

Cannabis to Hemp

And Everything In-between

Regulatory & Legal Issues for Commercial
Producers and Processors of Hemp

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of Saskatchewan**



What the Hemp?

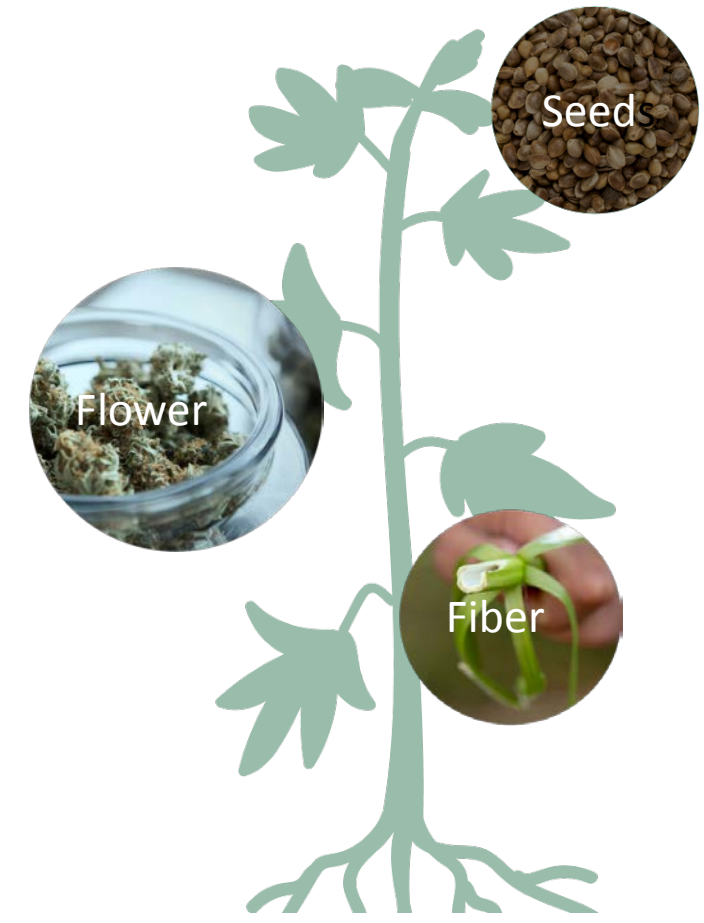
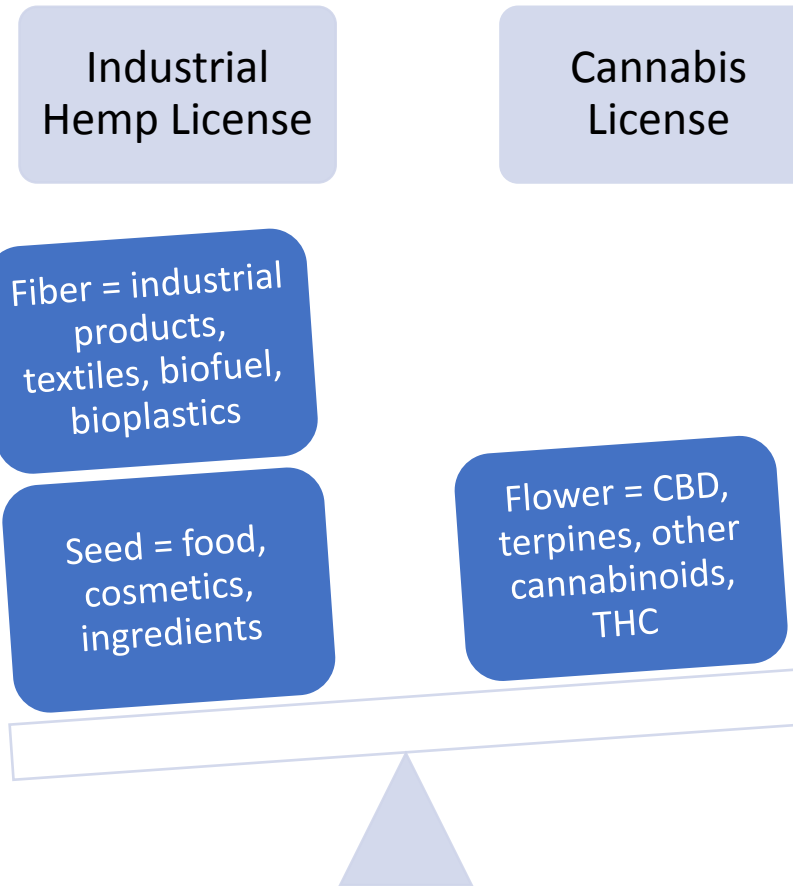
Smoke-able cannabis flower and the recreational THC industry is still young but has already seen the bust of its first commercial bubble.

On the heels of the first “cannabis crash”, we are starting to see the second wave of development in the industry driven by hemp: consistent supply; efficient production; new product categories (edibles, consumables, formulated vape); fractionated ingredients and a shifting regulatory framework (potential for “CHP” or “NHP”).

This presentation is focussed on the legal and regulatory issues specific to commercial producers and processors of industrial hemp (and cannabis in some measure), a growing industry on the Canadian prairies that is poised for significant expansion in the next few years.



Processing Hemp into Other Things



What's so special about Hemp?

The production of industrial hemp has been permitted in Canada for close to 20 years now. The regulatory theory is that because hemp has no meaningful level of THC (0.3%), the security and health concerns surrounding its production are few.

Canada has among the largest seeded (it may be the largest) hemp production in the world. Hemp is grown for the following purposes:

1. Seed for food and cosmetics;
2. Stalk for fibre (long fibres and hurd for various industrial purposes);
3. Flower and leaves for cannabinoid extracts (CBD) – this has only been legal since the introduction of the *Cannabis Act in 2018*.

All hemp is cannabis, but not all cannabis is hemp

The *Cannabis Act* is the federal legislation that will govern all activities involving the Cannabis plant (any plant that belongs to the genus Cannabis (s.2(1))

Hemp is a cannabis plant or part of a plant in which the concentration of THC is 0.3% or less in the flowering heads and leaves. (s. 1(2) *Industrial Hemp Regulations "IHR"*)

Therefore, all hemp is cannabis, but cannabis proper is only hemp if it meets the definition.

COMMERCIAL INVOLVEMENT WITH HEMP OR CANNABIS REQUIRES A LICENCE OF SOME NATURE: HEMP IS RESTRICTED!



All hemp is cannabis, but not all cannabis is hemp

Hemp is a special, small, excepted subject matter that is still governed by the Cannabis Act but gets special treatment pursuant to the *Industrial Hemp Regulations*.

If a party does not have a license pursuant to the Industrial Hemp Regulations, then they must possess the hemp as if it was cannabis proper – all the cannabis laws and regulations would apply.

AGAIN, no one can have viable hemp seeds or hemp flower or leaves without some nature of license!

What Does A Hemp License Permit?

Industrial hemp license, pursuant to s. 3(1) might allow you (depending on what your licence says) to:

1. Cultivate hemp;
2. Buy or sell hemp seed;
3. Buy or sell hemp flower and leaf material (as recognizable plant material);
4. Conditioning hemp seed;
5. Processing hemp seed into other products;
6. Process hemp fibre;
7. Export or import hemp or hemp seed (note that importing or exporting requires a permit for each lot shipped in addition to licence permission, and importing/exporting seed is ALSO subject to CFIA's general regulations regarding the import/export of seed)

As soon as seed, flower and leaves are removed, hemp fibre becomes unregulated. De-natured seed (not viable to grow) also becomes unregulated. Viable seed, and flower and leaf material require a licence to possess, buy, sell or process.





Growing Hemp

Growers need an Industrial Hemp Cultivation License

Growers must use the Cannabis Tracking and Licensing System (CTLS) to apply for a hemp cultivation license

- For a corporation or partnership, each Director or partner must establish her own CTLS account that is then added to the corporate/partnership CTLS account
- Growers must report acreage planted, variety and verify THC compliance through CTLS each season for each field
- Licenses are generally good for two production seasons





Growing Hemp

Hemp growers can sell seed to another party with an industrial hemp license. Seed needs to be rendered non-viable in order to sell them to a non-licensed party.

Hemp growers, pursuant to an industrial hemp license, may generally sell hemp flower and leaves to either:

- a) other industrial hemp licensees (hemp processors or hemp growers); or
- b) holders of a Cannabis License pursuant to the *Cannabis Regulations* (usually a Processing License, which is required to extract cannabinoids from the hemp).



Enforcement – How does Hemp stay Hemp?

1. Only Health Canada approved cultivars may be planted – HC maintains a registry of approved cultivars, and all plants must be grown from Certified Seed (governed through the Canadian pedigreed seed system).
2. Growers must report to HC through the CTLS prior to, during and post-harvest every year.
3. Growers must retain plant samples and have plants tested for THC potency at a HC licenced lab.
4. Hemp processors must be able to prove that seed, or derivative products from seed, has <0.3% THC

Establishing THC potency is not as simple as it might seem!



Analytics – Not that simple

Anyone who handles hemp needs to be able to establish that the plant is indeed hemp by proving it has a THC concentration of 0.3% or less.

The official method for handling field samples is to take “60 inflorescences”, retain 30 and dry the other 30, and reduce flower and leaves for delivery to the registered lab.

Office of Controlled Substances
Document Code : HECS-OCS-003
Revision Number: 002

How one selects and treats samples will have a tremendous impact on potency results – in a broad-acre field there will be “hot” plants – pulling one plant in a large field is bound to provide bad results



Analytics – Too Good To Be True = Illicit Material

One legal issue hemp processors, cannabis processors need to watch for is illicit biomass.

- US versions of “hemp” from Washington, Colorado and such places is not “hemp” by Canadian standards – it’s cannabis proper and although it might have 6% CBD concentration, it will be hot in THC and will not be an approved cultivar
- Brokers in Canada are constantly promising processors improbable volumes of hemp flower that is at improbable levels of potency – this usually turns out to be illicit outdoor grown cannabis from Canada or it’s illegally imported from the US and is represented as Canadian Hemp
- Approved cultivars of Canadian industrial hemp, in absolutely perfect orchard style conditions, might have CBD concentrations of 5% - most is between 1% and 2%.

Illicit Material Cont'd

There are three things processors should do to quell the trade in illegal biomass:

1. Request a copy of the grower's license that produced the biomass – brokers try to avoid that, but a buyer will eventually need that information for regulatory compliance regardless;
2. Request a small physical sample of the biomass and test it yourself for THC concentration and genetic variety;
3. Make any biomass purchase contingent on the results of the above two conditions.

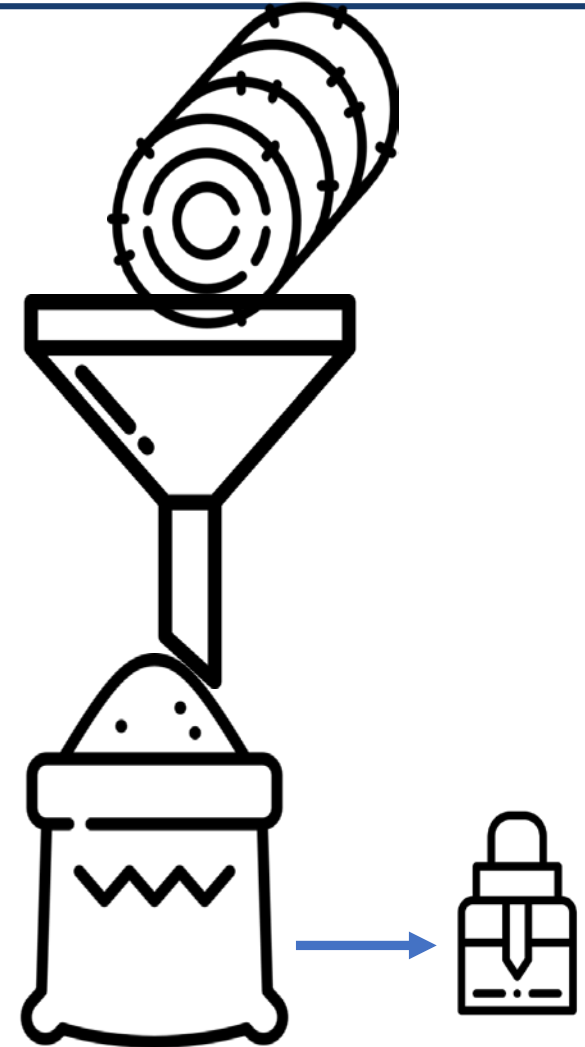
"Brokers" have no legal standing in Canada, nor are any (so far as we've seen) licensed to actually buy or sell cannabis or hemp - they're only value is information. Transactions must be between licensed parties.



When Hemp becomes Cannabis (again)

The Space Between Hemp and Cannabis

Drying, milling, sifting or otherwise separating hemp flower and leaves from other plant material – this seems to be permitted under hemp licencing and a lot of hemp producers – this is not clearly spelled-out in the Regulations, but Health Canada has issued correspondence on the issue.



Processing Hemp as Cannabis



An industrial hemp license **DOES NOT** permit you to extract cannabinoids from hemp!

In order to pull concentrated compounds out of hemp you require a Cannabis Processing license (Micro or Standard), pursuant to the *Cannabis Regulations*. Virtually no hemp licensees will have a Cannabis Processing license.



Processing Hemp as Cannabis

This requires a Standard (or Micro) Processing License pursuant to the *Cannabis Regulations* – this license permits processing of hemp or cannabis proper.

It also permits the processor to sell and/or distribute cannabis, and potentially, cannabis products, to other licensed processors, licensed retailers (provincial), medical distributors and research or analytical licensees.





Exporting or Importing

Hemp food products and fiber products are “reasonably” easy to export. Hemp seed oil, hemp “hearts”, hemp protein and hemp fiber move well into the US and other jurisdictions.

Viable hemp seed faces the same issues as other seeds in addition to being a regulated product. Under the Hemp Regulations, you can be licensed to export or import viable seed, but each lot also requires a Health Canada permit in addition to your license. CFIA protocols for seed must also be met.

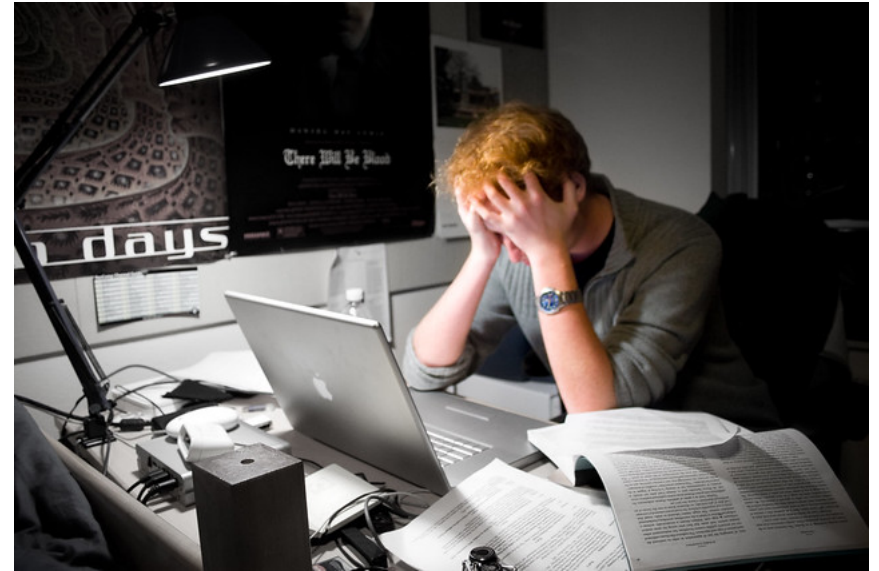
Hemp plant material and cannabis do not cross borders easily. Under a standard processing license, you can export cannabis for medical or scientific purposes, but you require a permit from Health Canada for each lot. Most borders are still closed to cannabis, with THC-free CBD showing the most potential for foreign distribution.



Getting a Standard Processing License is a Process

This process will take at least one year. Your client will need:

1. Qualified personnel: RPIC, QAP, HOS
2. Security clearance from Health Canada for all directors of a Corporation and all key personnel
3. A properly designed facility to Health Canada GMP standards
4. A comprehensive security plan with a live-monitored system
5. Comprehensive GMP-compliant operating procedures
6. Enough capital to build the facility, and the gumption to risk it, prior completion prior to licensing



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Things to Consider when Advising a Client on Licensing

1. Is there any potential issue getting your people security cleared? Criminal convictions for drug related charges, crimes of dishonesty or financial fraud are problems. Anyone who worked or spent significant time in a foreign country may be an issue.
2. Do you they have enough cash to make it? This process is long, there's no certainty on timelines and there's virtually no way to gain feedback or insight from Health Canada on the status of one's application – you can't force the Regulator.
3. Stigma of Cannabis: We have had people's personal PayPal accounts among other payment systems cancelled; Cross-border travel issues; difficulty with foreign payments (primarily US); rejection from domestic financial institutions – there is very little if nothing you can do to deal with these companies who reject or cancel service
4. Insurance: Insurers, always friendly at the best of times, but they rally on hemp and cannabis processors – insurance will be expensive
5. You NEED a qualified Quality Assurance person on staff – a qualified QA person is necessary to navigate this space in terms of establishing and maintaining GMP standards.





The 2 Primary things to Consider when Assisting a Licensed Party

- 1. License, license, license!** When looking at a financing, corporate structure, sales contracts – anything for a licensed processor (hemp or cannabis), you must always consider the limitations of licensing – what is your client licensed to do/sell, and what is the other party licensed to do, and what impact does the proposed action have on the proposed transaction?
- 2. What do the Regulations state?** Virtually every activity a client intends to undertake requires filtration through the regulatory framework – does it fall within or outside the Regulations? Clients suck at reading regulations, so you need to do it for them.

Beware Cannabis Precedents and Consultants

Again, there is no substitute for reading the Regulations!!

Consultants in the cannabis space are plenty and costly. They generally offer a cookie-cutter approach to license applications, building designs, SOP development, etc. They generally just do what was done before. **This is fraught with risk!**

Consultants have no official standing with Health Canada, nor any other relevant body, nor are they licensed in any nature... and many, it would seem, have trouble actually reading Regulations.

Your clients will need technical expertise in the form of process design, HVAC engineering, structural engineering, etc. They should hire designated professionals to provide that advice.... “cannabis consultants” may not fit the bill.



The Quagmires of a New Industry and New Regulations

Advising clients on a new activity in a new industry with new regulations presents challenges.

1. Other parties in the industry may have a different understanding of the Regulations;
2. The Regulator (Health Canada) may have a different, unique or straight-up wrong interpretation of the Regulations;
3. There is NO judicial guidance (yet) on these particular Regulations.



The Quagmires of a New Industry and New Regulations

Cannabis Regulations SOR/2018-144

1(2) site means, in respect of a holder of a licence, an area that is used exclusively by the holder and that consists of at least one building or one part of a building.

88.3 (1) A holder of a licence for processing must ensure that physical or other effective means are used to separate incompatible activities in order to prevent contamination of cannabis or anything that will be used as an ingredient.

(2) A holder of a licence for processing must not produce, package, label or store cannabis at a site set out in the licence if food that is to be sold is also produced, packaged or labelled at that site.

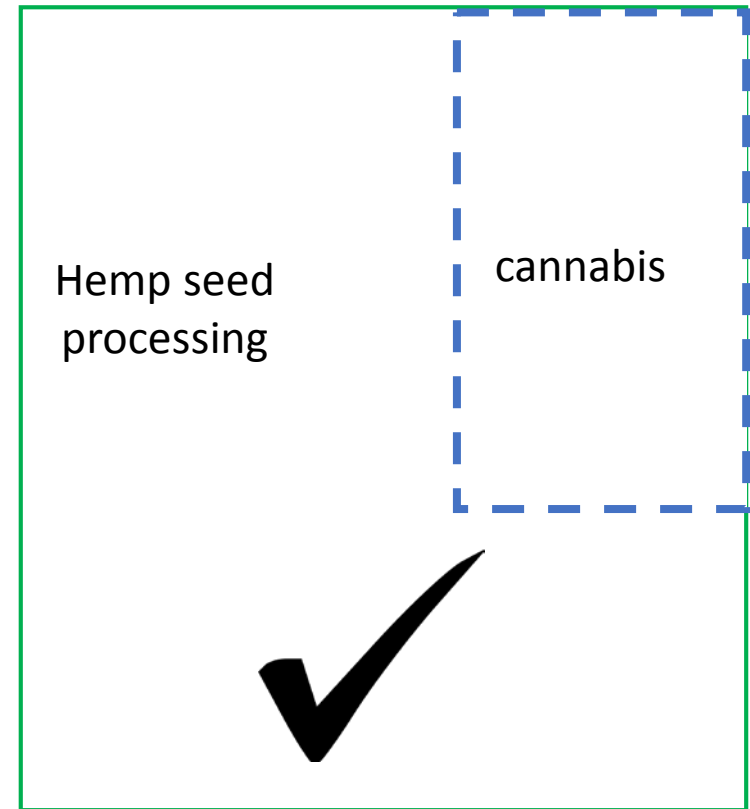
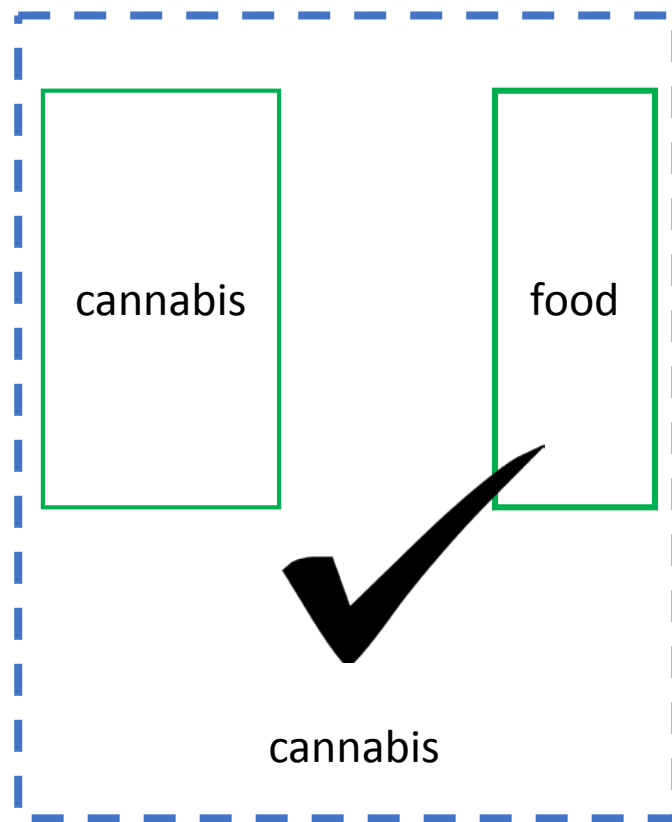
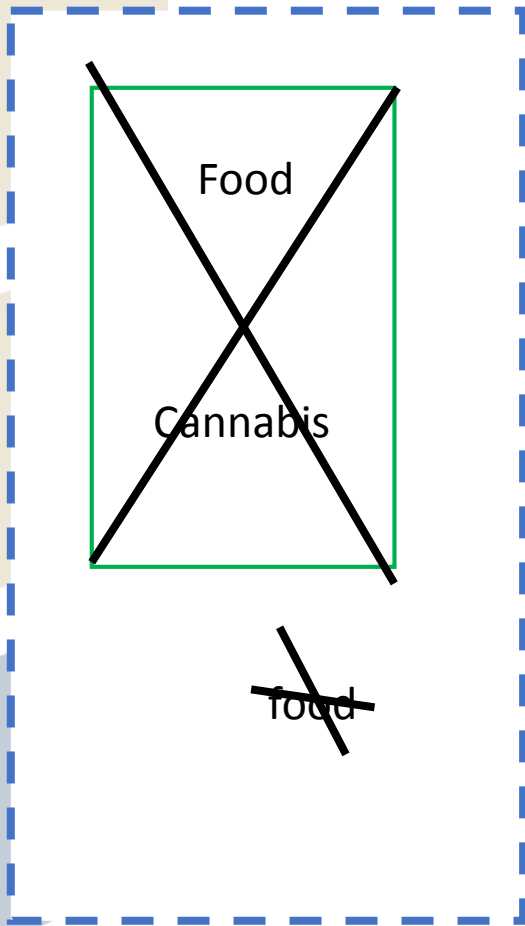
(3) Despite subsection (2), a holder of a licence for processing may produce, package, label or store cannabis in a building within a site where food that is to be sold is produced, packaged or labelled if the food is not produced, packaged or labelled in the same building.



Site A: Prohibited by 88.3(2)

Site B: Permitted by S. 88.3(3) exception

Blue Sky Facility: Compliant with 88.3(2)



- - - - - = secured perimeter of licenced site

————— = outline of building





Industry and Regulations Change Quickly

As a lawyer in this space, you need to stay CURRENT on both industry trends and changes to regulations

- Roughly one year after the initial *Cannabis Act*, we already had the first major revision to the *Regulations* – those changes had a significant influence on how the industry has developed subsequently
- Health Canada has already solicited comments on the next change – moving to CHP/NHP framework for certain classes of cannabis (CBD)
- New production processes are surfacing daily, but many are constricted by current Regulations – you need to understand how to frame your client’s activities within the regulatory framework
- Recognize that the civil servants working in Health Canada may not actually know or understand the current Regulations or your process – try to be helpful to them and guide them accordingly

Looking Ahead – Changes on the Horizon

Moving CBD into an NHP/CHP regulatory framework – Health Canada has already received and published results of its initial call for comments.

Changing THC limit from %0.3 to %1.0? This would mimic Australian Regulations and lead to much higher-CBD potency in approved cultivars.

Approving new harvesting methods that might constitute unacceptable levels of processing under current regulations.

Growing export opportunities for Canadian product.





Your Sources for The Regulatory Framework

Cannabis Act, S.C. 2018, c. 16

Cannabis Regulations, SOR/2018-144

Industrial Hemp Regulations, SOR/2018-145

All of the published “Guides” available from Health Canada:

<https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis.html>





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