this product in Canada as of November 2017. The manufacturer also confirmed that their flavoured purified alcoholic beverages were sold primarily in Quebec and Ontario, with limited distribution in Alberta and British Columbia.

Costs of the Regulations

Table 2 shows the projected total costs for the industry that would be directly impacted by these Regulations. It is assumed that the one-time costs would occur in the first year.

Table 2: Costs to industry (in 2018 dollars)

	Year 1	Year 2 to Year 10	Total (PV)	Annualized Average
Option: Resizing and relabelling containers				
External graphic design	\$7,188,754	\$0	\$6,718,461	\$956,558
Disposal of old packaging	\$515,439	\$0	\$481,719	\$68,586
<i>Total for resizing and relabelling containers</i>	<i>\$7,704,193</i>	<i>\$0</i>	<i>\$7,200,180</i>	<i>\$1,025,144</i>

Industry costs

Given that only one stakeholder provided the requested cost data, Health Canada applied a cost-per-unit-sold approach and extrapolated the data to the entire market that would be impacted by these Regulations. A typical approach in determining the cost to industry is cost per SKU (stock keeping unit). Health Canada is aware that there are other flavoured purified alcoholic beverages in the market, but it is difficult to determine the number of SKUs. A substitute approach is to estimate the volume of sales. As a result of receiving cost information from only one manufacturer, there is a possibility that compliance costs have been underestimated for some manufacturers, especially if the scale of production differs from the single manufacturer who provided data. Based on industry data, Health Canada estimated that there were 10.2 million units sold in 2017, with the majority of sales in Quebec. On a cost-per-unit-sold basis, the estimated cost to resize and relabel is \$0.75.

Health Canada did not receive complete information for the resizing and relabelling option. No cost data was provided for new containers of a different size; only costs for relabelling and disposing of old packaging were submitted. It is possible that a manufacturer may, in order to meet the proposed alcohol content limit, adopt smaller containers than the current size. This could lead to a cost savings to the

businesses. Health Canada is not able to substantiate this without actual data.

Other costs considered

Stakeholders indicated that liquor boards may require that they obtain new Universal Product Codes (UPC) and resubmit products for listing, which may result in listing fees. As stated in responses to the survey, it is not possible for stakeholders to quantify such costs until they know exactly which products will be impacted. Health Canada recognizes that there may be additional costs related to listing fees; however, in the absence of data from stakeholders, the Department could not quantify it in the analysis.

Stakeholders asked Health Canada to consider a 180-day transition period to allow retailers time to liquidate their inventory. Stakeholders did not provide cost data to quantify the impact of not having a transition period. As a result, Health Canada acknowledges that without a transition period there may be additional costs for manufacturers or retailers to dispose of non-compliant stock. Health Canada has considered the following three possible scenarios:

- 1. Given that the Regulations were pre-published in draft form and that Health Canada has conducted extensive consultations since March 2018, manufacturers may have already liquidated inventory. One major manufacturer has stated that all of their products will comply with these Regulations by early in the second financial quarter of 2019. This indicates that the company has ceased the production of non-compliant products some time ago. As a result, the remaining inventory loss may have been significant by the coming into force date.
- 2. If the common practice is for manufacturers to provide retailers with the products on a consignment basis, there may be costs for manufacturers to retrieve unsold units and dispose of them. It is difficult for Health Canada to estimate the cost of this inventory loss without appropriate data.
- 3. If the retailers have to absorb the cost of disposing non-compliant products, they may incur some costs. However, given that Health Canada consulted extensively and signalled its intention to regulate these types of products (pre-consultations throughout 2018 and pre-publication of the proposed Regulations in December 2018), retailers may have preemptively depleted much of their stock by means of discounts or other strategies to minimize losses. It is noted that the CBA takes into consideration the cost of production but not the costs related to profit margins.

Cost summary

The projected total PV costs to industry over a 10-year period (discounted by 7%) for resizing and relabelling containers is \$7,200,180.

Benefits of the Regulations

Qualitative benefits

The objective of these Regulations is to reduce the health and safety risks associated with unintentional overconsumption and acute alcohol poisoning as a result of consuming flavoured purified alcoholic beverages. As pointed out in the HESA report, the appearance of flavoured purified alcoholic beverages on the market at a time when rates of acute alcohol poisoning are on the rise is worrisome. Deaths due to alcohol poisoning in Canada have increased from 210 in 2007 to 313 in 2014. Moreover, between 2015 and 2016, there were approximately 77 000 hospitalizations entirely caused by alcohol compared with approximately 75 000 for heart attacks. There are many factors that influence the effects of alcohol on an individual; however, there are scientific studies linking health risks to the amount of alcohol consumed. This risk increases proportionally to the quantity of alcohol consumed.

Furthermore, flavoured purified alcoholic beverages appeal to youth because of their high alcohol content, sweet flavouring, attractive packaging, and low price. In addition, the large single-serve containers can promote unintentional overconsumption. Evidence from a study conducted in Sherbrooke, Quebec, showed that, in 2017, 17% of young people (12 to 24 years of age) who were admitted to emergency departments in this city due to alcohol poisoning had consumed this type of alcoholic beverage. The study also indicated that 56% of these patients presented with an altered level of consciousness. Short-term outcomes of overconsumption of alcohol include moderate to severe alcohol intoxication, which can lead to alcohol-related injury, impaired driving, hospitalization and even the risk of death. There are also long-term adverse outcomes when alcohol is introduced at an early age, namely the increased risk of developing alcoholism later in life.

Distributional analysis

Health Canada is aware of two manufacturers and one distributor of flavoured purified alcoholic beverages. One main manufacturer is located in Quebec. The company's products are mainly distributed within the province of Quebec. This company indicated that there may be revenue loss, product discontinuation and workforce reduction as a result of the proposed Regulations. However, after the Government of Quebec adopted Bill 170 in June 2018, the company resized and/or reformulated some of

their products to meet Quebec's new requirements. Although some of their products may have been discontinued, new flavoured purified alcoholic beverages were also introduced. Based on consultations, there was no indication that the company's sales have declined or that their workforce has been reduced.

Sensitivity analysis

Due to limited costing data, it is not possible to identify the potential financial impact of a manufacturer choosing to combine measures to reduce the alcohol content of their products. Based on the response Health Canada received, the estimated costs represent either reformulating or resizing but not a combination of both measures. Therefore, a manufacturer's costs are expected to fall within the range shown in the table below based on the measures or combination of measures that best suit their product lines.

All assumptions on costs remain the same as those outlined in the "Industry costs" section. Table 3 shows the one-time costs for each option.

Table 3: Range of costs (in 2018 dollars)

	Year 1	Year 2 to Year 10	Total (PV)	Annualized Average
Option: Resizing and relabelling				
External graphic design	\$7,188,754	\$0	\$6,718,461	\$956,558
Disposal of old packaging	\$515,439	\$0	\$481,719	\$68,586
<i>Total for Resizing/Relabelling</i>	<i>\$7,704,193</i>	<i>\$0</i>	<i>\$7,200,180</i>	<i>\$1,025,144</i>
Option: Reformulating and relabelling				
Reformulation	\$2,102,730	\$0	\$1,965,168	\$279,796
External graphic design	\$7,188,754	\$0	\$6,718,461	\$956,558
Disposal of old packaging	\$515,439	\$0	\$481,719	\$68,586
<i>Total for Reformulating/Relabelling</i>	<i>\$9,806,923</i>	<i>\$0</i>	<i>\$9,165,349</i>	<i>\$1,304,939</i>

Small business lens

All businesses impacted by these Regulations were identified as medium or large businesses. The small business lens does not apply, as there are no impacts on small businesses associated with these Regulations.

"One-for-One" Rule

These Regulations do not include new reporting requirements and will not impose new, or reduce existing, administrative burdens on business. Therefore, it has been determined that the "One-for-One" Rule does not apply.

Regulatory cooperation and alignment

Canada is not the only jurisdiction to enact regulations on this category of products. Some jurisdictions (e.g. the United States) chose a more targeted approach, focusing on flavoured malt-based products while others (e.g. the United Kingdom) focused on spirits-based mixes. The specific alcohol composition of these products in each jurisdiction was impacted by the existing regulatory/tax system, which allowed these products to be sold at a lower price. In each case, it appears that restrictions were enacted due to similar health and safety risks related to overconsumption among youth. Where possible, Health Canada has attempted to align these Regulations with existing regulations and policies, with necessary distinctions to address the particular circumstances in Canada.

United States

The regulatory environment for alcohol in the United States shares many similarities with Canada. In the United States, distilled spirits are subject to higher taxes and limited retail availability, whereas beer can be legally sold in more retail locations, including convenience stores and gas stations. As a result, manufacturers in the United States started producing flavoured purified "beer" products: for example, they started with a fermented malt beer base, which was then filtered to remove all taste, colour, and smell attributed to beer, and flavouring was added such that the final product bore the taste of the added flavouring.

On January 3, 2006, the U.S. Trade and Tax Bureau (TTB) released a regulatory ruling defining a new class of beverages called "flavoured malt beverages" and stipulating their compositional requirements: malt beverages that contain not more than 6% alc/vol may derive no more than 49% of their alcohol content from flavours and other non-beverage ingredients; for malt beverages containing more than

6% alc/vol, not more than 1.5% of the volume of the finished product may consist of alcohol derived from added flavours containing alcohol and non-beverage ingredients containing alcohol.

Most states adopted the TTB definition; however, the states of Utah, Maine, and California sought to reclassify these beverages as distilled spirits. The reclassification succeeded in Maine and Utah, and, as a result, flavoured malt beverages became subject to higher taxes and restrictions on points of sale in these states.

Health Canada's definition of flavoured purified alcoholic beverages is based on the TTB definition of flavoured malt beverages, with two key distinctions: (1) Health Canada's definition is not limited to malt beverages, in recognition that these products can be produced from sources other than malt; and (2) Health Canada is only regulating the alcohol content of these products and not their flavouring, as this was determined to be a more flexible approach to reducing the health and safety risks of these products.

The United States also enacted labelling requirements on a single manufacturer of flavoured purified alcohol. After several reports of deaths of young adults in 2013 due to the consumption of the flavoured alcoholic beverage, the Federal Trade Commission (FTC) examined whether the manufacturer violated federal law by using deceptive marketing and ordered alcohol facts labels on products disclosing the number of standard drinks contained in the product.

The order stipulated that all of the manufacturer's flavoured malt beverages containing more than two servings of alcohol must include disclosures. In particular, it required that the company seek approval from the U.S. TTB to place an "Alcohol Facts" disclosure panel on their containers.

The amount of alcohol equivalent to the definition of a standard drink in the United States is slightly higher than in Canada, at 17.7 mL of pure alcohol, or approximately 1.1 standard Canadian drinks. By setting the limit to 1.5 standard Canadian drinks instead of 1 standard Canadian drink, products containing 1 standard U.S. drink could continue to be imported into Canada without needing to be reformatted or reformulated.

United Kingdom

In the United Kingdom, like in Canada and the United States, distilled spirits are subject to higher taxes. However, when flavoured spirits-based alcoholic beverages were first introduced in the United Kingdom, they were classified as "wine coolers." Wine coolers at the time were subject to lower taxes than beer and spirits. Tax increases on flavoured alcoholic beverages were first applied generally in 1997, with an increase of 40% to place them in the same category as beer. In 2002, taxes on spirits-based flavoured beverages increased by 65% to become the same rate of duty as spirits.

A voluntary Code of Practice was also developed in 1996, which resulted in a number of changes to the marketing and branding of these products. Moreover, all of Britain's major retailers signed onto the Code of Practice and many supermarket chains underwent in-store changes to ensure that flavoured alcoholic beverages were properly displayed where there could be no doubt that their content was alcoholic, and that they could only be purchased by consumers over 18 years of age.

Australia

In April 2008, the Australian federal government imposed a 70% tax on "ready-to-drink" flavoured alcoholic beverages, effectively shifting them into the same taxation category as distilled spirits. This policy intervention aimed to reduce the harm from binge drinking among young people and address the risk posed by these products, which had packaging and marketing strategies specifically designed to attract youth. More specifically, this policy intervention, known as the "alcopops tax," sought to reverse a trend that had emerged in July 2000 when tax reforms created a loophole allowing these types of beverages to be taxed at 40% less per litre of alcohol than distilled spirits, and had resulted in the significant growth of these products in Australia.

The reduced tax on "ready-to-drink" alcoholic beverages in Australia between 2000 and 2008 statistically correlated with an increase in emergency room visits attributed to alcohol among females aged between 18 and 24. Following the "alcopops tax," a statistically significant decrease in emergency room visits was noted in males aged 15 to 50, females aged 15 to 65 years, and particularly females aged 18 to 24.

New Zealand

In 2013, the New Zealand federal government proposed limits on the number of standard drinks and the alcohol content in "ready-to-drink" flavoured alcoholic beverages in an Alcohol Reform Bill. The legislation originally proposed restricting "ready-to-drink" beverages to 5% alc/vol and limiting them to containers holding no more than 1.5 standard drinks. Following consultations, the Government of New Zealand introduced voluntary measures to limit the risks of these beverages, and indicated they would enact regulations should the voluntary measures prove ineffective.

Industry developed and introduced the following voluntary code: a maximum strength of 7% alc/vol and a

limit of 2 standard alcoholic drinks per single-serve container; use of clearly displayed labels indicating the number of standard alcoholic drinks on containers; prohibition of advertising targeting minors; limitations on advertising and/or sponsorship such that 75% of the audience must be 18 years or older; and a commitment to minimize harmful consumption.

Domestic alignment — Quebec

On June 12, 2018, the Government of Quebec adopted Bill 170, which restricted the sale of beer blends with more than 7% alc/vol to only the SAQ. As a result, the sale of beer blends with more than 7% alc/vol is no longer permitted in corner and grocery stores.

Common container sizes for single-serve beer and malt-based beverages are 341 mL or 355 mL. At 7% alc/vol, a 341 mL or 355 mL container would contain approximately 1.4 standard drinks. Therefore, Health Canada's Regulations will not further impact the majority of flavoured purified alcoholic beverages sold in Quebec in 341 mL or 355 mL containers.

There are currently no regulations specific to this type of product in any province or territory other than Quebec.

Trade considerations

Canada is subject to the provisions of the WTO Agreement on Technical Barriers to Trade (TBT), which seeks to ensure that technical regulations do not create unnecessary obstacles to trade. The TBT does not impede Health Canada's ability to make regulations to address a legitimate public health/safety concern. Article 2 of the TBT acknowledges and recognizes a government's right to regulate in the public interest, but such technical regulations cannot unjustifiably encumber trade or be more trade-restrictive than necessary to achieve policy objectives.

These Regulations aim to be origin neutral, and implementation should not negatively impact the competitive opportunities of imported products compared to similar products of domestic origin. Further, the objective of protecting human health allows for a strong argument that this is not an "unnecessary obstacle to international trade."

It is also unlikely that the amendments will discriminate between domestic and foreign investors or a third party, respecting national treatment and most-favoured nation treatment obligations under Canada's international investment agreements (IIA), as outlined in the North American Free Trade Agreement (NAFTA), the Comprehensive Economic and Trade Agreement (CETA), and as proposed in the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). With respect to the minimum standard of treatment obligation under Canada's IIAs, these Regulations are unlikely to meet the high threshold of arbitrary, capricious or egregious conduct required to establish a breach of that obligation.

Strategic environmental assessment

In accordance with *The Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals*, a preliminary scan concluded that a strategic environmental assessment is not required.

Gender-based analysis plus

A gender-based analysis plus (GBA+) was conducted and it was observed that the availability of highly sweetened, flavoured alcoholic beverages may impact some populations, including women, youth and low-income populations, more significantly.

According to the Canadian Tobacco, Alcohol and Drugs Survey (CTADS), in 2017, 78% (or 23.3 million) of Canadians reported consuming an alcoholic beverage in the past year. The rate of alcohol use among young adults aged 20 to 24 (83%) was higher than among youth aged 15 to 19 (57%) and adults aged 25 years and older (79%). These rates were unchanged from results of the 2015 CTADS.

Moreover, data from the 2017 CTADS indicates that young adults (aged 20 to 24) had riskier patterns of alcohol consumption compared to youth (aged 15 to 19) and adults older than 25 years. Twenty-nine percent (or 552 000) of young adult drinkers exceeded the guideline for chronic risk, defined as no more than 10 standard drinks a week for women, with no more than 2 a day most days, and 15 standard drinks a week for men, with no more than 3 a day most days. In comparison, 18% (or 203 000) of youth drinkers and 20% (or 3.9 million) of adult drinkers exceeded this guideline.

Although findings from the CTADS 2017 indicate a similar prevalence of males and females reporting past-year alcohol use (79% and 77%, respectively), this is a result of an increase in past-year alcohol use among females compared to 2015. Evidence from the United States suggests that females consume a higher proportion of flavoured alcoholic beverages than men, and that these products may be more appealing to women because of the marketing, advertising, packaging and flavouring.

For instance, a study published in 2014 in the American Journal of Drug and Alcohol Abuse examined the brand-specific consumption prevalence and consumption share of flavoured alcoholic beverages among a national sample of underage drinkers in the United States. Half of the respondents reported consuming a flavoured alcoholic beverage during the past 30 days, making these beverages second only to beer among all alcoholic beverage types. Consumption prevalence was higher among females (61.5%) than males (38.8%).

Women may also experience more harm related to the consumption of these particular types of beverages, as some products contain a quantity of alcohol that corresponds to heavy drinking, defined as 4 or more drinks per day for women and 5 or more drinks per day for men. Many flavoured purified alcoholic beverages contain as many as 4 standard drinks in a single-serve container. At the upper level, this amount of alcohol is double the recommended daily limit for women in *Canada's Low-Risk Alcohol Drinking Guidelines*. Moreover, the rate of alcohol-related hospitalizations and deaths is increasing faster for women than for men in Canada. Between 2001 and 2017, the rate of alcohol-related deaths increased 26% for women compared to 5% for men.

The low price combined with the high alcohol content of many flavoured purified alcoholic beverages means that these types of alcoholic beverages may be more appealing and more accessible to youth and people with lower incomes. Many of these products are marketed specifically at young people. At certain times of the year, discounts can bring prices as low as \$0.74 per standard drink. This price falls well below the recommended price of \$1.71 per standard drink, making these products very accessible.

Given that data suggests these beverages may disproportionately impact women, youth and low-income populations, the Government of Canada is taking a strict approach and limiting the maximum amount of alcohol in a single-serve container of these beverages to 1.5 standard drinks.

Indigenous considerations

Evidence suggests that Indigenous peoples are at a greater risk of experiencing complex mental health and substance use issues due to a variety of factors, including the intergenerational impacts of colonialism and the Indian residential school experience, as well as social, economic, and cultural inequities that persist today.

According to phase 3 of the First Nations Regional Health Survey, the only national health survey of First Nations living on-reserve and in northern communities across Canada, approximately 35% of First Nations adults (18 years and older) on-reserve reported heavy drinking and 25% of First Nations youth reported having consumed alcohol within the past year. Of these youth, more than 50% indicated that they had engaged in heavy drinking one or more times per month. The Canadian Community Health Survey — Annual Component, 2010–2012, a national survey conducted by Statistics Canada, provides information on First Nations living off-reserve, and Métis and Inuit adults. According to the survey, approximately 30% of First Nations living off-reserve, Métis and Inuit adults reported heavy drinking compared to approximately 19% of non-Indigenous adults.

Similarly, Indigenous youth living off-reserve reported more frequent heavy drinking than non-Indigenous youth. The Aboriginal Health Foundation indicates that premature death due to alcohol is two times greater for Indigenous peoples than for the general population, and Indigenous youth are two to six times at greater risk for every alcohol-related problem than their non-Indigenous counterparts. Given the above, alcohol is considered an urgent public health concern by many Indigenous communities across Canada, and has been ranked as the top challenge for community wellness.

All Canadians, including Indigenous peoples and their communities, will benefit from the public health and public safety approach taken in the development of these regulatory amendments pertaining to flavoured purified alcoholic beverages, particularly the restrictions on the amount of alcohol that these products can contain.

Recognizing the unique context, interests and priorities of First Nations, Inuit and Métis across Canada, tailored interventions may be required to address problematic alcohol use by Indigenous Canadians. This is why, under the CDSS, the Government of Canada will continue to work with Indigenous governments, leaders and communities to better address substance use and related issues from a culturally competent, holistic, distinctions-based approach that addresses the social determinants of health and ensures that the unique rights, interests and circumstances of the First Nations, Inuit and Métis peoples are acknowledged, affirmed and implemented in partnership.

Implementation, compliance and enforcement, and service standards

Implementation

Regulated parties were first made aware of Health Canada's intention to regulate in March 2018, and the Department has had ongoing engagement with industry and impacted manufacturers since then. However, due to the urgent health and safety issue demonstrated by the increase in emergency room visits by youth and two deaths attributed to these products over the past 18 months, there is no transition period after

these Regulations come into force.

Compliance and enforcement

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* as it relates to food.

While it is the responsibility of the industry to comply with regulatory requirements, compliance will be monitored as part of ongoing domestic and import inspection programs, respecting the resources that the CFIA has for enforcement and compliance verification. Appropriate enforcement action will be risk-based.

Compliance with and enforcement of alcohol regulations is also addressed at the PT level. Provincial and territorial liquor boards regularly assess alcoholic beverages to ensure that product listings adhere to federal and provincial/territorial regulatory requirements.

Health Canada has developed guidance in consultation with the CFIA and PT liquor boards to guide assessments and the implementation of these regulatory amendments.

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