

***Cannabis Regulations (New Classes of Cannabis) and the Proposed Order amending
Schedule 3 and 4 to the Cannabis Act***

Ontario Public Health Collaboration on Cannabis (OPHCOC)

The Ontario Public Health Collaboration on Cannabis is a group of professionals from 35 health units who have joined together to promote a comprehensive public health approach to cannabis legalization.

**This paper was developed by a sub-group of the OPHCOC and endorsed by the following
Public Health Units:**

Durham Region Health Department, Eastern Ontario Health Unit, Grey Bruce Health Unit, Haldimand-Norfolk Health Unit, Hastings Prince Edward Public Health, Huron County Health Unit, Lambton Public Health, Middlesex London Health Unit, Niagara Region, Northwestern Health Unit, Perth District Health Unit, Peterborough Public Health, Public Health Sudbury & Districts', Southwestern Public Health, Thunder Bay District Health Unit, Wellington-Dufferin-Guelph Public Health, Windsor-Essex County Health Unit, York Region Public Health

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Consultation questions on the proposed regulations for edible cannabis, cannabis extracts, and cannabis topicals

1. What do you think about the proposed THC limits for the new classes of cannabis products?

Canada's Lower-Risk Cannabis Use Guidelines recommend limiting the amount of THC-content in cannabis products to help mitigate the risks of both acute and chronic problems associated with cannabis use. High THC content in cannabis is linked to mental health problems and dependence (Fischer, et al. 2017). Recognizing that there are risks associated with high potency products, we agree that limiting the amount of THC-content in new classes of cannabis products is critical. The Canadian Task Force on Cannabis Legalization and Regulation acknowledged that there is insufficient evidence to identify a "safe" potency limit. As such, future changes to legislation may be warranted as further research and evidence becomes apparent on what is best for the public's health and safety.

The proposed limit for edible cannabis products (i.e. 10 mg THC per discrete unit and per package) is reasonable and aligns with edible cannabis products currently available for sale in Colorado and Washington (State of Colorado, 2018; Orenstein & Glantz, 2018). We are in support of Health Canada's proposed total package size limit of 10mg THC for cannabis edibles as it is a more conservative limit than Colorado places at 100mg per package, or Alaska at 50 mg per package (State of Colorado, 2018; State of Alaska, 2018); however, to further prevent potential overconsumption and encourage Canadians to consume cannabis responsibly by design, we recommend a mandatory requirement that multiple lower potency options (e.g. under 5mg THC) are made available on the market. This would allow novice users to select a lower potency option and follow Canada's Lower Risk Cannabis Use Guidelines. Other jurisdictions such as Alaska and Oregon have individual serving size, discrete unit and package size starting at 5mg THC (State of Alaska, 2018; Oregon Liquor Control Commission, 2016). If the serving size exceeds 5mg THC per serving of edible cannabis, we recommend that there should be a requirement to include a warning on the label, to advise first time/novice users that the THC quantity contained in one serving may be in excess of their individual tolerance.

The rationale for the 1000 mg limit of THC for cannabis extracts and cannabis topicals was not made apparent in the background document. To prevent overconsumption and reduce the risk to children and others who unintentionally ingest these products, Canada should place greater restriction on the maximum total THC allowed in a container of cannabis extracts or topicals than the currently proposed 1000mg. While California limits non-edible cannabis products such as topicals and concentrates to 1000mg THC per package, Washington State has restricted capsules, tablets, tinctures, transdermal patches, and suppositories to a maximum of 500 mg THC per package (Orenstein & Glantz, 2018). In Colorado, the total amount of THC allowed in a container with multiple servings as a tincture, capsule, or other ingestible product is 100mg (State of Colorado Department of Revenue, 2018). Similarly, Oregon has set a maximum container or package size of 100mg THC for capsules (Oregon Liquor Control Commission, 2016), and

Alaska has set a maximum package content for THC of 50mg for cannabis products which are to be eaten or swallowed (State of Alaska, 2018). Setting a maximum container size of 50-100mg THC for extracts and topicals would offer a significant improvement for consumer safety as compared to the proposed 1000mg THC per multi-serve container.

In terms of the potential variability for the doses of THC in edible cannabis, we recommend the variability should be no more than +/- 10%, applicable for edible cannabis and cannabis extracts, regardless of the dosage amount in one serving. This is in alignment with the current acceptable dosage for medicinal ingredients in Canada's Food and Drug Regulations (C.01.062 (1)) which is not less than 90% or more than 110% of the amount of the medicinal ingredient shown on the label.

- 2. Do you think the proposed new rules addressing the types of ingredients and additives that could be used in edible cannabis, cannabis extracts, and cannabis topicals appropriately address public health and safety risks while enabling sufficient product diversity?**

Cannabis Edibles (Solid and Beverage)

Consumption of edible cannabis products has become a popular route of administration in states that have legalized cannabis. From a health perspective, eating or drinking cannabis products may be preferred to smoking cannabis given that ingestion has, to-date, not been associated with the same negative health impacts on lung function or cancer risk. However, cannabis-infused edibles pose their own set of risks, including unintended consumption, inconsistency in potency and effect, and delayed onset of intoxication (Barrus, 2016). Studies from California further suggest that cannabis-infused edibles may be particularly popular among young users (Orenstein & Glantz, 2018), a group who has been shown to be especially vulnerable to the social and psychological harms associated with cannabis use (Fischer et al., 2011). In this context, and given the limited scope of evidence currently available, it is important that a precautionary approach be taken to the regulation of these products.

We support Health Canada's proposal to prohibit added alcohol in cannabis edibles and believe that it is crucial for this restriction to remain in place. We also support the proposed prohibition on added vitamin and minerals for these products to ensure consistent public health messaging regarding the risks and harms of cannabis products. This will also limit opportunities for conflating the health benefits of vitamins and minerals with the consumption of cannabis edibles.

In order to strengthen these regulations we would recommend that both nicotine and caffeine be prohibited as additives to cannabis edibles, allowing for a restricted amount of caffeine if it is naturally occurring in some ingredients such as chocolate and tea. The current proposed limit of 30mg of naturally occurring caffeine per serving is conservative and in line with a public health approach. The recommendations to prohibit nicotine as an additive in all forms of manufactured cannabis products, and prohibiting caffeine as an additive, are in line with those put forward by Orenstein and Glantz. in their summary review of cannabis regulation in California (2018).

In order to further protect youth from accessing and/or unintentionally ingesting edible cannabis products, and as it will be the provincial and territorial responsibility for distribution and retail sale of cannabis, we recommend that Health Canada advocate for provinces to restrict the sale of edibles to federally or provincially licenced and regulated premises (in Ontario this would be the Ontario Cannabis Store and future AGCO licensed retail stores), and not in local retail food premises including restaurants and convenience stores.

Additionally, we recommend Health Canada consider restricting the daily values (DV) of fat, sugar, and salt contained in a single cannabis edible package to under 5%. This is in line with the World Health Organization (2015), the Heart and Stroke Foundation (n.d.), and Diabetes Canada (2016), all of which recommend restricting total free sugar intake to less than 10% of an individual's daily calories, and ideally less than 5%. It is further in line with the Dietitians of Canada's interpretation of under 5% DV as 'a little' of the nutrient (unlockfood.ca, 2019).

Cannabis Extracts (Ingested, Inhaled, Concentrated THC)

Research has shown that flavoured tobacco products are more appealing to young people (Carpenter et al., 2005) and that e-cigarette use is often initiated through flavoured products (Ambrose et al. 2015). Observations from the current cannabis product market demonstrate that cannabis extracts and concentrates may resemble food (Abda-Santos, 2013) or market a food-like flavour (Goncus, 2016) which may pose a risk for unintentional ingestion (Orenstein & Glantz, 2018).

We support Health Canada's proposal to prohibit the use of sugars, colours, or sweeteners, as well as nicotine or caffeine in cannabis extract products.

With respect to extracts, it is imperative that Health Canada clearly defines what is meant by "appealing to youth." We recommend that all considerations included in vaping and tobacco regulations be included in extract cannabis requirements with respect to ensuring these products and their flavourings are not considered "appealing to youth." We recommend they not contain any flavouring that might make the product more appealing to youth, for example, if the product is a fruit-, dessert- or candy-type product.

Given the possible appeal and risk of unintentional ingestion we would further recommend a prohibition on adding characterizing flavours (e.g. menthol) to these products. This recommendation is in line with those put forward by Orenstein and Glantz (2018) in their summary review of cannabis regulations in California.

3. Do you think that proposed rules for other classes of cannabis will accommodate a variety of oil-based products for various intended uses, even though cannabis oil would no longer be a distinct class of cannabis?

Based on the definition and intent for use, the proposed new class of cannabis, 'cannabis extracts', sufficiently captures and accommodates a variety of oil-based products for various intended uses.

In addition, based on public health best practices from tobacco control, we recommend that cannabis regulations also incorporate a comprehensive ban on flavours and addictive additives and place strict limits on the potency of all cannabis extracts and topicals (Orenstein & Glantz, 2018), just as potency regulations were proposed for cannabis edible food, beverage and ingestible extracts.

Further we commend the federal government for its proposed regulation to include:

- Plain, child-resistant packaging
- No cosmetic, health or dietary claims; and must not be appealing to kids
- Caffeine limits (naturally occurring, under a threshold) and restrictions; no added vitamins, minerals or alcohol in edible cannabis and ingested cannabis extract; and no nicotine, sugars, colours or sweeteners in cannabis extract

4. What do you think about the proposed six-month transition period for cannabis oil? Is a six-month transition period sufficient?

We feel the proposed six-month transition period for cannabis oil is sufficient. A stop should be put on the manufacture of new stock and labels for the ‘cannabis oil’ class on October 17, 2019, a notice of this stop approximately one to two months prior.

5. What do you think about the proposed new rules for the packing and labelling of the new classes of cannabis products?

Packaging is an important marketing element. Companies use packaging to advertise their products and target them to specific demographic groups (Moodie, C. et al, 2012). Research suggests that plain packs of tobacco are viewed as less attractive than branded packs and are perceived as lower quality products, and even influences the perception of taste (Hammond D, 2014; World Health Organization, 2014; Moodie, C. et al, 2012).

With a few additions, the proposed regulations for packaging and labelling could be strengthened.

- We recommend all classes of cannabis include a message from Canada’s Lower-Risk Cannabis Use Guidelines in addition to Health Canada’s cannabis health warning messages currently proposed.
- We recommend the mandatory addition of a warning on all dried cannabis, edibles, extracts and concentrates stating, “do not combine with alcohol or other drugs”. Given the increased risk of harms when cannabis and alcohol are combined, it is critical the public is aware of this message.
- We would like to see the federal government commit to updating health labelling for cannabis products as new and effective practices are discovered. Regularly updating the content and style will help ensure health warnings are noticeable, memorable and engaging (Government of Canada, 2018); labels could be reviewed for relevancy every three to five years for example.

- We recommend that mandatory information such as health warnings, THC and CBD content, and the cannabis symbol be on the immediate packaging (the actual product) as well as packaging that may be exterior to the immediate packaging. For example, this standard of practice is used in tobacco where cigarette cartons abide by the mandatory health warning label regulations.
- We recommend the current approach of tobacco labeling be adopted in the cannabis regulations; that health warnings cover at least 75% of the two largest sides of the package or primary display areas (Government of Canada, 2018). This does not have to be limited to just the health warning, but could include all mandatory information in the style, size and format which is outlined in the proposed regulations.
- We recommend including standard packaging to the regulations to curb the marketing potential of products to certain demographics. We recommend product packaging be standardized to consist of rectangular or square shape cardboard with all sides meeting at 90^o angles, while prohibiting specialty packaging that would target specific demographics (World Health Organization, 2016). This would limit specialty targeting as well as limit environmentally unfriendly packaging. This recommendation applies to immediate packaging when possible as well as external packaging to the immediate container when the product is packaged within another box, for example, a tube of cream may be packaged inside a box for display purposes.
- We recommend prohibiting packaging which directly targets a specific demographic, including youth but not limited to youth, for example mothers and seniors.
- We recommend that packaging include information on the expected effects, how long that effect may last for, and safe disposal. For example, edibles should have an additional warning that states the delayed onset of psychoactive response, the estimated amount of time before effect may be felt, how long the effect is expected to last, and how to safely dispose of the product. This would help to reduce the risk of over consumption and accidental consumption.

6. With respect to edible cannabis, what do you think about the requirements for all products to be labelled with cannabis-specific nutrition facts table?

We recommend mandatory information for edible cannabis to include a list of ingredients, common name of product, indication of source of allergen, gluten, or sulphites that have been added, durable life date only on ALL products that deteriorate in 90 days or less, and a cannabis-specific nutrition facts table. There should be NO nutrient and/or health claims on these labels.

We also recommend the inclusion of the % Daily Value footnote, to improve ease to consumers when interpreting food labels. According to the newly published Canada's Dietary Guidelines, food labels help make the healthy choice the easier choice. The increased ability to interpret a % Daily Value, especially when it comes to ingredients that should be limited, is a necessary component of all food labels, including cannabis edible products. It is further recommended that mandatory front-of-package food labels for foods high in saturated fat, sugars, and/or sodium also be a requirement for all cannabis edible products. This is to ensure that Canadians can be quickly informed when making a purchasing decision.

With respect to the cannabis-specific Nutrition Facts Table (NFT), we are in agreement with the requirement of a cannabis-specific nutrition facts table (NFT) for all cannabis edible products, as Oregon continues to require. We strongly recommend the font size, font type, leading, and spacing of the NFT be completely consistent with the existing labelling requirements specified in the Canadian Food and Drug Act for pre-packaged foods (i.e., as per changes to the NFT specified in 2016). Edible cannabis is a type of food and as such, the NFT should be a standardized label on *all* edible cannabis foods. It will be confusing to the consumer if there are different types of labels for different food products. This product information of active ingredients and warnings must be easy to locate on each package, and follow a unified, consistent format that Canadian consumers are familiar with and can understand. It is also recommended that both caffeine content as well as THC content be displayed as part of the core list of declarations such that the consumer can make an informed decision with ease.

We are also in support of the proposal to prohibit any health claims to the consumer for all products (i.e. increases appetite, helps you sleep, increases energy) and nutrient claims (i.e. high fibre, low fat, low calorie, good source of calcium) which may entice the consumer and affect their decision-making.

7. What do you think about the proposal for the labelling of small containers and the option to display certain information on a peel-back or accordion panel?

We support the proposal of labeling small containers with the option for extended panels. This proposed regulation should be strengthened with the addition of the mandatory information (THC and CBD content, cannabis symbol and health warning) on the extended panel as well as the container itself. This would increase visibility of the messaging, while the consumer is reviewing other product information.

8. What do you think about the proposal that the standardized cannabis symbol would be required on vaping devices, vaping cartridges, and wrappers?

We support the proposal of the standardized cannabis symbol on all vaping devices, products, accessories, packaging and wrappings. The proposed regulation should be strengthened to include health warnings, and THC and CBD concentration on all vaping devices, products, accessories, packaging and wrappings. We also recommend that the standardized cannabis symbol should be visible on all products that contain cannabis even if the amount in the product is below 10 mg of THC.

9. Do you think the proposed new good production practices, such as the requirement to have a Preventive Control Plan, appropriately address the risks associated with the production of cannabis, including the risk of product contamination and cross-contamination?

The proposed new regulations appear to be consistent with standard food production safety measures.

The proposed amendment that the Quality Assurance Person (QAP) be required to proactively conduct an investigation any time they suspect that cannabis or an ingredient may present a risk

to human health or does not meet requirements will help enforce good production practices and prevent risk to human health.

The requirement that the production of edible cannabis be done in a building separate from conventional food products is an important requirement to prevent cross-contamination. As prevention of cross-contamination and assurance of consistent and appropriate potency is imperative, it is strongly recommended that edible cannabis products only be produced at federally or provincially licenced and regulated premises, and not in local retail food premises including restaurants.

Since the legal production of many of these new classes of cannabis products is brand new to both the licenced processing facilities and whomever is deemed to enforce Health Canada's national compliance and enforcement approach, we recommend additional inspections, mandatory and standardized preventative education, and progressive measures for non-compliance, over and above the regular enforcement process, be implemented for the first six months that the regulations come into effect in an effort to proactively mitigate risk. We also recommend that the enforcement agency that is responsible for ensuring compliance with the regulations have sufficient staff, from the onset, to support the licenced processors before and after implementation.

We request clarity as it pertains to protocols in the event of a recall. After the two-year record retention period presented in Section 88.94(3), and following the one-year retention of sample after last batch sold outlined in Section 92(2), there is a concern that affected recalled products may no longer have a means of tracking.

We believe the regulations would be strengthened by including robust testing of THC distribution throughout products. Colorado, found that following legalization there were concerns regarding consistency of products. This included testing for accurate THC levels as claimed on the package, as well as evenly distributed THC throughout the product. Consistent products will help prevent accidental overconsumption. Depending on the edible cannabis product and the manufactures practices, THC can be infused in the product in various ways, which can lead to inconsistency of THC throughout the product.

10. What do you think about the requirement that the production of edible cannabis could not occur in a building where conventional food is produced?

The proposed requirements for the separation of buildings producing edible cannabis and conventional food appear to be aligned with Health Canada's aim to reduce the risk of unintentional consumption. While production of edible cannabis in separate buildings from conventional food production may be effective in reducing the risk of cross-contamination and unintentional consumption, we recommend the following measures to further mitigate these risks:

- Completely separate cannabis-only sites (conventional food would not be permitted to be produced or packaged on or shipped from these sites), and
- Shipping procedures for edible cannabis that are completely separate from conventional foods.

Additionally, we feel the regulations should specify that all edible cannabis products can only be sold in its original package and not outside of its approved packaging in places where they are sold. We also recommend that cannabis is prohibited to be sold along-side non-cannabis food products and other substances, such as alcohol and tobacco products. This will help decrease the accidental sale or purchasing of cannabis products. The harms associated with cannabis greatly increase when used with other substances. It is our belief that prohibiting the sale of multiple substances together in one location will put the consumer at decreased risk of harms associated with co-use.

11. What do you think about the overall regulatory proposal?

No comment.

12. Are there any additional comments you would like to share on proposed regulations for the new classes of cannabis?

Reducing product appeal to young persons

Under the *Cannabis Act*, “it is prohibited to sell cannabis or a cannabis accessory that has an appearance, shape or other sensory attribute or a function that there are reasonable grounds to believe could be appealing to young persons,” (Government of Canada, 2018). We support the proposed regulations for edibles, extracts, and topicals which state that products cannot be appealing to young persons. We strongly recommend Health Canada to include strict regulations related to advertising on television, radio, social media, the internet, and other media sources.

The Federal Government should provide explicit definitions in the regulations for manufacturers which clearly identify prohibited elements of products which may be appealing to youth. Prohibitions should follow the *Task Force on Cannabis Legalization and Regulation’s recommendation* to “prohibit any product deemed to be appealing to children, including products that resemble or mimic familiar food items” (2016). For example, as of April 2019, Washington State will be explicitly prohibiting certain cannabis edible products, including hard candies, tarts, fruit chews, colourful chocolates, jellies, cotton candy, and other products that are especially appealing to young children. Cookies cannot contain any sprinkles or frosting and mints must not be coloured anything other than white. These recommendations are based in part on the research identified by Washington State Liquor and Cannabis Control Board (2018). In order to prevent unintentional ingestion of cannabis by children and adults alike, the Federal Government should also consider a ban on such products, as well as other confection and snack foods such as soft candies, brownies, chocolate bars, muffins, cakes and cookies. Alternatively, prohibiting characteristics of these edible products so that they are not appealing to children and youth, as Washington State has done, would be a positive step.

In addition, the Federal Government needs to consider key factors that influence children’s food choices. There is research to support that certain factors can influence children’s decisions to consume food and beverages. These factors include:

- **Colour** - children prefer foods that are red, orange, yellow or green.

- **Shapes** - children are more attracted to novel shapes such as animals, stars, etc., over plain shapes such as circles or squares. Colorado has banned edibles in the shape of fruit, animals or humans.
- **Odours** – children are more attracted to sweet, fruity and candy-like odours. (University of Washington School of Law, 2016; (Colorado General Assembly, 2016).

To make the regulations easy to follow for manufacturers, it is recommended that Health Canada provide a list of examples to cannabis edible manufacturers with regards to prohibitions on the appearance, shape, or other attribute or function that could be appealing to young persons.

13. Are there any additional comments you would like to share regarding the legalization and strict regulation of cannabis in Canada?

Public Education

The Federal Government should continue to educate Canadians and enhance awareness of the health risks associated with cannabis, especially among priority populations such as pregnant and breastfeeding women, young adults aged 18-25, and individuals at risk of or living with a substance use disorder or mental illness. In addition to proper and safe storage of edible products, Canadians should be informed of the unique risks associated with the delayed onset of effects of edibles, extracts, and topicals which may cause overconsumption. Individuals need to be warned that the use of such products may cause stronger and longer-lasting effects than comparable doses of smoked cannabis (Barrus et al., 2017).

As well, public education initiatives should focus on key cannabis legislation, *and Canada's Lower-Risk Cannabis Use Guidelines*. In a focus group study in Colorado and Washington State, participants suggested that education in a variety of formats, such as web and video-based education, would be useful in informing consumers about the possible risks of edibles (Kosa, Giombi, Rains, & Cates, 2017).

Places of Use

To reduce public health risks of consumption of edibles, the Federal Government should consider a ban on the sampling and ingesting of cannabis edible products in a retail storefront or in specialty consumption cafes or lounges. This will encourage individuals to use these products in the home, reducing the risk of impaired driving, public intoxication, and the co-use of cannabis edibles in public with other substances such as alcohol.

Retail Spaces

As it will be the provincial and territorial responsibility for distribution and retail sale of cannabis, we recommend that Health Canada advocate for provinces to restrict the sale of edibles to federally or provincially licenced and regulated premises (in Ontario this would be the Ontario Cannabis Store and future AGCO licensed retail stores), and not in local retail food premises including restaurants and convenience stores. Furthermore, it is recommended that these be standalone, specialty stores, and not co-located in a premise with other substances or non-cannabis products, nor sold alongside any other product or substance (i.e. edible products,

extracts and topicals that do NOT contain cannabis, alcohol, tobacco, etc). Having a restriction on selling cannabis alongside other products will reduce the risk of co-use of alcohol and cannabis for instance, as well as reduce the risk of consumers in unintentionally purchasing or consuming products that contain cannabis. Maintaining that cannabis products be sold only in standalone specialty stores will also make it easier to restrict access and exposure to minors.

Cannabis Production and Manufacturing Facilities

Discussion should occur with the Ministry of Labour for current health and safety practices of the growing, manufacturing and producing of cannabis products to assess and mitigate any risk to the health and safety of the worker. For example, UV exposure and indoor air quality issues should have to follow standard workplace health and safety regulations.

Research and Evaluation

We emphasize the need for investing in baseline surveillance systems and research, and the importance of a comprehensive policy monitoring and evaluation framework. Ensure mechanisms to share data across sectors and levels of government are established, and appropriate indicators are chosen to monitor the impacts on communities.

Thank you for the opportunity to provide our input on the proposed regulations of the new classes of cannabis. We look forward to the summary from Health Canada following this comprehensive review of the regulations.

Sincerely,

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