



Legal Landscape Applicable to the Regulation of Cannabis in Canada

Overview

On April 13, 2017, the Government of Canada introduced Bill C-45, the *Cannabis Act*, in the House of Commons. Based on the input of public health, law enforcement and justice experts, the *Cannabis Act* provided a national framework to provide restricted access to regulated cannabis and to control its production, distribution, sale, importation, exportation, and possession. The *Cannabis Act* received Royal Assent on June 21, 2018, and was brought into force on October 17, 2018.

The legalization of cannabis has been accompanied by a rapid growth of cannabis-related industries. These range from licensed producers to online retailers to technology companies designing improved methods of cannabis cultivation, extraction and delivery. Those working in the cannabis industry, along with consumers and the general public, generally have many questions about where cannabis can be purchased legally, from whom and, more generally, what can and cannot be done, now that cannabis is legal. These questions are frequently directed to a legal community tasked with keeping abreast of an ever-evolving set of laws and practices.

In this update, we provide an overview of the legal landscape applicable to the regulation of cannabis in Canada. We do so by: (a) setting out applicable Federal Laws and Regulations; (b) providing a summary of the applicable provincial and municipal laws and regulations; and (c) identifying ancillary areas likely of interest to those participating in the cannabis industry.



Federal Laws and Regulations

The *Cannabis Act*

The *Cannabis Act* creates a legal and regulatory framework for controlling the production, distribution, sale, and possession of cannabis in Canada. Subject to provincial or territorial restrictions, adults who are at least 18 years of age or older (depending on the province or territory), are legally able to:

- purchase limited amounts of fresh cannabis, dried cannabis, cannabis oil, cannabis seeds, or cannabis plants from retailers authorized by the provinces and territories;
- consume cannabis in locations authorized by local jurisdictions;
- grow up to four cannabis plants per household (not per person) for personal use, from licensed seeds or seedlings from licensed suppliers;
- share up to 30 grams of dried cannabis or equivalent with other adults; and
- make legal cannabis-containing products at home for personal use, such as food and drinks, provided that dangerous organic solvents are not used in making them.

Possession, production, distribution, and sale outside the legal system will remain illegal and subject to criminal penalties proportionate to the seriousness of the offence, ranging from ticketing up to a maximum penalty of 14 years' imprisonment.

The *Cannabis Regulations*

The *Cannabis Regulations*, which also came into force on October 17, 2018, established the rules and standards that apply to the authorized production, distribution, sale, importation and exportation of cannabis (with the exception of industrial hemp), as well as other related activities respecting the five classes of cannabis (*i.e.*, dried cannabis, fresh cannabis, cannabis oil, cannabis plants, and cannabis plant seeds) that can be sold by authorized persons.

The *Cannabis Regulations* set out a comprehensive public health approach to regulating the production, packaging and labelling of all classes of cannabis.

Among other things, the *Cannabis Regulations* provide that:

- Licences are required in order to cultivate or process cannabis, to sell cannabis for medical purposes, to manufacture prescription drugs containing cannabis, or to conduct analytical testing of or research with cannabis. The licensing requirement and process by which licences may be obtained are set out in Part 2 of the *Cannabis Regulations*;
 - An application for a licence is submitted to Health Canada for approval by the Minister of Health and must include the information required by the Minister. Although not having the force of law, the *Cannabis Licensing Application Guide*, published by Health Canada provides instructive details on what should be included in an application and the form and manner in which it should be submitted.
 - The publication of guidance documents of this sort is a practice commonly adopted by Health Canada when an applicant requires regulatory approval to manufacture or sell a given product, such as a pharmaceutical.

- Licence holders are subject to strict physical and personnel security requirements. These requirements are set out in Part 3 and 4 of the *Cannabis Regulations*.
- The production of cannabis products by licence holders is subject to strict rules and standards, including limits on tetrahydrocannabinol (THC) content, cannabidiol (CBD) specifications and the use of additives, as well as good production practices (GPP). Details concerning GPP and the composition of cannabis products, including dried leaves and oils, are set out in Parts 5 and 6 of the *Cannabis Regulations*, respectively;
- Plain packaging and labelling is required for cannabis products, including strict limits on the use of logos, colours, and branding. Packaging and labelling requirements are set out in Part 7 of the *Cannabis Regulations*; and
- Continued access to cannabis for medical purposes is provided for patients who qualify. Part 14 of the *Cannabis Regulations* sets out the provisions relating to access to cannabis for medical purposes.
 - Before the passing of the *Cannabis Act*, cannabis for medical use was regulated by the *Access to Cannabis for Medical Purposes Regulations (ACMPR)*.
 - The *Cannabis Regulations* endeavoured to improve patient access to cannabis by permitting patients to purchase cannabis at authorized retail outlets or online sales platforms.
 - Previously, patients authorized by their health care provider to access cannabis for medical purposes could only do so by buying directly from a federally licensed seller, registering with Health Canada to produce a limited amount of cannabis for their own purposes or designating someone to produce it for them.



But Can They Eat Cannabis Cake?

One area that is of particular interest to consumers, manufacturers, and sellers is the availability of edible cannabis products. Indeed, the market is replete with stories of new cannabis infused foods and companies are embarking on ways to make water-soluble derivatives of cannabis to allow for a wider array of cannabis-infused beverages.

At present, Schedule 4 of the *Cannabis Act* limits the type of cannabis that may be lawfully sold to dried cannabis, cannabis oil, fresh cannabis, cannabis plants, and cannabis seeds. However, on December 22, 2018, the Government of Canada published a Regulatory Impact Analysis Statement (RIAS) that proposed that regulations be passed that add three classes of cannabis to Schedule 4, namely:

- Edible cannabis: products containing cannabis that are intended to be consumed in the same manner as food (*i.e.*, eaten or drunk);

- Cannabis extracts: products that are produced using extraction processing methods or by synthesizing phytocannabinoids; and
- Cannabis topicals: products that include cannabis as an ingredient and which are intended to be used on external body surfaces (*i.e.*, skin, hair, and nails).

The RIAS indicates that regulations directed at these classes of cannabis products should, among other things, address:

- the appeal that such products may have to youths;
- the risk of accidental consumption;
- the risk of overconsumption (in the case of edibles, because of the delay in experiencing the effects of cannabis when it is ingested rather than inhaled and, in the case of extracts, because the products contain a higher THC concentration);
- the risk of dependence and other negative health outcomes associated with cannabis products that contain ethyl alcohol or caffeine; and
- the potential health, and, in some cases, safety, risks associated with the use of certain solvents, carriers, and diluents.

The RIAS indicates that amendments to the *Cannabis Regulations* to address these classes of cannabis must be brought into force by no later than October 17, 2019. A consultation with the public was held between December 20, 2018 and February 20, 2019.

Provincial Laws

The General Approach

The regulation of the retail cannabis industry is a shared responsibility across federal, provincial, territorial, and municipal governments.

Generally speaking, provinces and territories are responsible for determining how cannabis is distributed and sold within their jurisdictions. They set rules around how cannabis can be sold, where stores may be located, and how stores must be operated.

Provinces and territories also have the flexibility to set added restrictions, including lowering possession limits, increasing the minimum age, restricting where cannabis may be used in public, and setting added requirements on personal cultivation.

Ontario

The approach taken in Ontario provides an instructive example. At present, Ontario permits consumers to purchase up to 30 grams of dried recreational cannabis at one time for personal use. For some time, the Ontario Cannabis store (OCS) website was the only legal way to purchase recreational cannabis. However, on April 1, 2019, privately run retail stores were permitted to start selling cannabis in addition to the OCS, though the OCS remains the sole online retailer in Ontario. This represented a change from the initial approach contemplated by the provincial government, which envisioned the sale of cannabis by government-run stores in a manner akin to the way alcohol is sold in Ontario.

The Alcohol and Gaming Commission of Ontario (AGCO) is the provincial regulator authorized to grant store licences and make sure stores sell recreational cannabis safely, responsibly, and lawfully. The OCS serves as the exclusive wholesaler to these stores.

To open a retail store and sell recreational cannabis, there are two licences and an authorization that are required from the AGCO. These are:

- Retail Operator Licence;
- Cannabis Retail Manager Licence; and
- Retail Store Authorization.



The eligibility criteria necessary to become a licensed retail operator are described in the *Cannabis Licence Act, 2018* and its regulations. Due to a shortage of legal cannabis supply from federally licensed producers, the government of Ontario only provided authority for the AGCO to license up to 25 stores in the initial phase. A lottery system was implemented to determine who would be able to apply for a licence for one of the 25 initial stores.

Municipal Considerations

The sale of recreational cannabis in privately-owned stores will also require regulation by municipalities both from a zoning and licensing perspective. For example, in 2013, when the federal government enabled commercial production of medical cannabis, the City of Toronto amended its Zoning By-laws to define such facilities and prescribe where such uses would be permitted, including through the use of separation distances from sensitive uses. It is expected that consideration of where and when cannabis retail stores can operate will be the subject of ongoing debate.

Notably, Ontario municipalities had a one-time option to opt-out of having cannabis retail stores in their communities. Municipalities had until January 22, 2019 to inform the AGCO if they wished to opt out. While municipalities that chose to opt out have the right to opt back in at any time, once they have opted in, the right to opt-out again is lost.

Ancillary Considerations

The need to grapple and understand the laws and regulations that speak directly to the regulation of cannabis in Canada can make it easy to forget that there are a host of other strategic legal considerations that are relevant to legal practitioners and those seeking to participate in the cannabis industry. The building and structuring of a cannabis business requires careful attention be given, not only to the aforesaid regulatory issues but to establishing appropriate governance, raising capital, entering into licensing arrangements and intellectual property issues.

The role of intellectual property in the cannabis sphere is a matter that is of particular importance. Cannabis producers are making large investments in creating new technologies and compelling brand identities. Canadian law offers a number of different avenues that allows companies to protect their investments in technology and goodwill.

Patents: Protection for new and inventive technology

Patents, which are issued in accordance with Canada's *Patent Act*, provide their owners with the right to have a Court prevent anyone else in Canada from making, using, selling, importing or exporting what is claimed as the patent's invention. Patents are meant to protect inventions, meaning novel, non-obvious and useful solutions to practical problems. A party who discloses their invention to the public in a patent is rewarded with a time-limited monopoly in exchange for so doing. A patent enables a party with an existing market to maintain exclusivity in that market or obtain a remedy if someone else infringes that patent. In addition, patents, in and of themselves can generate value for companies: venture capital often seeks companies with patent applications on file because the applications can mature into assets which can be monetized either by protecting a market for the owner, or through assignment or licence to others. That said, obtaining a patent is not without its risks. Since a patentee is obliged to disclose its invention, a competitor can often receive a "blueprint" of a patentee's business plan and gain an appreciation of its technology.

Cannabis researchers and producers have already filed hundreds of patent applications in Canada. These application relate to a wide range of inventions in the cannabis field including new cannabis resins and oils, methods of producing cannabis having improved properties, specific new growing processes, new harvesting methods, new extraction techniques, new formulations for human and veterinary use as foods, medicines and supplements, new delivery devices, new purification methods, new analytical methods, and new stabilization methods. For some of these companies, the mere filing a patent application projects that the company has value and a clear vision of its business.

As cannabis companies rush to obtain patent monopolies for their technologies, minefields are created for operating companies. Cannabis producers should obtain reports on what patents exist and might be asserted against their operations. With that intelligence in hand, the cannabis producer can understand what threats can be safely ignored and what patents must be addressed by assignment or licence, by 'design around' or by developing an argument as to why the patent is invalid and thus unenforceable.

Plant Breeders' Rights: Protection for new plant varieties

Not all classes of technical innovations are protectable by patent. For example, patents are not available for a whole cannabis plant because no patents are allowed on higher, multicellular organisms. Unlike the *Patent Act*, Canada's *Plant Breeders' Rights Act* does provide intellectual property protection for whole plants.

The *Plant Breeders' Rights Act* focuses on the material used to propagate a new variety of plant, such as its seeds. The owner of a plant breeder's right can stop others from selling, producing or reproducing the propagating material, conditioning the propagating material for use, exporting or importing the propagating material, repeatedly using the protected variety to commercially produce another variety, and stocking the propagating material for the purpose of doing any of the above acts. The owner can also assert these same rights to stop another's activities as they relate to another plant variety that is essentially derived from the protected variety.

Plant breeder's rights are available for new cannabis plants, whether they are the product of genetic engineering or more traditional cross breeding. There are already several registered denominations of cannabis plants under the *Plant Breeders' Rights Act*, with more expected to follow.



Trade secrets: Protection for confidential know how

A trade secret is specific, commercially-valuable know-how that is kept confidential and cannot generally be reversed-engineered. A trade secret provides protection over any type of know-how and is not subject to any expiry date. Trade secret protection is lost only when the know-how becomes available to those outside the company. For the trade secret to be maintained, the producer will need to take steps to ensure that access to the know-how and associated documents is restricted only to those who need to know the secret for purposes of carrying out their function at the company.

Unlike a patent or a plant breeder's right, there are no statutory conditions that must be met to obtain a trade secret and there is no need to make any public disclosure. A trade secret is acquired simply upon the generation of valuable know-how that is kept confidential. As a best practice, defining the trade secret in a document can be useful as evidence in proceedings when the limits of the trade secret are in dispute. A trade secret's very confidentiality provides its principal value. A competitor cannot copy what it has no ability to discern. However, when an employee 'goes rogue', such as by using the know-how for his or her own account or for that of a new employer, the owner of the trade secret must act quickly and bring the matter before the Court to prevent further dissemination. If the action is brought before the trade secret is broadly disseminated, the trade secret may be reinstated and enforceable in the future. If the owner of the secret acts too slowly and the dissemination of the trade secret becomes too broad, the trade secret may be lost forever.

Cannabis producers can generate all kinds of valuable know-how that would not be apparent from examining the vended product. Specific methods of cross-breeding, of cultivation, of harvesting, of extraction, of processing, specific customer lists, and specific business methods that a producer uses to create and market its product may not become available to the public simply by inspecting the product. If this knowledge is kept confidential, it can be a trade secret.

Trademarks: Protections for brands and goodwill

Cannabis businesses must not only protect their investments in their technical creations, but also must protect their brand identities. A cannabis producer can invest heavily in making a desirable, high-quality product, and can advertise and sell this product so as to generate customer interest and goodwill, but if the customer cannot distinguish the producer's product from that of competitor, this investment is for not.

A trademark provides its owner with the right to have the Court stop another entity from using the trademark, or using a similar trademark in a way that confuses the public. When the trademark is infringed, the Court can also make a monetary award in favour of the trademark owner. Trademarks are identifiers of a particular source of manufacture and they can take virtually any form. Trademarks can be words, phrases, symbols, names, designs, letters, numbers, colours, three-dimensional shapes, holograms, moving images, modes of packaging, sounds, scents, tastes, textures, or any other distinguishing element. What a trademark cannot be is a mere descriptor of the goods or services themselves because such a trademark would prevent other entities from describing their products in their ordinary terms. Further, trademarks become unenforceable when they are no longer distinctive. For this reason, trademark owners must keep abreast of any use of trademarks similar to their own by third parties, and must act quickly to either license such uses or to restrain them.

In choosing a trademark, the cannabis producer must balance competing impulses: The desire to choose a trademark that is suggestive of the product itself so as to have an immediate meaning to customers without need of an expensive marketing campaign; and the desire to coin a unique and striking trademark which is instantly eye-catching and memorable, but which must be advertised before customers can understand the product to which it refers. In addition, the producer must be mindful of the restrictions imposed

on promotion in sections 16 to 24 of the *Cannabis Act*, including the use of images that depict persons, characters or animals and which associates cannabis with glamour, recreation, excitement vitality, risk or daring.

Cannabis businesses have been very busy applicants for trademarks. More than 1700 such applications are now on file, though on a comparative few have yet been registered. Trademark applications in this area are likely to increase further with the coming changes to the *Trademarks Act* that remove the requirement that applicants show use of the trademark prior to registration.

Copyright: Protection for works of creative expression

Canada's *Copyright Act* provides that the owner of copyright has the exclusive right to make copies of copyrighted work for the lifetime of its author, and for fifty years thereafter. The Court will enforce this copyright, stopping infringements and ordering infringers to compensate the owner for its damages, to disgorge any profits it earned as a result of the infringement, and to deliver up infringing material for destruction. Intentional copying or renting out of a copyrighted work is also an offence that can attract imprisonment. The owner of a copyright can also request the seizure of infringing articles being imported or exported in Canada.

In the course of describing and marketing its products, the cannabis producer will prepare or have prepared any number of articles, instructions, write-ups, photographs, videos, drawings, packaging, labelling and the like. The producer is likely to have a web site having a specific and attractive layout. Copyright protects all such literary and artistic works from being copied by another.

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