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December 22, 2018

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

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. ¹ However, they do not taste like alcohol, as the alcohol base is purified, flavoured ² and often highly sweetened, which masks the alcohol taste. These flavoured purified alcoholic beverages ³ are formulated, packaged, and marketed in a manner that can appeal to a younger, more impressionable 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 ⁴ in what appears to be a single-serve container. Some of these products contain as much alcohol as four 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 ⁵ — 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 instructed the national public health director to examine cases of alcohol poisoning following the consumption of beverages that were highly sweetened with high alcohol content, and that the provincial Minister of Public Health report back with findings and recommendations. The ministère de la Santé et des Services sociaux asked the Institut national de santé publique du Québec (INSPQ) to study the issue. The INSPQ published its report ⁶ 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. ⁷

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. ⁸ There were another four cases of alcohol overdoses (e.g. poisoning) related to these products documented in the Canadian Hospitals Injury Reporting and Prevention Program in 2017. ⁹

In December 2017, one of these products was implicated in the death of a 30 year old male in Quebec, and another product was potentially implicated in the death of a 14 year old female in Quebec in March 2018. Although the exact cause of death of the 14 year old female is pending a coroner's investigation, 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) 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 ¹⁰ was tabled 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 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 trade purposes and can provide consumers with predictability on what is contained in certain foods. Currently, 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 marketing, 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. ¹¹, ¹²

In response to the death in March 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.

This new class of flavoured purified alcoholic beverages is 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 taxes (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. ¹³, ¹⁴ The results of an experiment ¹⁵ exploring the acceptability of a range of alcoholic and non-alcoholic beverages among youth and young adults (aged 12 to 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 \(https://ro.uow.edu.au/cgi/viewcontent.cgi?referer=&httpsredir=1&article=2141&context=hbspapers\)](https://ro.uow.edu.au/cgi/viewcontent.cgi?referer=&httpsredir=1&article=2141&context=hbspapers) ¹⁶ 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, ¹⁷ 100% 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 heavy or excessive drinking and increases the risk of unintended intoxication. The non-resealable nature of these containers 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 four standard drinks.

At four standard drinks per container, consuming 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 amount 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). ^{18, 19}

The impact would be even greater for teenagers who, on average, weigh less than adults. For a youth weighing 100 lbs, consuming a single flavoured purified alcoholic beverage containing four standard drinks would result in severe intoxication (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 (<http://www.ccsa.ca/ResourceLibrary/2011-Summary-of-Evidence-and-Guidelines-for-Low-Risk-Drinking-en.pdf>) ("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. ²⁰ Cost and convenience are key factors in youth's choice of which alcoholic beverage to consume (after taste and alcohol strength), ²¹ 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. ²² Spirits and spirits-based beverages with more than 7% alc/vol have the highest excise duty rates. This results in a market incentive for spirits-based coolers to be lower alcohol (i.e. 7% or less alc/vol) and for flavoured purified alcohol to be higher alcohol (i.e. between 7.1 and 11.9% alc/vol).

Lower excise rates also allow for lower retail prices, making these 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 ²³ 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. ^{24, 25}

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. They heard testimony from 15 witnesses and received seven 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 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 grams or 17.05 millilitres 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 proposed Regulations.

Caffeine

Initially there were media reports of caffeine being mixed with flavoured purified alcoholic beverages, which can increase the risk of unintentional overconsumption (e.g. caffeine masking the depressant effects of alcohol). It is important to clarify that it is illegal in Canada to sell alcoholic beverages containing 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 in their products. However, the amount of caffeine contributed to beverages by such flavourings is very low. 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 below 1 mg per 568 mL can (as confirmed through testing by the Canadian Food Inspection Agency). 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 this proposal 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. This would be achieved by regulatory amendments that limit the alcohol content in single-serve containers of flavoured purified alcoholic beverages.

Description

Health Canada is proposing to amend Division 2 (Alcoholic Beverages) of the FDR 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 taste.
2. Restrict the alcohol content in beverages in this new class. Beverages that meet the definition of the new class would be 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 would 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.

The amendments would come into force upon their registration following publication in the *Canada*

Gazette, Part II. There would be no transition period.

1. Definition

The products of concern are 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 have subsequently been flavoured and/or sweetened such 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 are currently malt-based.

For further clarification, the proposed definition would explicitly exclude 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 the proposed Regulations. As noted in the “Background” section, spirits are subject to higher excise taxes 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 1.0 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 reduces the health and safety risks associated with unintentional overconsumption of spirits-based beverages, Health Canada is not including spirits-based beverages in the scope of this regulatory proposal.

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 not used to determine the scope of alcoholic beverages affected by the amendments.

2. Restriction of the amount of alcohol

It is proposed that the amount of alcohol be restricted to 25.6 mL of alcohol per container to reduce the risks of unintentional alcohol intoxication, particularly among youth. This limit is equivalent to 1.5 standard alcoholic drinks.

The 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. 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. ²⁶

Alcohol generally takes at least 30 minutes to be fully absorbed into the bloodstream, ²⁷ 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 the drinking has stopped. ²⁸ 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 of 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 proposed 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 proposes to set the single-serve threshold at 1 000 mL regardless of whether the container can be resealed. Furthermore, the proposed Regulations are not specific to aluminum pull-tab cans in recognition of ongoing single-serve packaging innovation (e.g. Tetra Pak, pouches).

An exemption is proposed for glass bottles of at least 750 mL in volume. 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 drink) of alcohol. The policy intent is not to capture multi-serve containers. Although multi-serve containers may also be abused, the consumer would be making a conscious decision to overconsume alcohol and would be more aware of the consequences. Therefore, glass bottles of 750 mL and above would be exempted from the proposed Regulations.

4. Coming into force and transitional 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.

Large, single-serve flavoured purified alcoholic beverages have been implicated in numerous hospitalizations and at least one death within the past year and potentially another death pending the results of a coroner's investigation 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.

It is therefore proposed that the Regulations come into force upon their registration following publication in the *Canada Gazette*, Part II, with no transition period.

Regulatory development

Consultation

Consultations on the notice of intent and stakeholder engagement

Health Canada published a notice of intent (NOI) on its website ²⁹ on March 19, 2018, and in the *Canada Gazette*, Part I, ³⁰ 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 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.

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, the Department hosted a stakeholder meeting with provinces and territories, health stakeholders and major industry organizations to discuss shared areas of responsibility, namely on the subject of marketing and advertising.

Based on 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. Health Canada received 18 submissions in total: 5 from government organizations; 7 from health stakeholders; and 6 from industry stakeholders.

During the 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.

Stakeholder feedback

The vast majority of Canadians and stakeholders who submitted comments were supportive of the federal government taking action to reduce the health risks associated with these products. There were no major changes in stakeholder positions between the NOI and the follow-up consultation.

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.

Health Canada took into consideration all feedback received during consultations, as well as recommendations by HESA, literature reviews, and market research.

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, e.g. 7% 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 strikes 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 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 has proposed an exemption for flavoured purified alcoholic beverages in glass containers of 750 mL or more.

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. ³¹

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.

Modern treaty obligations and Indigenous engagement and consultations

When Health Canada published its March 19 NOI to amend the FDR, the Department notified and asked for input from all health, government, academic, and industry stakeholders registered in its Stakeholder Registry (CSIMS). The notice also went out to all Canadians who registered in the 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 notice was sent to a number of Indigenous organizations and Councils registered in the CSIMS. Health Canada did not receive any submissions from these stakeholders on its NOI.

Health Canada did receive feedback from many regional/municipal health units, including two regional health units that service Indigenous communities in Northern Ontario. Both 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 and 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, marketing and advertising, and pricing.

The Government of Quebec has enacted legislative changes to restrict the sale of beer blends with more than 7% alc/vol to the Société des alcools du Québec (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 would 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 in Quebec and were only manufactured by a few companies. However, market analysis indicates that these types of products are 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 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.³² Although educational campaigns can increase knowledge and shift attitudes,³³ 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 potentially implicated in a death, similar products containing up to 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 are already below 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 Quebec government has taken action to restrict the distribution of these products, they continue to be sold in other jurisdictions. Therefore, regulatory action is recommended to (1) address the immediate issue; and (2) prevent the proliferation of products outside of Quebec. 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.

The proposed Regulations have been designed to mitigate the risks associated with the high alcohol content of these products while providing industry the flexibility on how they would modify their products to be compliant with the proposed Regulations. Manufacturers would be able to reformulate their products, change the size of containers, or use a combination of both measures.

Regulatory analysis

Benefits and costs

The cost-benefit analysis (CBA) seeks to explain the qualitative and quantitative costs and benefits of the proposed Regulations. A conservative approach to the costs and benefits has been taken whereby Health Canada is of the view that the benefits in this analysis are understated and 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 figures (PV) have been discounted by 7% as required by the Treasury Board Secretariat.³⁴

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

It is anticipated that the proposal would 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\$)

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 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. 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 cost as a result of these amendments).

The proposed Regulations have been 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 proposed 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 has taken into account the fact that (1) the Government of Quebec has enacted legislative changes to restrict the sale of beer blends with more than 7% alcohol to the 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; 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 regulatory proposal

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

Table 2: Costs to industry (2018\$)

	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
Write off 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 this proposal. 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 costs associated with complying with the proposed Regulations 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 the survey, it is not possible to quantify this cost until the regulated parties 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.

Cost summary

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

Benefits of the regulatory proposal

Qualitative benefits

The objective of the proposed 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 about 77 000 hospitalizations entirely caused by alcohol compared with about 75 000 for heart attacks.³⁵ 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.³⁶

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) were admitted to emergency departments due to alcohol poisoning from this type of alcoholic beverage. The study also indicated that 56% of the 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.³⁷

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 in the province. This company has 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 to date, there is 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 costs should a manufacturer choose 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 and 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 cost for each option.

Table 3: Range of costs (2018\$)

	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
Write off 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
Write off 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 this proposal were identified as medium or large businesses. The small business lens does not apply, as there are no impacts on small businesses associated with the proposed Regulations.

“One-for-One” Rule

This regulatory proposal does not include new reporting requirements and will not impose new, or reduce existing, administrative burden 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 the products to be sold at a cheaper 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 the proposed 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.³⁸ 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. ³⁹

On January 3, 2006, the U.S. Trade and Tax Bureau (TTB) released a regulatory ruling defining a new class of beverages called “flavored 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 flavors and other nonbeverage 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 flavors containing alcohol and nonbeverage ingredients containing alcohol. ⁴⁰

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. ⁴¹

Health Canada’s proposed definition of flavoured purified alcoholic beverages was based on the TTB definition of flavored malt beverages, with two key distinctions: (1) Health Canada’s proposed 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 the flavouring, as that 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. ⁴²

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. ⁴³

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, ⁴⁴ or approximately 1.1 standard Canadian drinks. By setting the limit to 1.5 standard Canadian drinks instead of 1.0 standard Canadian drinks, products containing 1.0 standard U.S. drinks 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. ⁴⁵ 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. ⁴⁶

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 the content was alcoholic, and that they could only be purchased by consumers over 18 years of age. ⁴⁷

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 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. This had resulted in significant growth of these products in Australia. ⁴⁸

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 by males aged 15 to 50 and females aged 15 to 65 years, and particularly by females aged 18 to 24, was noted. ⁴⁹

New Zealand

In 2013, the New Zealand federal government proposed limits on the number of standard drinks and 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 with industry, the Government of New Zealand agreed to allow industry to introduce voluntary measures to limit the risks of these beverages, and to only enact regulations should the voluntary measures prove ineffective. ⁵⁰

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. ⁵¹

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 stores 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 proposed Regulations would 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 World Trade Organization (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 Agreement 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.

The proposed 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 proposed amendments would 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, the proposal is 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%).⁵²

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 up to 4 standard drinks in a single-serve container. 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.⁵³

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.⁵⁴

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.^{55, 56}

According to phase 3 of the Regional Health Survey, the only national health survey of First Nations living on-reserve and in northern communities across Canada, about 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.⁵⁷ 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, about 30% of First Nations living off-reserve, Métis and Inuit adults reported heavy drinking compared to about 19% for non-Indigenous adults.⁵⁸

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.⁵⁹ 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 proposed 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. ⁶⁰

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 at least one death attributed to these products over the past 12 months, there will be no transition period after the Regulations come into force.

Compliance and enforcement

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

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

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

Health Canada will develop guidance that will be available to the CFIA and PT liquor boards to guide assessments and implementation of these proposed regulatory amendments.

Contact

Bruno Rodrigue
Policy, Planning and International Affairs Directorate
Health Products and Food Branch
Health Canada
Holland Cross, Tower A, Suite 14, Ground Floor
11 Holland Avenue
Ottawa, Ontario
K1A 0K9
Address locator: 3000A
Email: hc.lrm.consultations-mlr.sc@canada.ca (mailto:hc.lrm.consultations-mlr.sc@canada.ca)

PROPOSED REGULATORY TEXT

Notice is given that the Governor in Council, pursuant to section 30 ^a of the *Food and Drugs Act* ^b,

proposes to make the annexed *Regulations Amending the Food and Drug Regulations (Flavoured Purified Alcohol)*.

Interested persons may make representations concerning the proposed Regulations within 45 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Bruno Rodrigue, Director, Office of Legislative and Regulatory Modernization, Health Products and Food Branch, Department of Health, Address Locator: 3000A, 11 Holland Avenue, Suite 14, Ottawa, Ontario K1A 0K9 (email: hc.lrm.consultations-mlr.sc@canada.ca (<mailto:hc.lrm.consultations-mlr.sc@canada.ca>)).

Ottawa, December 13, 2018

Jurica Čapkun
Assistant Clerk of the Privy Council

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

Amendment

1 The *Food and Drug Regulations* ⁶¹ 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 volume capacity that is less than or equal to 1,000 mL 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 volume capacity that is equal to or greater than 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 any combination of substances that imparts taste.

Coming into Force

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

Footnotes

¹ Unless otherwise stated, in this document the term “single-serve” means a container that is 1 000 mL or less in size.

- 2 Unless otherwise stated, in this document the term “flavoured” includes flavours imparted by sugars and sweeteners, as defined in section B.01.001 and by sweetening agents, as defined in section B.02.002 of the *Food and Drug Regulations*.
- 3 In this document, “flavoured purified alcoholic beverage” means an alcoholic beverage as described in the “Description” section. In other jurisdictions, similar products go by the names “beer blends”, “alcomalt”, “flavoured malt beverages”, and “ready-to-drink”; however, there may be slight differences in how these terms are applied, which is detailed later in this document.
- 4 One standard drink is equivalent to 17.05 mL of ethyl alcohol, as defined by the Canadian Centre on Substance Use and Addiction in [Canada’s Low-Risk Alcohol Drinking Guidelines \(http://www.ccsa.ca/Resource Library/2011-Summary-of-Evidence-and-Guidelines-for-Low-Risk-Drinking-en.pdf\)](http://www.ccsa.ca/Resource%20Library/2011-Summary-of-Evidence-and-Guidelines-for-Low-Risk-Drinking-en.pdf), e.g. 341 mL of beer at 5% alc/vol, 142 mL of wine at 12% alc/vol and 43 mL of distilled alcohol (spirits) at 40% alc/vol are all equivalent to one standard drink.
- 5 For the purposes of this document, the term “youth” refers to the 15 to 24 age range unless otherwise specified.
- 6 Institut national de la santé publique du Québec. 2018. [Acute Alcohol Poisoning and Sweetened Alcoholic Beverages \(PDF\) \(https://www.inspq.qc.ca/sites/default/files/publications/2388_acute_alcohol_poisoning_sweetened_alcoholic_bevrages.pdf\)](https://www.inspq.qc.ca/sites/default/files/publications/2388_acute_alcohol_poisoning_sweetened_alcoholic_bevrages.pdf)
- 7 Based on product information submitted to Health Canada by manufacturers.
- 8 Unpublished data. Study was submitted to Health Canada by the Canadian Centre on Substance Use and Addiction during consultations.
- 9 Unpublished data provided to Health Canada by the Public Health Agency of Canada.
- 10 Standing Committee on Health. 2018. [Report on Highly Sweetened Pre-Mixed Alcoholic Beverages \(http://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-18/\)](http://www.ourcommons.ca/DocumentViewer/en/42-1/HESA/report-18/)
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Government of Canada activities and initiatives

#YourBudget2018 – Advancement





https://www.budget.gc.ca/2018/docs/themes/advancement-advancement-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Advancement&utm_campaign=CAbdgt18

Advancing our shared values

#YourBudget2018 – Reconciliation



https://www.budget.gc.ca/2018/docs/themes/reconciliation-reconciliation-en.html?utm_source=CanCa&utm_medium=%20Activities_e&utm_content=Reconciliation&utm_campaign=CAbdgt18

Advancing reconciliation with Indigenous Peoples

#YourBudget2018 – Progress



https://www.budget.gc.ca/2018/docs/themes/progress-progres-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Progress&utm_campaign=CAbdgt18

Supporting Canada's researchers to build a more innovative economy