

February 20th, 2019

Health Canada Consultation – Strict regulation of edible cannabis, extracts and topicals

Health Canada is seeking feedback on draft regulations to minimize the public health and public safety risks posed by edible cannabis, cannabis extracts, and cannabis topicals. These products will be permitted for legal sale under the *Cannabis Act* no later than October 17, 2019.

The Middlesex-London Health Unit (MLHU) has prepared the following responses to offer its input on the draft regulations related to product rules, THC limits, packaging and labelling requirements, and guidelines related to quality control of cannabis products.

Consultation	Response
Question	
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 (1).
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	High Potency Products
	• Recognizing that there are risks associated with high potency products, MLHU agrees 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 (2). 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.
	 Availability of Lower Potency Products MLHU recommends there should be a mandatory requirement that multiple lower potency options (e.g. under 5mg THC) are made available on the market.
	Having lower potency options available will allow novice users to select a lower potency option and follow <i>Canada's Lower-Risk Cannabis Use Guidelines</i> (1).
	 Serving Size Exceeding 5mg THC If the serving size exceeds 5mg THC per serving of edible cannabis, MLHU recommends 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.
	 Variability Limit MLHU recommends the variability should be no more than +/- 10%, applicable for <i>all</i> cannabis products.



	 The above mentioned limits are in alignment with Oregon's variability allowances (3), regardless of the dosage amount in one serving. This is also consistent with the current acceptable dosage for medicinal ingredients in Canada's <i>Food and Drug Regulations</i> (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 (4). THC allowed in Cannabis Extract and Topical Class MLHU recommends that Health Canada place greater restriction on the maximum total THC allowed in a container of cannabis extracts or topicals, to prevent overconsumption and reduce the risk to children and others who unintentionally ingest these products.
	In Colorado, the total amount of THC allowed in a container with multiple servings as a tincture, capsule, pill or oral consumption concentrate is 100mg (5). Setting a maximum container size of 100mg THC would offer a significant improvement for consumer safety as compared to the proposed 1000mg THC per multi-serve container.
2. Do you think the proposed new rules	Recommendations:
addressing the types of ingredients and additives that	 Flavouring MLHU recommends a prohibition on the addition of flavours to all cannabis extracts as outlined in Schedule 3 of the <i>Tobacco and Vaping Products Act</i> (6).
could be used in edible cannabis, cannabis extracts, and cannabis topicals appropriately address public health and safety risks while enabling sufficient product	While MLHU supports the proposed prohibition to display that a cannabis extract or cannabis accessory has a flavour set out in Column 1 of Schedule 3 of the <i>Tobacco and Vaping Products Act,</i> we are concerned that flavours themselves are still permitted, and could still be appealing to youth. Research has shown that flavoured tobacco products are more appealing to young people (7) and that e-cigarette use is often initiated through flavoured products (8). Observations from the current cannabis product market demonstrate that cannabis extracts and concentrates may resemble food (9) and can be marketed based on containing food-like flavours (10). These products pose a risk for unintentional ingestion (11).
diversity?	 Adding Tobacco and Nicotine MLHU supports the proposed regulations that tobacco and nicotine cannot be added as an ingredient to any class of cannabis. MLHU recommends that tobacco flavouring agents be prohibited by regulation.
	Tobacco-flavoured cannabis could normalize tobacco and tobacco products within the youth and young adult populations, and could create potential legislative loopholes counter-productive to existing tobacco control efforts to restrict tobacco product marketing (12).
	 Alcohol For edible products, MLHU supports the proposed regulations to cap the concentration of ethyl alcohol in edible cannabis (that does not exceed 0.5% w/w) and prohibit the addition or mixing of alcohol to any edible product.



	• For cannabis extracts intended to be ingested, such as tinctures, the current proposed regulations state that the use of ethyl alcohol would be permitted, with a maximum container size of 7.5g. While MLHU supports a maximum container size, we would recommend a disclosure of alcohol content and a cap on the concentration of ethyl alcohol within the cannabis extract to provide the consumer with product information.
	 Fat, Sugar, Salt MLHU recommends Health Canada consider restricting the daily values (DV) of fat, sugar, and salt contained in a single cannabis edible package to under 5%.
	These types of restrictions are in line with the World Health Organization (13), the Heart and Stroke Foundation (14), and Diabetes Canada (15), 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 value (16).
	 Commercially manufactured food products MLHU recommends that commercially manufactured food products not be allowed as ingredients unless they are unrecognizable in the final product, and are in no way to be advertised containing a commercially manufactured product.
	Numerous organizations in the United States have required that commercially manufactured food products should not be used as ingredients unless they are unrecognizable in the final product, and are in no way to be advertised containing a commercially manufactured product. For example, in Colorado, a cannabis edible manufacturer cannot partner with an existing commercial food brand (e.g., Oreo) to produce an Oreo edible, the only exception being that the cookie is no longer recognizable in the final product and is not used for any promotional purposes (5).
3. Do you think that the 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?	There are ample options for products, dispensing methods and concentrations. Since cannabis oil will be subsumed by the Cannabis Extract class, they will still be available.
4. What do you think about the proposed six-month transition period for cannabis oil? Is a	 Recommendations: MLHU recommends a stop should be put on the manufacture of new stock and labels for the 'cannabis oil' class on the date that these regulations come into effect.



six-month transition period sufficient?	 MLHU recommends that a protocol be established whereby any cannabis oil product remaining available for purchase six-months following regulation date of effect be pulled from market. MLHU recommends a thorough investigation and enforcement of non-complying companies at the six-month cut-off to ensure those products are no longer available. MLHU agrees that a transition period is needed to allow producers of currently manufactured oil-based products (such as oil drops, capsules, and sprays) to incorporate new regulations, and it limits the time that these lesser regulated products can proliferate the market. As these products could pose harms intended to be mitigated by current regulations related to overconsumption in particular (i.e. due to lack of regulation currently on dosage labelling and metering of dosing), providing a reasonable but conservative timeline for transition is warranted.
5. What do you think about the	Recommendations:
for the packaging and labelling of the new classes of cannabis products?	 Child-Resistant Packaging MLHU recommends child-resistant packaging, as set out in C.01.001[2] of Canada's Food and Drug Regulations (4), as it is an imperative step in protecting children from accessing cannabis products, and is in alignment with the <i>Task Force on Cannabis Legalization and Regulation</i> (2).
	 Original Packaging MLHU recommends that a product should only be sold in its original packaging and that it should also be prohibited to remove it or repackage it from the original packaging prior to reaching the consumer. Samples of edible cannabis should <i>NOT</i> be permitted under this regulation. MLHU recommends that packaging for edible cannabis products be "food-grade".
	 Opaque Packaging MLHU recommends only opaque packaging for the immediate container as opposed to the current "opaque or translucent" option as set out in the <i>Cannabis Regulations</i> 108(a).
	Opaque packaging would help to eliminate any visual appeal to a young person and is in alignment with the final report from the Task Force on Cannabis Legalization and regulation (2).
	 Colouring of Cannabis Extract Capsules MLHU recommends that coloured capsules not be allowed in the manufacturing of cannabis products.
	During the most recent webinar hosted by Health Canada discussing the proposed cannabis regulation amendments, it was noted that although the colour of a cannabis extract itself in a capsule form could not be coloured, that the capsule itself could be



coloured. Any type of coloured product could be attractive to children and youth, and therefore, no part of the product (including capsules) should be coloured.

Discrete Unit Packaging/Labelling

• MLHU recommends that the full serving size of the cannabis product should be equal to the total package size to avoid confusion and overconsumption. For example, for a single packaged cannabis edible cookie product, the whole cookie should be the full serving size, rather than a quarter or half of the cookie.

The rationale for full serving sizes per edible cannabis package is that some individuals may not understand that they need to portion the product, and instead may consume a larger amount of the product (17).

- If Health Canada does allow multi-serving products, MLHU strongly recommends requiring clear labelling on the package to describe how to divide the product into accurate serving sizes.
- If the decision is to have multiple discrete units, then MLHU recommends an individual serving size packaging requirement (see below).

Individual Serving Size Packaging

If a package contains more than one serving (multiple discrete units), MLHU
recommends that each serving be separated with it's own individual package with
appropriate labelling. For example, if one package of cannabis edible cookies
contains two 5mg cookies, each 5mg cookie should be individually packaged (within
the larger product package).

Individual serving size packaging will help to minimize confusion around what constitutes a single serving and reduce unintended overconsumption.

 With respect to cannabis extract packaging, MLHU agrees that the immediate container must be designed in such a way that the extract cannot easily be poured or consumed directly from the container in which it is packaged to reduce the risk of accidental consumption or overconsumption.

Imprinting/Stamping of Standardized Cannabis Symbol

 MLHU recommends each edible unit to be individually marked, stamped, or imprinted with the standardized cannabis symbol.

Having each edible unit individually marked, stamped, or imprinted with the universal cannabis symbol will help to minimize Canadians (both children and adults) from accidentally ingesting a cannabis product that has been removed from it's original packaging. Colorado has recently updated their regulations to require this type of imprinting to be distinguishable and easily recognizable (5). Categories of edible products including chocolate, soft confections, hard confections or lozenges, consolidated baked goods (e.g. cookie, brownie, cupcake, granola bar) and pressed pills and capsules have been deemed "practical" to have the imprinted universal symbol in Colorado (5). The referenced regulations also set out stipulations as it pertains to placement and size of the imprint/stamp.



Labelling - Health Warning Messaging

MLHU agrees with the proposed regulation that health warning messages be included on products as this will enhance public awareness of the health risks associated with cannabis use, regardless of its form.

• MLHU recommends that Health Canada update cannabis health warning messages to include new messages as new evidence emerges.

MLHU is in full agreement with the aim of helping Canadians "more effectively distinguish between lower THC-concentration and higher THC-concentration cannabis products, and thereby to promote informed consumer choices."

MLHU recommends additions to the list of current warning messages including:

- Messages that clearly warn consumers about the delayed intoxicating effects of edible products, as well as clearly indicating to NOT consume additional cannabis during that time period,
- Messages that cannabis should not be combined with alcohol (18),
- Messages that cannabis may affect a parent or caregiver's ability to respond to a child's needs and react to emergencies (19),
- Messaging that encourages consumers to talk to their healthcare provider if they are concerned about their cannabis use,
- Messaging from Canada's Lower-Risk Cannabis Use Guidelines (1), and
- Messaging or warnings regarding consumption by pets/other animals.

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

- MLHU recommends that information regarding the importance of keeping cannabis products out of sight and reach from children, as well as storing all cannabis products in a locked area to reduce the risk of unintentional ingestion by children be included on all cannabis product packaging and labels.
- MLHU recommends that the Government take a similar approach to cannabis product packaging and labelling that is proposed for tobacco products, including prominent health warnings and product information, dictated by product package size (20).
- MLHU recommends 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.
- MLHU recommends prohibiting packaging which directly targets a specific consumer group, including, but not limited to, youth, expectant mothers, seniors, etc.
- MLHU recommends that packaging include information regarding safe disposal of unused product to reduce the risk of unintentional consumption.
- MLHU recommends including standardized packaging to the regulations to curb the marketing potential of products to certain consumer groups. MLHU recommends product packaging be standardized to consist of rectangular or square shape



	cardboard with all sides meeting at 90 degree angles, while prohibiting specialty packaging that would target specific consumer groups.
	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.
	 Labelling – Important Product Information MLHU recommends that all important product information of active ingredients and warnings should be easy to locate on each package, and follow a unified, consistent format which Canadian consumers can easily understand. Clear and standardized language is imperative.
6. With respect to	Recommendations:
edible cannabis, what do you think about the requirement for all products to be labelled with a cannabis-specific nutrition facts table?	 MLHU recommends 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 <i>ALL</i> products that deteriorate in 90 days or less; and, a cannabis-specific nutrition facts table. There should be <i>NO</i> nutrient and/or health claims on these labels. MLHU agrees that it should be prohibited to represent edible cannabis as being suitable for people with specific physical or physiological conditions (e.g., part of a low-calorie diets, for weight loss). With respect to the cannabis-specific Nutrition Facts Table (NFT), MLHU strongly recommends 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.
	 MLHU recommends that caffeine, alcohol, and THC/CBD content be displayed as part of the core list of declarations such that the consumer can make an informed decision with ease. MLHU recommends that cannabis-specific NFTs be required for cannabis extracts as well, and that nutrient content claims also be prohibited for cannabis extract products. It may be that flavouring agents, carrier substances, and substances that maintain the quality and/or stability of a product may contain nutrients that could lend itself to a nutrient content claim.



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?	 Recommendations: MLHU is in support of labelling small containers with the option to display certain information on a peel-back or accordion panel, provided that the cannabis health warning messages, standardized cannabis symbol and information pertaining to the THC and CBD content of the product are visible on the exterior display surface, regardless of the size of the container, as the current proposal states. MLHU recommends that the serving size should be displayed on the exterior to reduce the risk of overconsumption.
8. What do you think about the proposal that the standardized cannabis symbol would be required on vaping devices, vaping cartridges, and wrappers?	 Recommendations: MLHU supports the proposal of the standardized cannabis symbol requirement on all vaping devices, products, accessories, packaging and wrappings. MLHU recommends that the proposed regulation be strengthened to include health warnings, and THC and CBD concentration on all vaping devices, products, accessories, packaging and wrappings. MLHU recommends that the standardized cannabis symbol should be visible on all products that contain cannabis even if the amount of THC in the product is below 10 mcg/gram.
9. Do you think that 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?	Overall, the proposed good production practices requirements are in line with the Safe Food for Canadians Act (SFCA) and we feel they are sufficient to proactively reduce the risks of foodborne illness, cross-contamination, and unintentional consumption. Recommendations:
	 MLHU recommends 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. These additional proactive actions are very important given that the legal production of many of these new classes of cannabis products is new to both the licenced processing facilities and whomever is deemed to enforce Health Canada's national compliance and enforcement approach.
	 MLHU recommends 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. Request for Further Information: MLHU recommends that clarity be provided 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.



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?	 MLHU recommends that all processes and equipment, including producing, packaging, labelling, storing and shipping, be completely separate from conventional food processes. 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 cross-contamination leading to unintentional cannabis consumption.
11. What do you think about the overall regulatory proposal?	MLHU would like to commend Health Canada for creating draft regulations that seem focused on preventing harm and mitigating potential health risks. Recommendations:
	 To monitor regulatory impact, MLHU recommends that Health Canada employ a federal cannabis legalization monitoring strategy, with appropriate, population-level indicators focused on both health and societal impacts. MLHU recommends engagement with local public health agencies, provincial health organizations, and health agencies that operate at a national level to ensure cooperation and system-level coordination.
12. Are there any additional comments you would like to share on the proposed regulations for the new classes of cannabis?	Recommendations: 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." MLHU supports the proposed regulation amendments for edibles, extracts, and topicals which state that products cannot be appealing to young persons.
	 MLHU recommends that the Federal Government provide explicit definitions in the regulations for manufacturers which clearly identify prohibited elements of products which may be appealing to youth to avoid any misinterpretation. To make the regulations easy to follow for manufacturers, MLHU recommends that Health Canada provide a list of examples to cannabis manufacturers with regards to prohibitions on the appearance, shape, or other attribute or function that could be appealing to young persons.
	Providing a list of examples regarding prohibited items and attributes can help to reduce misinterpretation of what is prohibited. 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 (21). Other examples include stipulations that cookies cannot contain any sprinkles or frosting, and mints must not be coloured anything other than white (21).



Other key factors that influence children's food choices include (22, 23):

- 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.

Flexibility and Monitoring Activities

 MLHU recommends that Health Canada monitor and report on the breadth of health impacts, consumption patterns, unintended consequences, impact on the illicit market and enforcement/compliance activities.

Monitoring cannabis activities was indicted in the 2016 Final Report of the Task Force on Cannabis Legalization and is essential to create a flexible legislative framework that can adapt to new evidence on specific product types, on the use of additives or sweeteners, or on specifying limits of THC or other components (2).

Restrictions on Marketing of Non-Cannabis Food

- MLHU recommends additional regulations to prohibit conventional food products from being marketed in reference to cannabis use.
- In accordance with current tobacco and cannabis advertising regulations, MLHU recommends that all "lifestyle" advertising in reference to cannabis should be prohibited, regardless of what the advertised product is.

To further protect Canadians from the harms of increased normalization of cannabis use and marketing practices which would encourage consumption, there should be a prohibition on conventional food product cannabis marketing. For example, Hershey's introduced the "Oh Henry 4:25 chocolate bar" across Canada in 2018. This product was marketing itself as the perfect snack to have at 4:25 pm, in reference to directly eating after cannabis use. This marketing approach can have cannabis normalization effects.

Vape Cartridges Containing THC

 MLHU recommends that inhaled cannabis products should contain an integrated dispensing mechanism that dispenses no more than 10 mg of THC per unit, taking into account the potential to convert THCA into THC just like other cannabis extract items under the proposed regulation amendments under Section 122.15.

Integrated dispensing mechanisms for inhaled cannabis products could reduce overconsumption of THC through vaping. This would also align with the proposed regulation for extracts to limit each discrete unit of 10mg THC and maximum container size proposed of 1000mg THC (or MLHU recommended 100mg THC per Question #1 of this consultation). As with other cannabis labelling, clear, simple language must be used on the cannabis e-liquid container or cartridge itself to effectively communicate what consists of one unit to the consumer.



13. Are there any additional comments you would like to share regarding the legalization and strict regulation of cannabis in Canada? For example, are there measures the Government could take to support individuals to be in compliance with the public possession limits for cannabis (i.e. 30 grams of dried cannabis "or equivalent")? Do you have views on how to minimize environmental concerns associated with packaging, while maintaining key aspects, such as child resistant packaging, that help to prevent accidental consumption?

Recommendations:

Public Education

- MLHU strongly recommends that the Federal Government 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.
- MLHU recommends that the Federal Government educate Canadians about 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 (24).

• MLHU recommends that Federal public education initiatives focus on key cannabis legislation and Canada's Lower-Risk Cannabis Use Guidelines (1).

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 (25).

Additional Research Regarding "Standard Cannabis Serving Size"

 MLHU recommends that Health Canada prioritize research to help establish limits or "standard serving size" information for cannabis consumption and associated intoxication similar to what has been done for alcohol in *Canada's Low-Risk Alcohol Drinking Guidelines.*

"Lower-risk" amounts or standard serving sizes for cannabis have not been established, however, it is known that consumption of high-potency cannabis products increases the risks of negative health outcomes, both acute and long-term (1).

Advertising and Promotion

- MLHU recommends that all "lifestyle" advertising in reference to cannabis be prohibited.
- MLHU recommends strict regulations related to advertising and promotion of any cannabis product, including but not limited to, prohibition of advertising on television, radio, social media, the internet, and other media sources.

Places of Use

 MLHU recommends that the Federal Government consider a ban on the sampling and ingesting of cannabis edible products in a retail storefront or specialty consumption cafes or lounges, to reduce public health risks of consumption of edibles.

Banning cafes/lounges will encourage individuals to use these products in the home if they choose to use edible cannabis. This will help to reduce the risk of impaired driving,



public intoxication, the co-use of cannabis edibles in public with other substances such as alcohol, as well as the normalization of cannabis use.
Retail Spaces

As it will be the provincial and territorial responsibility for distribution and retail sale of cannabis, MLHU recommends that Health Canada advocate to restrict the sale of all cannabis products to standalone, specialty stores. Furthermore, sale of cannabis products should not be co-located in a premise with, nor sold alongside, other substances or non-cannabis products (i.e. non-cannabis food products, 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 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.

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