

THE NEW REGULATIONS

BC Micro License Association

Recent BCMLA media

<https://mjbizdaily.com/british-columbia-cannabis-production-scheme/>

A while back, we heard a rumour that BC was thinking about implementing its own licensing system for cannabis producers. Turns out, that's not in the cards at the moment so everyone's going to have to continue dealing with Health Canada.

Insurance for micro-licensees

Insurance is not the sexiest thing ever, but nurseries, micro-licensed cultivators and processors will need insurance. We had a conversation with an BC-based insurance professional who deals exclusively with coverage for licensed cannabis operations. We learned a few things, like how expensive coverage might potentially be. If anyone is getting ready for their HC application, insurance is a major thing that needs to be taken care of early on - send us an e-mail and we will pass along this guy's contact information.

Who knew?

Bill Blair has such an awesome sense of humour. From his Twitter this week:

"The Federally regulated supply inventories are showing impressive growth since implementation and clearly supply is adequate to demand".

<https://twitter.com/BillBlair>

An American perspective

<https://mjbizdaily.com/america-canada-cannabis-edibles-market-wary-costly-regulations/>

Here's what some Americans think about our proposed regulations, as compared to theirs.

Make your voice heard

<https://www.canada.ca/en/health-canada/programs/consultation-strict-regulation-edible-cannabis-extracts-topicals-questions.html>

If you have opinions about the new draft regs, you have the opportunity to let HC know what you think. The public consultation period ends on February 20, 2019, so send in your responses to the questions before then. We definitely will.



The basics

The draft regulations released by Health Canada in December, 2018 (<http://www.gazette.gc.ca/rp-pr/p1/2018/2018-12-22/html/reg4-eng.html>) deal with three categories of cannabis products: (1) edibles, (2) extracts, and (3) topicals. Strictly speaking, the regulations will be applicable to those who will apply for or possess processing licences, micro or standard. At the beginning of the draft regs, the feds included a 42 page Regulatory Impact Analysis Statement. This is a well written, plain language summary of what's in the draft regs and we strongly encourage our members who are thinking about pursuing a micro-processor licence to read it.

Standard and micro cultivation operations will continue to be governed by the existing Cannabis Act regulations, which have already been enacted (<https://laws-lois.justice.gc.ca/PDF/SOR-2018-144.pdf>).

The following is **not** legal advice; it is our non-exhaustive summary of what we have interpreted to be some of the high-lights of the new draft regs - for advice about or specific interpretation of the regs, please consult a lawyer.

Edibles include products containing cannabis that are intended to be eaten or drunk. Extracts are products that come from an extraction or synthesis process, and will include 'cannabis oil' and concentrates. Topicals are for the use on external body surfaces. Of the three categories, edibles will be most heavily regulated.

The draft regs address four broad subjects for each of the three categories:

(1) HC licensing - there will be no changes to existing requirements for physical or personnel security requirements if a processor plans to manufacture any or all of the three types of products.

(2) GPP - the GPP requirements for processors found in the existing regs will continue to apply, but the new regs contain additional requirements related to the prevention of contamination and the risk of food borne illness in edible products. Edibles cannot be manufactured in the same building as any other non-cannabis food products - a totally separate building may be required. Additional GPP requirements will be applied to 'conveyances' (transporting cannabis and ingredients), ventilation that provides clean air and removes unclean air that may affect cannabis or other ingredients, and for employees' protective coverings. Of course, no pets, animals or pests will be permitted in any place where cannabis is being processed. And, any water being used (including ice or steam) that comes into contact with cannabis has to be potable (capable of human consumption). Processor-licensed sites will require bathrooms and hand sanitation facilities. Testing will be permitted at either the final step in the production process or when the final form of the cannabis product is



Health Canada's round-table

On January 17, 2019 Health Canada held an in-person stakeholder engagement event related to the new draft regs. The BCMLA had a seat at the table. There were many topics covered during the all-day event - here are three high-lights:

- there was significant concern among those present about the 10mg limit for edibles, it being too low, creating excessive packaging and the "appealing to your persons" prohibition is too broad and perhaps undefinable without specific guidelines;
- hydro-carbon and organic solvent use for the manufacture of extracts / concentrates is an issue that is still open for discussion. HC is currently engaged in some scientific fact-finding, so there are no final answers at this time. HC is working through testing issues related to residues;
- those seeking micro-processor licences will require a sort of sub-licence or endorsement to be able to manufacture edibles, extracts and / or topicals, which will likely be part of the initial micro-processor licence application.

Interestingly, a representative of the provincial Cannabis Secretariat reached out to us during the HC event, so we are planning further engagement with them. Stay tuned.



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A significant new addition - a new Preventive Control Plan (PCP) will also need to be prepared, which will require the QAP's approval prior to implementation. The QAP will also have an additional new responsibility to proactively conduct an investigation any time he or she suspects the cannabis or other ingredient(s) presents a risk of injury to human health or does not meet other QA requirements, and take action to eliminate the risk.

A second significant new addition - in section 19 of the draft regs, the feds have added a requirement to the QAP's necessary qualifications. "...who has the training experience and technical knowledge...that are applicable to the class of cannabis in respect of which activities are conducted under the licence." There seems to be a carve-out for edibles, whereby another person with the training, experience and technical knowledge may be retained. However, this apparent carve-out applies to edibles only - not to extracts and / or topicals. Please note that with respect to the manufacture of edibles, employees are required to have the necessary qualifications as found in the Safe Food For Canadians Act (link below).

A third significant new addition - the HC license holder will have to conduct a product recall simulation every 12 months so that they can evaluate the effectiveness of their recall procedures. Paperwork related to the simulated product recall will have to be generated and retained.

(3) Products - there will be THC limits. For edibles, it will be 10mg per unit and per package (ex. a package could contain 1 x 10mg cookie or 2 x 5mg cookies). For extracts, each unit can contain 10mg, but each package could contain 1,000mg. For topicals, the limit is 1,000mg for each packaged product. The interesting thing about HC's approach to the THC and CBD limits will be the permitted variability (margin for error). For edibles, a 15% - 25% variability will be allowed, depending on the total quantity of THC or CBD. For extracts and topicals, the variability will be 15%.

For product ingredients, there will be strict rules. For edibles, in addition to the Cannabis Act and its regulations, the processor will have to comply with the Food and Drug Regulations (https://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._870.pdf), as well as the Safe Food For Canadians Act (<https://laws-lois.justice.gc.ca/PDF/S-1.1.pdf>) and its regulations (<https://laws-lois.justice.gc.ca/PDF/SOR-2018-108.pdf>). Licensees thinking about manufacturing edibles will have *three* sets of federal legislation and regulations to follow, *plus* possibly provincial laws and regulations governing food preparation. For extracts, a flavour agent may be used, but not a sweetener. Also, anything prohibited in the federal Tobacco and Vaping Products Act (<https://laws-lois.justice.gc.ca/PDF/T-11.5.pdf>) is also prohibited for extracts. For topicals, HC's 'Cosmetic Ingredient Hotlist' will govern what can and cannot be added (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients/hotlist.html>).

(4) Packaging and labelling - the existing rules in the Cannabis Act and its regulations will continue to apply (see sections 16-28 of the Act and section 105-137 of the regs). Again, edibles will have the most rules - a nutrition facts table must be included in the products' labelling. For extracts and topicals, all ingredients must be listed and no qualitative or health enhancement statements may appear on labels. No associations with alcoholic beverages must appear on labels (ex. a cannabis drink cannot be labelled as 'Cannabis Wine'), nor will alcoholic beverage companies be allowed to use their logos on cannabis products.

With respect to packaging, the new draft regs contain some adjustments of the requirements found in the Cannabis Act and its regulations. An 'immediate container' (which is in direct contact with the cannabis product) may be made of metal and a non-immediate package does not have to have a matte finish. Peel-back labels will be allowed. For extracts, the immediate container must be designed in a way to prevent easy pouring or drinking and must contain a dispensing mechanism that dispenses no more than 10mg of THC at a time. Packages may not contain more than one immediate container.

Our take-away

The new draft regs contain a significant amount of very detailed information. We have not covered all of it here, just the high-lights. By far, we believe the *most* important provisions are related to the expansion of GPP requirements and the additional QAP qualifications and responsibilities. We have expressed the opinion in the past that it will be easier to find a family of brightly coloured unicorns frolicking on Sunset Beach than it will be to find a qualified QAP and we have no reason to amend our opinion at this time. Currently, it seems possible that there may never be more than a handful of micro-processing licences in BC - in fact, we are aware of only one prospective licensee who is in the position to apply for a micro-processing licence, but has not yet been able to locate a site in a municipality that has appropriate zoning. If it's not one thing, it's another :(

https://www.instagram.com/bc_micro_license_association/?hl=en