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In High Demand: Health Canada Releases Final Regulations for Cannabis Edibles, Extracts and Topical Products

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Health Canada has released the final regulations (Regulations) that will govern cannabis edibles, extracts and topical products. The Regulations will come into force on October 17, 2019, in substantially the same form as the draft regulations published by Health Canada in December 2018.

Market participants and the public have been eagerly awaiting legislative changes to allow for the production and sale of alternative cannabis products such as edibles, beverages and cannabis concentrate vaporizers. In a recently released report, Deloitte estimated that the Canadian market for these alternative cannabis products could be worth as much as \$2.7 billion annually. With significant consumer demand looming, licensed processors will need to quickly figure out how to navigate the Regulations in order to bring alternative cannabis products to market in short order.

Overview of the Regulations

Products

The Regulations prescribe a maximum of 10 milligrams of THC per package of edible products and a maximum of 1,000 milligrams of THC per package of cannabis extract (such as a vape cartridge) or a cannabis topical intended to be applied to skin, hair or nails.

The Regulations prohibit products that are appealing to youth, causing many to question the permissibility of popular edible cannabis product forms such as cannabis-infused gummy bears. Health Canada officials have indicated that whether a product is appealing to youth will be assessed on a case-by-case basis, taking into account factors such as shape, colour, branding, packaging and overall presentation.

Packaging and Branding

Consistent with the requirements for other forms of cannabis currently available for purchase, the Regulations require that edibles, extracts and topical products be packaged in child-resistant, plain packaging and prohibit the presentation of any health-related claims.

The Regulations also prohibit the use of brand elements that would associate the product with alcoholic beverages, tobacco products or vaping products. This prohibition would appear to restrict the use of known alcohol, tobacco or vape brands on cannabis products. Health Canada has suggested that this prohibition would also restrict the use of terms generally associated with alcoholic beverages, such as "cannabis beer" or "cannabis wine."

Production Facilities

The Regulations have maintained one of the most controversial provisions from the draft legislation: the prohibition on producing cannabis products in the same facility that conventional food products are produced in. The capital cost associated with building a standalone cannabis processing facility, coupled with the strict product requirements set out in the Regulations, may deter existing food processors and traditional consumer packaged goods companies from entering the market. This may afford vertically integrated

licensed producers who have invested in production facilities for alternative cannabis products with a first mover advantage over unlicensed competitors looking to take advantage of a new market opportunity.

Challenges Ahead

Timing

In order to produce and sell cannabis edibles, extracts and topical products, federally licensed processors will need to seek a licence amendment authorizing such activities. Health Canada will begin accepting licence amendment applications on July 15, 2019, but is not expected to start approving amendments until the Regulations come into force on October 17, 2019.

Consistent with the *Cannabis Regulations* currently in force, licensed processors are required to provide Health Canada with a written notice at least 60 days before making a new cannabis product available for sale. Health Canada will begin accepting new product notices for alternative cannabis products on October 17, 2019. As a result, the earliest that consumers can expect to see cannabis edibles, extracts and topical products on the shelves is mid-December 2019.

Given the likely volume of licence amendments and new product notices that Health Canada will need to process, it is expected that a limited variety and quantity of products will be available initially.

Products

The onus to ensure that any new cannabis product complies with the Regulations falls on the licence holder. Health Canada has indicated that it will not entertain pre-approval requests for new cannabis products. The nebulous requirement that these alternative cannabis products not be appealing to youth, together with other ambiguous product requirements set out in the Regulations, creates uncertainty for licensed processors as they develop cannabis edibles, extracts and topical products to bring to market. There is a risk that time and capital will be spent developing products that Health Canada ultimately deem to be non-compliant.

As a result of the potential regulatory burden of processing licence amendment applications and new product notices, there is a risk that licensed processors may have to hold significant amounts of inventory while awaiting the requisite approvals. Many licensed producers have earmarked significant amounts of dried cannabis flower to use in the production of edibles, extracts and topical products in anticipation of robust demand for such products. However, ultimately Health Canada will control the quantity of and speed at which alternative cannabis products are introduced into the consumer market. It appears likely that demand for such products will exceed supply for a prolonged period.

Finally, Health Canada has suggested that it may engage in a consultation process with respect to the regulation of CBD, the non-intoxicating cannabinoid found in cannabis, which is purported to have therapeutic benefits. No timeline has been proposed for such consultation process. Currently, CBD is subject to the same regulation as THC, the intoxicating cannabinoid in cannabis. Many industry participants have argued that products containing only CBD, and not THC, should be subject to less stringent regulation as a natural health product. However, for the time being, the Regulations will apply to such products.

Conclusion

The next generation of cannabis products has been greatly anticipated by cannabis consumers and producers alike. Although the Regulations present a number of challenges for licensed processors to develop and bring products to market, with definitive regulations now in place, industry participants now have a road map and four short months to prepare to bring alternative cannabis products to market.

We will be watching closely as the next exciting chapter in Canada's nascent cannabis industry unfolds.

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