



Brief Submitted to the Health Canada Consultation on Regulations for Cannabis Edibles, Extracts and Topicals

Introduction

The Canadian Centre on Substance Use and Addiction (CCSA) welcomes the opportunity provided by Health Canada to support cannabis regulations that promote public health and public safety. CCSA supports a precautionary approach to the regulation of edibles and extracts in particular for the following reasons:

- The increased levels of THC possible in these products;
- The risk that cannabis products, particularly edibles, might be consumed by individuals who are not aware that the products contain THC;
- The risk of over-consumption due to increased time to onset of effects when THC is ingested rather than smoked; and
- The duration of impairment associated with the increased duration of effect when THC is ingested rather than smoked.

CCSA supports the objectives identified in Health Canada's *Regulatory Impact Analysis* as consistent with reducing these risks.

Key Considerations

Maintaining a Public Health Focus

Product diversification is a strategy used to increase product consumption by both increasing sales to existing consumers and opening sales to new markets. Diversification is in direct competition with public health interests, which include reduced prevalence and frequency of cannabis use. The *Cannabis Act* reflects these interests, specifically through the stated purpose of “protect[ing] young persons and others from inducements to use cannabis.”

The challenge of meeting market demand while restricting product diversity is particularly relevant to the consideration of edibles. For example, chocolate and baked goods such as cookies are products that are broadly appealing to the public and that certainly appeal to youth. Taking a precautionary public health approach would support restrictions up to and including a complete prohibition on these product formats.



CCSA recognizes that a degree of product diversity is necessary to support transition from the illegal to the legal market; however, CCSA encourages the use of other levers such as quality assurance to prevent incentivizing use overall. The results of the fourth quarter 2018 National Cannabis Survey indicate, for example, that those reporting cannabis use in the past three months are most likely to identify quality and safety as the factor considered when determining where to purchase cannabis (Statistics Canada, 2019).

Beginning with more restrictive regulations aligns with both public health and business interests. The cost of changing production processes or packaging is significant, with a particularly high impact on smaller, independent businesses. Beginning with a more restrictive approach reduces the likelihood of requiring these changes at a later date, while allowing the potential for the expansion of product options in the future as we learn more about consumer and market behaviour and associated health and social impacts (Canadian Centre on Substance Abuse, 2015).

Appeal to Youth

Ensuring that products do not appeal to young children is an important way to prevent accidental ingestion. Data presented in the *Monitoring Health Concerns Related to Marijuana in Colorado: 2018* report demonstrate the importance of reducing appeal and access for young children. In this report, Colorado poison control data indicate that rates of unintentional exposure reported for children aged 0–8 has been low but steadily increasing, from an average of five per year in 2000–2009 to 64 in 2017. Edibles account for the majority of these exposures, with 65.6% in 2017 versus smokable products at 23.4% and other products at 10.9% (Marijuana Health Monitoring and Research Program, 2018).

The proposed regulations prohibit appeal to youth. CCSA has heard stakeholder concerns about the need for greater specificity about the product and package characteristics that could be considered appealing to youth. This greater specificity includes clarifying the age group or groups being referred to, given that characteristics appealing to youth aged 15–17 will differ considerably from those appealing to youth below the age of ten, for example. Increased specificity would provide guidelines that are more concrete and facilitate both consistency and enforcement. For example, Washington state provides a list of prohibited characteristics in the legislation itself ([WAC-314-55-105](#)) as well as a list of [approved and prohibited shapes](#) and requirements for dull (low saturation and lightness) versus bright (high saturation and lightness) [colours for edible products](#). The list should not, however, be considered exhaustive in order to ensure flexibility as trends and products evolve. The onus should remain on the producer to determine and avoid potential appeal to youth. Experience with the alcohol, sugar and tobacco industries indicates that industry self-regulation and corporate social responsibility is not sufficient to ensure a public health focus (Nova Scotia Department of Health and Wellness, n.d.).

There is also a distinction to be made between product formats that appeal to youth and product packaging that appeals to youth. For example, chocolate is a product that appeals to youth; however, cannabis-infused chocolate is permitted provided it is not in the shape of a cartoon character or contained in a glossy wrapper. There is an opportunity to go beyond the current focus on packaging and labelling that may appeal to youth to also consider product formats that may appeal to youth.

Public Education and Awareness

Public awareness is fundamental to reducing the risks associated with edibles and extracts. Because of the increased risk to naïve consumers and the risk of accidental consumption, education and awareness should extend beyond consumers to reach all Canadians. Key messages should focus on:



- Time to onset of effects associated with different product formats, emphasizing “start low and go slow” with edibles in particular;
- Duration of effects associated with different product formats and how this duration can impact consumers’ ability to safely operate vehicles or perform other safety-sensitive activities;
- Recognition of the cannabis symbol on packaging to accurately identify cannabis and non-cannabis products;
- Appropriate storage of cannabis products to prevent accidental ingestion, particularly by children; and
- Personal possession limits and product equivalents.

Research and Monitoring

CCSA commends the federal government’s commitment to a three-year legislative review that will provide an opportunity to evaluate the impact of the regulations and make course corrections as appropriate. A comprehensive approach to measurement and monitoring is necessary to inform this review. This includes not only population data, but the application of a health equity lens that considers the social determinants of health such as gender, race, and income. Analyzing whether the implementation of the regulations is having an inequitable impact also requires proactive development of data collection approaches that support disaggregation according to indicators such as age, sex and gender, and race.

The rapidly developing body of evidence about the properties and impacts of cannabis will also inform the legislative review. Identifying a standard dose is an essential step in promoting clarity and consistency in the field and among consumers, and should therefore be a priority moving forward.

Consultation Questions

The following sections align with the questions outlined in Health Canada’s consultation guide.

1. THC Limits

CCSA supports the establishment of THC limits by unit and package. This approach provides a means of preventing overconsumption, while supporting transition from the illegal market by meeting product demand. CCSA also supports the application of these dosage restrictions to cannabis accessories and dispensing devices, especially devices for vaporization.

Cannabis containing high levels of THC is associated with greater health risks and harms, including increased levels of impairment, dependence, and experience of psychotic episodes (Fischer et al., 2017). Promoting the use of products lower in THC is therefore an important way to reduce the level of risk associated with cannabis. Unfortunately, there is not yet agreement on a standard dose of THC. Research does indicate that the starting dose for observable effects is in the range of 2.5 mg to 5 mg of THC (Barrus et. al. 2016; Sulak, 2018).

Reducing the per-unit limit of THC from 10 mg to 5 mg aligns with a precautionary, public health approach for the following reasons:

- Reducing the amount of THC in the product would reduce the harms associated with accidental consumption.



- A 5 mg unit size would allow more precise dosing depending on consumer characteristics (e.g. sex, level of experience, etc.) to achieve the desired effect. For example, purchasing regular strength acetaminophen provides the choice of taking one or two pills in proportion to the severity of pain versus only having the option of a higher dose with extra strength pills.
- Beginning with more restrictive regulations and providing opportunities to expand them over time is easier and less costly to industry than trying to impose more restrictive regulations should there be unanticipated negative impacts (Canadian Centre on Substance Abuse, 2015).

Volumetric pricing is another lever that has been established as a best practice in promoting lower-risk consumption of alcohol (National Alcohol Strategy Advisory Committee, 2015). Applying this model would mean increasing minimum price according to the level of THC contained in the product.

2. *Ingredients and Additives*

Increased product diversity is associated with broader consumer appeal, particularly in terms of new consumers. Controlling the ingredients and additives permitted in cannabis products, in particular sweetening agents, therefore aligns with the objective of controlling levels of use by restricting the extent of product diversity and consumer appeal. The increasing popularity of flavoured oils for vaping among youth indicates the importance of restricting the use of flavouring agents in extracts, particularly those products intended for vaporization.

CCSA strongly supports prohibiting or strongly restricting mixing cannabis products with Schedule 5 substances (nicotine, caffeine and ethyl alcohol) due to the health risks inherent to any tobacco use and to the multiplier effect on impairment of combined alcohol and cannabis use (Beirness & Porath, 2017). Lessons learned with caffeinated, high-sugar alcoholic beverages provide grounds for caution about possible adverse effects and appeal to youth (Paradis, April, Cyr, Morin, & Niquette, 2019; Standing Committee on Health, 2018). CCSA also notes the importance of the proposed 30 mg cap on caffeine levels due to the variation in “naturally occurring” levels of caffeine in ingredients such as guarana. CCSA also supports the proposed prohibition of product formats such as eye drops or injectables that pose a greater risk to human health.

3. *Incorporating Oil-Based Products into other Classes*

The public health and safety impact of regulations is partly determined by the ease with which they can be communicated and enforced. Incorporating oil-based products into other classes rather than maintaining a distinct class appears to be a more streamlined regulatory approach. This reduces the challenge to both regulators and the public of distinguishing between products that meet the broader definition of “produced using extraction processing methods.”

4. *Six-Month Transition Period for Oils*

Operating under two regulatory structures can be a source of confusion for regulators, industry and the public. However, providing a transition period to allow time for the sale of existing stock recognizes industry compliance with current regulations and provides time to implement new production processes. CCSA has heard concerns from government distributors and private industry that the proposed six-month period might not allow sufficient time to change procedures and clear existing stock. CCSA does not have concerns with extending the period to one year. This timeframe is consistent, for example, with the one-year transition period for new edibles packaging, labelling and design regulations implemented in Washington state. Retailers should not be permitted to



implement sales strategies such as price reductions and product promotions that could encourage consumption to meet transition deadlines.

5. Packaging and Labelling

CCSA supports an approach to packaging and labelling that maximizes consumer information and minimizes marketing. Marketing is a fundamental part of promoting sales and generating revenue. These interests are inherent to any for-profit distribution system or system component, whether private or publicly owned. They are also in opposition to the public health objective of reduced levels of consumption.

Evidence from the tobacco industry indicates that plain and standardized products and packaging reduce product appeal, particularly to youth, and are associated with reduced prevalence of use (U.S. Department of Health and Human Services, 2012; McNeill et al., 2017). Although these effects might not be desirable from a profit-making perspective, they are very much in alignment with a public health approach. Research from the tobacco field also supports the use of standardized packaging in increasing the salience and effectiveness of health warnings and standard dose, and increasing the accuracy in consumer perceptions of product strength and harm (Stead, et al., 2013).

The unique qualities of cannabis edibles and extracts in terms of less intuitive dose sizing and longer time to onset also support the inclusion of additional product information. Research conducted with alcohol labels, for example, indicates that information on standard dose and low-risk use guidelines allow consumers to make more accurate estimates of consumption than percentage of alcohol volume alone (Hobin et. al, 2018). In the case of cannabis products, additional packaging information could include a guide to dosage equivalencies across product types, time to onset, duration of effect and package proportion of the personal possession limit. The latter information is important to educate the public and prevent accidental transgression of the law, given the smaller quantities required to meet possession limits with more concentrated products.

CCSA very strongly supports the prohibition of any branding or representation that would associate cannabis products with alcoholic or tobacco beverages or manufacturers. CCSA also supports opaque packaging requirements for edibles as a reasonable precaution to reduce accidental ingestion. The proposed requirement for an integrated dispensing mechanism that prevents easy pouring of infused liquids from containers is also a reasonable precaution against accidental overconsumption.

CCSA supports the prohibition of representations about health benefits, vitamin and mineral content, or cosmetic benefits, and the making of any false or misleading product claims. Beyond anecdotal reports, there is very little evidence available on the use and effects of topical cannabis products (Gabrys, in press). CCSA therefore supports restrictions on the ability to make claims with regard to applications of these products in particular.

Clear and simple information using plain language about dosage is essential to reducing the risk of overconsumption. Packaging and labelling is one way to convey this information, but must be supported by a comprehensive approach to consumer education. Experience with prescription medication, for example, indicates that detailed dosage information on labels might not be used or understood by all consumers, especially those with lower literacy levels (Barrus et. al., 2016).



6. Nutrition Facts Tables for Edibles

Providing nutrition information is part of helping Canadians make informed dietary choices. Providing this information on cannabis edibles in a manner that is comparable to but visually distinct from a standard nutrition facts table will help to differentiate cannabis-infused from standard food products.

7. Labelling of Small Containers

Ensuring that consumers are informed about the products they are consuming is essential in promoting responsible consumption and reducing adverse effects. Studies have demonstrated that increased visibility of health warnings and product information is associated with increased consumer recall of that information (Hammond, 2011). Best practices established in tobacco labelling support increased visibility of health warnings and product information to achieve greater public health impact (Orenstein & Glantz, 2018). This finding suggests that although pullout or accordion labelling could help reduced package size, it might come at the cost of consumer awareness. Key health messaging should remain clearly visible on external packaging. Alternative formats such as accordion or pullout labels could be used to communicate additional recommended information such as dose equivalents and lower-risk use guidelines. Consideration should also be given to accessibility, for example, for consumers with limited manual dexterity.

8. Standardized Cannabis Symbol on Vaping Devices, Cartridges and Wrappers

CCSA supports the requirement that all products related to cannabis, including vaping devices, cartridges and wrappers, feature the standardized cannabis symbol. The inclusion of the symbol is an important way to distinguish between cannabis and non-cannabis products.

9. Good Production Practices

CCSA does not have specific expertise in the production of cannabis, but supports the application of regulations to ensure that cannabis products meet the health and safety standards Canadians expect for any food or beverage product, and the established variability limits for THC and CBD. Based on lessons learned in other jurisdictions (i.e., Colorado and Washington state), CCSA further recommends that Health Canada ensure adequate resources are allocated to consistent and timely inspection and enforcement of all health and safety standards, including production practices and product testing (Canadian Centre on Substance Abuse, 2015). CCSA supports the additional proposed requirements to ensure effective recall systems and processes to ensure timely removal of potentially unsafe products from the market.

Quality control is also an essential means of ensuring that devices manufactured for the vaporization of cannabis concentrates operate within the temperature range that is optimal for releasing active cannabinoids without the harmful chemicals created by higher-temperature combustion (Russell, Rueda, Room, Tyndall, & Fischer, 2018).

10. Separation of Edibles and Conventional Food

CCSA does not have specific expertise in this area. The separation of edibles and conventional food production appears to be a reasonable precaution to prevent cross-contamination and potential errors in labelling or shipping.



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