



February 10, 2021

BY EMAIL

Office of Legislative and Regulatory Affairs  
Controlled Substances Directorate  
Health Canada  
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Dear Sirs,

To: Health Canada (cannabis.consultation@canada.ca)  
John Clare  
Director General  
Strategic Policy, Cannabis  
Controlled Substances and Cannabis Branch

**Subject:** Notice of intent — Consultation on the *Cannabis Regulations*: Cannabis research and other regulatory issues

***In Response to Canada Gazette, Part I, Volume 154, Number 50: GOVERNMENT NOTICES:***

***Re: Micro class and nursery licences: PART 2: Feedback on additional regulatory issues***

As per your Gazette request, the CR sets out a licensing framework intended to enable a diverse, competitive legal industry that is comprised of a range of market participants, including both small and large players.

Three of the licence subclasses — micro-cultivation, micro-processing, and nursery — are intended to enable the participation of small-scale players. The micro-cultivation and micro-processing licences authorize the same activities as a licence for standard cultivation and standard processing respectively, but at a smaller scale. The nursery licence is intended to enable a legal source of starting materials (both for commercial and personal cultivation), and the development of new varieties of high quality cannabis.

These licences are subject to reduced regulatory requirements (e.g. in the area of physical security), which reflects the level of risk related to the scale of the operation.

- 14. Are the regulatory requirements for the micro-cultivation, micro-processing and nursery licences (e.g. cultivation and processing limits) appropriate given their scale?
- 15. Are there any elements of the regulatory framework that put micro-cultivation, micro-processing and nursery licence holders at a competitive disadvantage compared to larger companies? If so, how, and what adjustments would you propose?

### **General Discussion and Comments**

The current regulations are highly prejudicial towards small scale operators (“Micro” or “Micros”). They work to effectively cap revenues and gross margins and hence discourage investments. They also pose a great deal of execution risk which also limits available risk capital and exposes Micro owners to undue execution and regulatory risk. They also pose large incremental cost hurdles during growth phases of the business which again create uncertainty and discourage investment.

### **Main Points:**

1. **Pre-built Site Requirement:** Health Canada’s requirement to have a pre-built facility prior to applying for a licence is exceptionally prejudicial towards prospective small scale operators, especially given the long time frames required to achieve a licence and become cash flow positive. This biases the licencing regime to favour participants with deep pockets and access to large amounts of capital in several ways:
  - a. The long delay between capital deployment and payback: the current licencing process can add 18 to 30 months (12 to 18 months for design, permitting, and buildout + 6 to 12 months to applying for and receive HC licence) at the front end of a project during which capital is deployed as a licencing prerequisite with little prospect of achieving a licence and generating cash flow to recoup capital for a very long time. The practical effect of this is to substantially decrease the potential rates of return on an investment after adjusting for the time value of money.
  - b. The uncertain time frames associated with achieving licencing cause investors to require higher rates of return, causing risk capital to shy away from these investments and substantially increasing the cost of capital.

**Solutions/Suggestions:** Allow for a hybrid model which prequalifies micro-cultivators based on demonstration of i) proof of tenancy for a proposed site, ii) an

engineered design of that site that complies with the regulations, iii) a minimum amount of working capital that would carry the costs associate with maintaining the site location in good standing (i.e. making mortgage or lease payments and other associated carrying costs), and iv) pre-screening the principals for security clearance.

2. **Arbitrary Canopy Size Limit for Micro-cultivators:** The premise is that Micro's benefit from the reduced security requirements, in turn based on the "reduced risk" for a micro-cultivator or micro-producer. This poses several problems for micro-cultivators and processors:

- a. Scaled Risk Premise is faulty: The current application of the regulations, which limit canopy size and enforce weight caps on processing amounts, implies that security risk scales with production capacity and/or the amount of cannabis product on site at a given time. Simply put, it implied that the risk scales according to some linear (or other) formula. We do not see this demonstrated to be true by any peer reviewed literature. In fact, Health Canada itself tacitly acknowledged this in July 2018 by erasing the "vault" requirement for Standard Licenced Producers from the regulations, claiming that risk "analysis" and/or empirical evidence had showed that the vault requirement was not a necessary deterrent in mitigating the enhanced security risk profiles of Standard license holders. While we agree that security is important, the risk is not demonstrably greater for an increased canopy size or production capacity. We also know that Health Canada's application of mandated security requirements, irrespective of the operation's size, are highly prejudicial to the Cannabis industry in general. For example: In Ontario, retail pharmacies are not limited by law or regulation to limit the amount of opioid which they can store on premises. Neither are they required, by law or regulation, to demonstrate secure storage for opioids on premises. The only "requirement" is a guideline by the Ontario College of Pharmacists, that opioid products be locked up, preferably in a safe. These are provided by the OCP as suggestions for best practice within their profession. So here we see Health Canada regulated products (i.e. legal opioids) being given a preferential treatment by federal rules and regulations. This again implies that there is no demonstrable scaled risk due to concentration of product at a given site.

- b. Misapplication of the (faulty) Scaled Risk Premise: Assuming the “scaled risk” premise were correct, an illogical and non-fact based application of the premise severely limits potential economic returns for micro-cultivators. The security requirements for Standard Producers are onerous to say the least. Security requirements for micro’s are substantially reduced. This is a good start however it still creates an arbitrary cap on revenue and economic upside by limiting the canopy size of micro cultivators to 200 square meters and 600kgs of dry flower (or equivalent) for processors. This forced cap limits the valuation for these businesses from the outset and does not allow for organic growth of the business. This again causes risk capital to avoid this otherwise attractive business segment. The binary line set between micro and standards caps the ultimate return on capital for these small scale businesses. In order to grow these businesses must invest in large and discretized chunks of capital by either adding on additional micro facilities at separate sites, or applying to amend their licenses to a Standard Licence and incurring the hard dollar costs associated with complying with the increased security requirements as well as the opportunity costs associated with the disruption to their existing business to facilitate an expansion.

**Solutions/Suggestions:** Expand the Canopy limits and production caps for Micro’s. The current caps discourage investment and unfairly cap economic returns. Based on our cash flow modelling, expanding the Canopy to 270 square meters and processing limits to 900 kg annually would dramatically enhance the potential profitability of aspiring Micro’s and make them competitive with Standard producers through enhanced margins and spreading of substantial fixed costs over more units of production.

3. **Lack of Clarity on QAP requirement:** The QAP requirement, as it currently stands, is a large impediment to micro cultivators also acting as processors and extracting higher sales margins by selling directly to provincial stores. The licensing guide does not explicitly set out that 3<sup>rd</sup> party QAP consultants are a viable option for micros. Further, since this is a new industry, there is a dearth of qualified QAP’s. Taking on the fixed costs associated with hiring a full time QAP again caps the potential economic return for these small scale businesses.

**Solutions/Suggestions:** Health Canada to state clearly that Micro’s can outsource their QAP function to qualified 3<sup>rd</sup> party contractors or consultants.

4. QAP requirement imposes a cost without a compensating benefit: Micro's need to see a substantial economic return in order to justify hiring a QAP.

**Solutions/Suggestions:** A hybrid model whereby the hiring of a full time QAP by a Micro creates an "enhanced Micro" class which has all benefits of reduced security requirements while being allowed to produce in greater volume.

5. Medical Sales are currently tied to Standard class security requirements: If risk scales with size, Micro's should be allowed to apply for Medical Sales without having to meet Standard class security requirements. This is currently not possible. Not having access to the Medical Sales market is highly prejudicial to Micro's and caps their potential total revenue and net margins. Again, making Medical Sales security requirements the same as those required by Standard class licencees does not align with the "scaled risk" premise which underpins the current application of the Regulations. If a micro were to also conduct Medical Sales within the constraints of the existing Canopy limits and (600kg) processing limits, it's unclear (according to Health Canada's internal logic) why they would have to also meet Standard class security requirements.

**Solutions/Suggestions:** Allow Micro's to apply for Medical Sales without having to meet the enhanced security requirements.

Best Regards



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