

THE NEXT PHASE OF CANADIAN CANNABIS: WHAT TO EXPECT IN 2019 AND BEYOND

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On June 14, 2019, Health Canada unveiled its *Final Regulations for New Cannabis Products: Edible Cannabis, Cannabis Extracts and Cannabis Topicals* (the “Regulations”), addressing the production and sale of edible cannabis (eating or drinking), cannabis extracts (ingesting or inhaling), and cannabis topicals (applying to skin, hair, or nails). The Regulations are substantially similar to the related draft regulations released in December 2018. The Government of Canada’s Task Force on Cannabis Legalization and Regulation^[1] (the “Task Force”) recommended, subject to strict regulatory controls, the legalization of a diverse range of cannabis products to displace the illegal market. In accordance with the Task Force’s recommendations, the Regulations, once in force, will permit the sale and manufacturing of edible cannabis products, cannabis extracts, and cannabis topicals.

Government Objectives Underlying the Regulations

The Regulations highlight Health Canada’s and the Government of Canada’s three main concerns: (i) the potential for cannabis products to be overly appealing to young persons; (ii) overconsumption or accidental consumption by adults; and (iii) advancements in research relating to the use of cannabis products as forms of primary or supplemental mental health and other therapies.

Appeal to Young Persons

Concerns with these new classes of cannabis products include appeal to young persons and risks of accidental consumption or overconsumption. Accordingly, a key component of the Regulations is the overarching prohibition against promoting cannabis products in a manner that would reasonably appeal to young persons. To determine whether a product falls under this strict prohibition, a wide range of factors will be considered on a case-by-case basis. These include but are not limited to the shape, colour, smell, flavour, name, label, and presentation of the cannabis products and packaging – this is particularly relevant to edible cannabis. Health Canada has made it clear this is an important issue and while the industry may be innovative and competitive in determining products they choose to manufacture, produce, and sell, there will be zero tolerance for non-compliance with the Regulations when it comes to directly or indirectly marketing cannabis products to young

persons.

Overconsumption

Health Canada has expressed its concerns that both new and seasoned cannabis users often do not fully understand the dosing effects of cannabis, particularly edible cannabis. The Regulations prescribe precautionary limits on the amount of tetrahydrocannabinol (THC)^[2] that can be contained in edible cannabis, cannabis extracts, and cannabis topicals to address the concerns of overconsumption and accidental consumption. Moreover, Health Canada will be investing in educational campaigns for adult consumers regarding recommended dosing and ways to reduce the risk of overconsumption – for example, Health Canada advises that new consumers should choose an edible cannabis product that contains 2.5mg of THC or less and wait to feel the full effects before consuming more. Warning messages and information on how to consume edible cannabis products have also been updated and guidelines will be provided by the Center of Addiction and Mental Health (“CAMH”) and other participating agencies.

Advancements in Research Around Use in Mental Health and Therapy

Another key objective for the Government of Canada is to invest in increased research related to the use of edible cannabis and cannabis extracts as forms of primary or supplemental mental health and other therapies. Funding will be included for research, the CAMH and other federally funded organizations. Current funding supports 26 projects across Canada that cover the use of cannabis and cannabidiol (CBD) oil for treatment of pain and anxiety, as well as research teams that explore the therapeutic potential for cannabis in areas such as chronic pain, cancer, and neurodevelopment.

Timeline and Process

The Regulations are expected to be formally published in the *Canada Gazette*, Part II, on June 26, 2019.

On July 15, 2019, federal licence holders seeking to produce and sell new classes of cannabis will be able to apply to Health Canada for amendments to their existing licence(s).^[3]

The Regulations are scheduled to come into force on October 17, 2019,^[4] which means that the *Cannabis Act*^[5] will authorize the sale of edibles containing cannabis along with cannabis extracts and cannabis topicals. Federal licence holders must provide Health Canada with a 60-day notice of their intent to sell any of the new categories of cannabis. This requirement remains unchanged from the initial *Cannabis Act* for the initial classes permissible for sale. Accordingly, the market should expect the actual sale of edible cannabis, cannabis extracts, and cannabis topicals to be permitted no earlier than December 16, 2019, for those who are timely to file notifications of new classes of cannabis product offerings.

Given the timeline established by Health Canada, it is likely that the selection of new classes of cannabis products available in mid-December 2019^[6] will be limited, with increased product diversification and availability likely occurring in 2020 as the market matures.

Products and Quantity

The Regulations surrounding the manufacturing of edible cannabis, cannabis extract, and topical cannabis products remain substantially unchanged from the draft regulations. Under the Regulations, manufacturers are prohibited from producing any cannabis products (not just edible products) in buildings where non-cannabis food products are also produced. This is aimed at reducing risks of mislabelling and cross-contamination. Moreover, the area in which edibles containing cannabis are manufactured and produced must be compliant with the security and sanitary requirements under the *Cannabis Act*. Since the timeline for obtaining a federal cannabis licence and entering into the market for the first time will continue to be a time-intensive process, current federal licence holders will likely have a first mover advantage over food processors on the edibles side. However, the Regulations also place new requirements on federal licence holders surrounding food safety and food borne illnesses as well as obligations in line with current regulatory frameworks for items like cosmetics and topical creams and ointments. These processes will be new for cannabis companies, so we expect some creative licensing frameworks to emerge so that both industries are able to take advantage of the other's expertise.

Edibles

One of the overarching principles of the Regulations is that cannabis products may not be promoted in a manner that appeals to young persons. As a result, federal licence holders will need to be strategically cautious in creating and marketing their edible cannabis products to ensure that the products do not trip over this prohibition. Health Canada is not seeking to provide the industry with guidance on what acceptable products look like. Instead, Health Canada will leave it up to the industry to act responsibly (in accordance with the Regulations) and will make this determination as the marketplace develops. Importantly, public officials have begun indicating what unacceptable products look like – specifically, Border Security and Organized Crime Reduction Minister Bill Blair has outlined that gummy bears that are appealing to children would be prohibited.^[7] It is unclear what level of reduction of such appeal, if any, would allow a similar product to exist: for example, a colourless, flavourless, gummy product in a bear shape and unappealing packaging may or may not be permissible.

Cannabis infused edibles cannot include additional caffeine or alcohol. The only method for caffeine or alcohol to be found in edible cannabis products permitted by the Regulations is if it has naturally occurred in ingredients like chocolate (caffeine) or vinegar (alcohol).^[8] It is worthy to note that natural occurrences of

caffeine is restricted to a maximum of 30 milligrams (mg).^[9]

Due to the presence of an unlicensed (illegal) cannabis market in Canada, federal licence holders will be competing with products such as gummy bears, chocolates, or candies available to consumers from unregulated and unlicensed (illegal) producers, without the ability to replicate or produce comparable products due to stringent regulations. The Regulations may pose additional challenges to federal licence holders given restrictions on ingredients that federal licence holders would be subject to, as well as the restrictions on mg of THC per packaged cannabis product. The Regulations impose a limit of 10mg of THC per discrete unit and per container (a multi-pack). This means, for example, that a container could contain one discrete unit of edible cannabis (e.g. cannabis beverages) that contains 10mg of THC or two discrete containers that each contain 5mg of THC provided that the total amount of THC in the multi-pack does not exceed 10mg. Since a multi-pack with six beverages would result in a per unit THC amount of approximately 1.67 mg, we anticipate that four-packs may be more in line with anticipated market demand for beverages with approximately 2.5 mg of THC per can or bottle, which would also be in line with Health Canada's recommended maximum initial dose for new consumers.

Notwithstanding the packaging limitations, one of the greatest strengths that federal licence holders have when compared to the illegal market is that consumers can have assurances from federal licence holders with respect to the ingredients and dosages contained in a cannabis product. Whether consumers purchase edible cannabis products in the illegal market or migrate to the legal market remains to be seen. However, when compared to alcohol, it is a trite statement to say that the majority of spirits drinkers purchase regulated spirits rather than resorting to unregulated moonshine. If the cannabis market follows the same consumer preferences as alcohol, then federal licence holders have a discernable competitive advantage.

Extracts

Oils containing cannabis are currently permitted as a class under the *Cannabis Act*. However, they may only have two ingredients, the CBD and the carrier oil, and may not include sugar, sweetener or colour. Under the Regulations, the class of oils will remain but will be effectively subsumed under the extracts class. Under the new class, federal licence holders will be allowed to add certain prescribed additional ingredients, colour and some flavour (provided that the flavour does not appeal to young persons) into the product.

Under the Regulations, the limits for the cannabis extracts, as is currently the case for cannabis oil, will be a limit of 10mg of THC per discrete unit that is intended to be ingested or inserted (such as in the form of a capsule). In addition, there will be a new limit of 1,000 mg of THC per container.^[10] This means, for example, that a container could contain 100 capsules of an extract that each contain 10mg of THC or 200 capsules of an extract that each contain 5mg of THC.

Cannabis vaping is not restricted so when the Regulations are in place, companies will be able to offer concentrates such as cannabis oils.^[11] However, vape scents still cannot appeal to children. Notwithstanding the inclusion of the Extracts class, any vaping products will also remain subject to the Tobacco and Vaping regulatory framework.

Topicals

The Regulations set out strict limits for the production and sale of cannabis topicals. Cannabis topicals are products applied to skin, hair, or nails. They are not to be used in the eyes or on damaged skin. A cannabis topical is limited to 1,000 mg per package,^[12] and cannot include any nicotine or alcohol.

Each Cannabis topical label must include the standardized cannabis symbol for products containing THC, a health warning message, the THC/CBD content, the equivalency to dried cannabis to determine the public possession limit, ingredient list, allergens, and the intended use. The prohibited ingredients comply with Health Canada's cosmetic ingredient hotlist, which are prohibited for use in cosmetics.^[13]

Additionally cannabis topicals mirror the other cannabis products in that they cannot be appealing to young persons, and must not make health claims. They also cannot be associated with alcoholic beverages, tobacco products or vaping products, nor can the label make any cosmetic claims.

Packaging

Under the Regulations, in addition to the prohibition on promoting cannabis in a manner that could appeal to young persons, manufacturers will be prohibited from packaging and labeling cannabis products in a manner that evokes an alcoholic beverage or references alcohol or tobacco. The rationale behind this prohibition is the preclusion of cannabis products that incorporate other substances like alcohol or nicotine. What will ultimately be deemed to "evoke" an alcohol or tobacco product is still difficult to interpret. Accordingly, federal licence holders should encourage Health Canada to be proactive and informative with their reviews of cannabis products to provide guidance on how labeling rules will be applied in practice.

Under the Regulations, lower possession limits and limits on the quantity of cannabis per package applies to cannabis products containing more than 3% THC by weight. Under the Regulations, there is a maximum quantity of 7.5 grams of cannabis (which is the deemed equivalent to 30 grams of dried cannabis) per package and public possession.^[14] This rule applies to edible cannabis, cannabis extracts, and cannabis topicals that contain more than 3% THC.

An additional requirement set out in the Regulations is the need for products to be packaged in child-resistant containers. This is the same for dried and fresh cannabis and cannabis oil. While there is some flexibility to the way cannabis is packaged (e.g. in a pill container, a cardboard box, etc.), packaging should not be considered a

market barrier. The need for the packaging to be child resistant is non-negotiable; however, Health Canada has pointed to new products that may be less waste producing than traditional medical packaging as examples of opportunities for the industry to be creative and competitive.

The Regulations will continue to include restrictions on brand elements and locations and sizing of the standard cannabis symbol. On review, the labeling rules remain difficult to navigate. The industry would benefit from swift product reviews from Health Canada on how labelling rules will be applied in practice.

Colorado, California, and Washington State all have different regulatory schemes regarding the control of edibles. In the states where cannabis is legal (pursuant to state, rather than federal, law), the state allows up to 10 mg of cannabis per serving, in contrast to the 10 mg per package to be allowed in Canada,^[15] Colorado^[16] and California^[17] have also specified that each package is allowed up to 100 mgs, which is a much broader regulatory allowance than under the Regulations. As a result, there may be additional overhead costs for companies doing business in both the United States and Canada because they will have to adjust the way they produce and package cannabis products to accommodate for the varying regulations across different jurisdictions.

Cannabis packages in Canada are required to display THC and CBD concentrations on cannabis product labels, and must also display the product's equivalency to dried cannabis to provide consumers with a new tool to help determine their public possession.

Other Matters

The Regulations have put a number of restrictions on restaurants being able to sell cannabis infused products. It is important to remember that a federal cannabis licence is required to make any product containing cannabis for sale. In addition to being required to have the applicable federal license to allow production and sales, a restaurant hoping to produce or sell cannabis products will also have to package the cannabis according to the Regulations,^[18] pay the required tax on those products, and comply with requirements that the cannabis products be "shelf stable". While the Regulations do not prohibit selling cannabis products in restaurants, they have made it logistically impractical (read: practically impossible) to do so. For example, a cookie, provided that it did not appeal to young persons and was packaged and labelled in accordance with the Regulations, could comply with the Regulations but a baked lasagna likely could not (because, among other things, it is not "shelf stable"). Bars and restaurants that do not sell but allow consumption of cannabis products will remain subject to local provincial and municipal regulations for consumption lounges.

No changes have been made with respect to how CBD is regulated. CBD is still regulated the same way as cannabis pursuant to the *Cannabis Act*^[19] unless it is a prescribed drug, which would place it under the regulations of the *Food and Drug Act*.^[20] Health Canada has, however, stated that they will hold consultation

on CBD in order to determine how to best provide regulatory oversight. As a result, the regulatory scheme surrounding CBD may change, but there is no timeline for further consultation.

Conclusion

The Government of Canada seeks to rely on a regulated cannabis industry with federally licensed products to eliminate (or at least reduce) the existence of an illegal market. Until the elimination of the illegal market, federal licence holders will compete with such products available from unlicensed and unregulated sources, with the additional restrictions placed on them from the Regulations. Legal cannabis products will provide consumers with certainty regarding the use of ingredients, the safe handling of cannabis products, and the dosage of a cannabis serving or package. This, without question, is a competitive advantage for federal licence holders.

At the initial stages of the legalization of edible cannabis products, there will be a lack of diversity of regulated products, but, over time, as more cannabis products are developed, the industry may provide enough variety of trusted products to significantly reduce the illegal market. While the Regulations do offer strict controls over the industry, federal licence holders will be left to define these standards as they apply to Health Canada for approval and populate the industry with new cannabis products. It is likely that, as the industry begins to take shape with these new products theoretically hitting the market starting December 16, 2019, the interpretation of how Health Canada will apply the Regulations will subsequently emerge, and the industry will have examples of products that passed the screening process to build from.

Canada was the first G7 country to legalize and regulate recreational cannabis. The emergence of the legal edible, extracts, and topicals market in Canada is another opportunity for federal licence holders in Canada to be innovative, develop new products, and remain leaders on the world stage.

About McMillan's Cannabis Practice Group

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by James Munro, Morgan T. McDonald, Roland Hurst, Sasa Jarvis, and Temporary Articled Students – Stephen Lewis and Vanessa Yee

[1] Health Canada, A Framework for the Legalization and Regulation of Cannabis in Canada: The Final Report of the Task Force on Cannabis Legalization and Regulation, (Final Report) (Ottawa: Health Canada, November 2016).[ps2id id='1' target='']

[2] House of Commons, Final Regulations for New Cannabis Products: Edible Cannabis, Cannabis Extracts and Cannabis Topicals (June 2019) online (pdf).[ps2id id='2' target='']

[3] Kathleen Harris, "Canadians can expect tight supply when cannabis edibles become legal mid-December, officials say" (14 June 2019), online: CBC.[ps2id id='3' target='']

[4] Health Canada, News Release, "Health Canada finalizes regulations for the production and sale of edible cannabis, cannabis extracts and cannabis topicals" (14 June 2019), online: Government of Canada.[ps2id id='4' target='']

[5] Cannabis Act, SC 2018, c 16.[ps2id id='5' target='']

[6] Ibid.[ps2id id='6' target='']

[7] Ibid.[ps2id id='7' target='']

[8] Supra note 2 at 14.[ps2id id='8' target='']

[9] Ibid.[ps2id id='9' target='']

[10] Supra note 2 at 12.[ps2id id='10' target='']

[11] Hannah Thibedeau, "Cannabis edibles available for sale legally in mid-December" (14 June 2019) online.[ps2id id='11' target='']

[12] Supra note 2 at 57.[ps2id id='12' target='']

[13] Health Canada, Cosmetic Ingredient Hotlist (Canada: Health Canada, 2018) online: Government of Canada.[ps2id id='13' target='']

[14] Supra note 5 at part 3.[ps2id id='14' target='']

[15] US, National Environmental Health Association, Food Safety Guidance for Cannabis-Infused Products, online: National Environmental Health Association.[ps2id id='15' target='']

[16] US, Colo Rev Stat §44-12-202(d)(IV).[ps2id id='16' target='']

[17] US, Cal Code Regs tit 14, § 757.[ps2id id='17' target='']

[18] This includes, among other things, child-proof packaging.[ps2id id='18' target='']

[19] Supra note 5.[ps2id id='19' target='']

[20] Food and Drugs Act, RSC 1985, c F-27.[ps2id id='20' target='']

A Cautionary Note

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.

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The logo for mcmillan, featuring the word in a lowercase, sans-serif font. The 'm' and 'c' are in a dark red color, while the 'm', 'i', 'l', 'l', 'a', and 'n' are in a light blue color. The logo is positioned in the upper left corner of the page.

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