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Submission to the: Consultation on the *Cannabis Regulations*: Cannabis research and other regulatory issues

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The Cannabis Economic Development Council (Council) represents the interests of a wide cross section of industry stakeholders including retailers, cultivators, and processors among other market incumbents and aspirants in south eastern British Columbia. The Council was recently formed but collectively brings a broad and deep expertise in the cannabis sector, business development and policy transitions. We are grateful for the opportunity to participate in this consultation on the Cannabis Regulations. We are pleased to submit our the response below, organized to align with the questions in the consultation and followed by our additional comments.

NON-THERAPEUTIC CANNABIS RESEARCH

General comments

The Council's support for the initiative to realign the regulatory regime for non-therapeutic research with cannabis involving human participants under the *Cannabis Act,* rests upon a broad based consensus amongst its members on the following issues:

- The current regulatory regime requiring dual compliance with both the *Cannabis Act* and the clinical trial requirements under *Division 5 of Part C of the Food and Drugs Act Regulations* does little to enhance public awareness of the health risks associated with cannabis use, nor does it improve access to a quality-controlled supply. Instead, it imposes unnecessary regulatory barriers and costs that discourage the very research that would help realize these objectives.
- The *Notice of intent — Consultation on the* Cannabis Regulations*: Cannabis research and other regulatory issues,* states that (emphasis added) *"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*." It is the view of the Council that a great deal of economic activity in the cannabis sector is being precluded or bottlenecked by the lack of data that could be addressed by non-therapeutic research with cannabis involving human participants. As such, it is the Council's position that any measures taken by Health Canada to facilitate such research will have a direct impact on the ability of the legal

market to compete against illicit or illegal markets. Furthermore, facilitating such research, in the Council's view, will enhance the ability of legal market participants to compete with each other on subjective criteria that drive consumer decisions, (particularly with respect to so called "2.0 Cannabis products") such as palatability and appearance amongst other competitive parameters including dosage sizes and forms and their relative effects onset.

- Cannabis producers and processors, like the producers of any consumable product, must have the ability to undertake product and market research. As with any sector, this is vital for developing product, expanding business opportunities and staying relevant to changes in the market, consumer trends and needs. In an emergent industry, such as cannabis, the ability to conduct cost effective product research is critical.
- Such product and market research should be allowed so that it can be undertaken by personnel within the company and with a designated group of consumers who can help to identify characteristics of the product and help to refine it, including but not limited to flavour, aroma, effect of growing and curing methods, and palatability of consumables.
- Testing needs to be possible throughout the drying and curing process
- There needs to be an ability for producers and processors to collaborate on product research and refinement
- There needs to be a mechanism that allows the end consumer to provide product feedback to the producer
- The next step would be to allow on-site cannabis tasting rooms and sales such as are allowed for wineries, and craft breweries.

1. How likely would you conduct non-therapeutic cannabis research involving human participants? How many studies do you envision conducting in a year?

The Cannabis Economic Development Council (Council) will not be conducting any non-therapeutic cannabis research itself. However, internal consultations amongst the Council's members has revealed strong, broad based support for Health Canada's plans to amend the *Cannabis Regulations* and associated regulatory frameworks to facilitate non-therapeutic research with cannabis involving human participants, and to facilitate testing activities with cannabis.

2. Should the requirements to conduct non-therapeutic cannabis research involving human participants under the CR be similar to those that currently apply to clinical trials under the FDR (e.g. protocol review by a research ethics board, submission of extensive quality [chemistry and manufacturing] information, review of written informed consent, and submission of an investigator's brochure)? If the requirements should differ, how?

No, the requirements to conduct non-therapeutic cannabis research involving human participants under the CR should not be similar to those that currently apply to clinical trials under the FDR, with the sole exception being for synthetically derived cannabis. While safety concerns should remain paramount, it is important to remain cognizant that the properties of cannabis (other than synthetically derived cannabis) are quite dissimilar to the properties of other substances that are regulated under the FDR. As such, the safety concerns presented by non-therapeutic human cannabis trials present, by and large, substantially different risks than human trials with other restricted substances currently regulated under the FDR. Therefore, it is the Council's submission that the requirements for conducting non-therapeutic cannabis research involving human participants under the CR should reflect and addresses these differences. For example, clinical research conducted to date has established that while it is possible to ingest sufficient cannabis to achieve an overdose, such an overdose is rarely, if ever, in and of itself, fatal.

In addition, cannabis consumption remains stigmatized to a great extent in Canadian society, regardless of whether the consumption is medicinal or recreational. Should the government create requirements to conduct non-therapeutic cannabis research involving human participants under the CR that are substantially the same as those currently existing under the FDR, the amended CR will effectively reinforce this stigmatization by failing to recognize that cannabis consumption carries a different risk profile than the substances the requirements were designed manage.

3. Should non-therapeutic research involving human participants be restricted to certain participants (e.g. exclude individuals with previous/current mental health or substance use disorders, age restrictions)?

Absolutely not. It is the Council's submission that such a requirement would preclude research into some of the very issues that are most critical to market incumbents at this time. For example, palatability studies and their like are crucial to developing and understanding the effects of new cannabis 2.0 products. Unless individuals with previous/current mental health or substance use disorders will be precluded from obtaining access to cannabis products, excluding them as a class from such research would unduly limit the efficacy of the amendments and the attainment of their stated objectives.

As the cannabis 2.0 product markets currently offer the best market conditions for legal market participants to compete against their illicit market counterparts, such a restriction would continue to unduly inhibit players in the legal market from competing against the illicit market and would represent a missed opportunity to further the objectives of the proposed amendments.

4. Should there be restrictions on the types of cannabis used in non-therapeutic cannabis research involving human participants? If so, under what circumstances? What should the quality requirements be for cannabis derived from synthetic sources?

It is the Council's submission that the only restriction on the types of cannabis used in non-therapeutic cannabis research involving human participants is to preclude the use of synthetically derived cannabis, which should remain under the current FDR. Synthetically derived cannabis presents other health risks than those posed by naturally derived cannabis and the amended CR should reflect this fact.

5. Should there be restrictions on the dosage, frequency, duration and route of administration (e.g. smoking or vaping) of cannabis used in non-therapeutic cannabis research involving human participants?

It would be appropriate to apply few or no restrictions on the dosage, frequency, duration and route of administration in the requirements for conducting a non-therapeutic trial other than intravenous administration. As naturally derived cannabis dosages in the context of a human trial have not been shown to present a direct risk of death or substantial increase in the risk of chronic disease, the allowable dosage, frequency and duration in the requirement needs to be exceedingly liberal to permit research into as wide a range of potential concern as possible while imposing appropriate safeguards. Additionally, any undue restrictions in this regard are likely to be seen by the public as condoning the stigmatization of cannabis consumption in general, unless such restriction can be conclusively justified on the basis of peer reviewed scientific and medical research results.

6. Should adverse reaction reporting for non-therapeutic cannabis research involving human participants be treated in a similar manner as adverse reaction reporting for clinical trials under the FDR? Why or why not?

No, adverse reaction reporting should not be treated in a similar manner as adverse reaction reporting for clinical trials under the FDR. Adverse reaction reporting, as it currently stands, provides a necessary safeguard for trial participants as well as consumers and the public in general. This safeguard imposes significant costs upon market participants which is justified by the medical, public safety and health concerns the safeguard addresses. However, beyond drawing a simple distinction between commercially available products and those that are being tested prior to commercial release, non-therapeutic cannabis research involving human participants is inherently more likely to create an adverse reaction which, in some cases, could be an objective of the study. That being the case, a new adverse reaction reporting regime is necessary as some highly encouraging avenues of research could be precluded by failing to address the differing risk profiles presented by cannabis vis a vis other restricted substances under the FDR.

7. What are your thoughts on expanding the production, distribution and sale activities of cannabis reference standards and test kits? What are the potential risks and benefits of this approach (e.g. by exempting reference standards from GPP requirements)?

8. Are there any impediments stemming from the current requirements for the "head of laboratory" under the CR?

PUBLIC POSSESSION LIMIT

9. Do you think the public possession statement on cannabis product labels helps adults comply with the public possession limit?

No. The Council members' experiences with the public possession limit and equivalencies closely reflect those received by Health Canada in February 2020. As such, the Council is of the strong view that the public possession limit is arbitrary, at least in the view of consumers, if not in actual fact. This appears to be reflected in the general public's awareness of the restriction and their laissez-faire approach to complying with the restriction. This is an unfortunate situation as the equivalencies contained in Schedule 3 to the *Cannabis Act* serve to compound the general public's confusion and perception of the arbitrary nature of the limitation on possession. The current limits have no clear relationship to an individual's cannabis use.

10. Currently, the CR require labels to display a statement to express the amount of cannabis a product is equivalent to in terms of grams of dried cannabis. Do you see any issues with this approach? Are there any benefits or challenges you think an adult may have in interpreting this information on different kinds of cannabis products (e.g. edible cannabis, cannabis topicals, vaping products, etc.)?

Consumers appear to view the possession limit as arbitrary and the equivalencies are confusing. Therefore, the CR requirement that labels to display a statement to express the amount of cannabis a product is equivalent to, in terms of grams of dried cannabis, is of limited utility at best. At worst, it would appear to undercut the public's confidence that the possession limitation itself provides any protection or benefit whatsoever. The Council submits that the potential benefits an adult may receive as a result of the possession limitation or a label's equivalency statement is marginal at best. In practical terms the benefits are completely overborne by the confusion created by the complicated equivalencies that do not offer any practical guidance to consumers and undermine public confidence in the utility and validity of the possession limitation.

Cannabis has different effects depending on the cannabis use, the form and method in which it is used. Providing the dried cannabis equivalency may lead to a false understanding about what a person is consuming. The most useful information is to know the type and total amount of an extract in the product, the amount per serving, and the concentration (% and weight) of specific active ingredients (thc, cbd). The testing requirements are overly onerous and miss the fact that the plant has over 400 compounds that work together.

11. Do you think the current public possession limit for cannabis beverages (which is currently approximately 2 litres) should be increased? If yes, please explain what you think an appropriate public possession limit would be for these products and why.

The Council feels this is an arbitrary number that does not appear to have any basis in science. Nor does it take into consideration the concentration of active ingredients or needs of the consumer. Appropriate limits would be similar to that of alcohol.

PRODUCT LABELLING

Cannabis contains hundreds of chemical substances, including cannabinoids (such as tetrahydrocannabinol [THC] and cannabidiol [CBD]) and terpenes. The CR require that product labels indicate the quantity or concentration of the THC and CBD in cannabis products. Licence holders may choose to display the name, quantity or concentration of other cannabinoids and terpenes in the product, provided that the labelling and packaging comply with the CR.

12. Should Health Canada require product labels to display information about other cannabinoids and terpenes (e.g. quantity or concentration)? Why or why not? If yes, which cannabinoids and terpenes and why?

No, cannabis product labels should not be required to display information about other cannabinoids and terpenes in terms of quantity or concentration, a company chooses to include it. Such information is of marginal utility to consumers in general and would impose an unnecessary cost on licenced producers while the corresponding benefit to consumers in being able to make a more informed purchasing decision would remain largely unaffected by the imposition of such a requirement. By allowing licenced producers to include such information on their labels, the CR permits producers to compete on such matters without imposing costs while precluding any impact to quality.

The ability to include information about other cannabinoids and terpenes is an important option since the division between medical and recreational users is porous. Recreational consumers may also want to benefit from the medicinal characteristics of the product.

13. Is there any other labelling information that would help consumers make decisions to support informed and responsible use?

- As in any sector, for smaller-scale producers, the ability for the producer to tell their story is vitally important to overcome the economic disadvantages of scale.
- Legacy growers understand that the consumer wants to know the story of the product, including how it was grown, by whom and where. This needs to be possible on the label and product information. Where product size results in space constraints on the label, QR codes or other such supplementary information platforms should be allowed.
- Certification claim labels should be allowed
- Reduce the size and detail of required health warnings. They are generally not used by consumers and give an inappropriate intensification of risk. Because they are so overdone, the Council believes they have less effect overall.

- Give companies a larger area of the label for their own information so they can market their brand and products, provided they meet other regulations (I.e. strain and production details, no health claims).
- The Council is of the view that the CR should recognize regional production, particularly for outdoor grown cannabis, permitting an appellation system similar to wine which would increase Canadian brand recognition globally

MICRO CLASS AND NURSERY LICENCES

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.

General Comments

- As with others such as the meat sector, the cannabis sector is characterized by the very large and the very small. The very large have emerged with the legalization of recreational cannabis. Yet the market is well established and strong for craft cannabis production. The micro licences are a good first step but are too still restrictive.

14. Are the regulatory requirements for the micro-cultivation, micro-processing and nursery licences (e.g. cultivation and processing limits) appropriate given their scale?

- There are still too many disincentives and barriers, including of regulatory origin, that are keeping legacy producers from transitioning. The Canadian public would benefit by having all the talented legacy growers transition into the new regulatory framework.
- The high costs associated with the requirement to test and release each batch limits the options to produce specialized crops to meet consumer needs.
- Not all the barriers are regulatory in nature – some are internal practice at Health Canada and therefore easier to amend:
    - Security clearance must be shifted to the beginning of the licencing process and PRIOR to any significant investment by the proponent. Given the fact that Canada's financial institutions are mostly linked to American counterparts, obtaining financing is virtually impossible. The current sequence of approvals that requires the licence proponent to overcome this financing barrier while still not having a confirmed security clearance by Health Canada is not acceptable.
    - Criminal record checks are standard for many activities in Canada, such as volunteer sports coaching. Draw on this model to delegate security clearance to relevant authorities outside HC and which can provide a faster turn-around for licence propoents at the beginning of their licensing process.
    - Background security requirements limit participation of those who have been in the legacy market, severely restricting who may enter the legal industry and

continuing cultural stigmas against cannabis. Ensure that non-violent records do not preclude successful security clearance.

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 Comments

- The limitation on the scale of micro class licences puts them at an economic disadvantage because they cannot realize scales of economies or produce amounts that would enable them to maintain a retail presence for more than short periods of time.
- Consider annual limits for micro licences that are based on the volume harvested, not on space constraints. An annual volume of production (determined in consultation with craft producers) would allow producers to meet that limit as they see fit and that best aligns with their business and sustainability goals. Another option would be to follow the licence model used by California, that enables a licence holder to produce on the corresponding acreage (ie. A licence to produce on 1, 2, 4 acre plots).
- The current packaging restrictions put micro-cultivation and micro-processing facilities at an extreme disadvantage compared to larger companies. Specifically, it is smaller scale companies that have a story that is of interest to consumers. It is smaller scale companies that grow organically, grow in small batches, hang dry, hand trim, cure slowly, grow using aquaponics, aeroponics, or living soil, and work tirelessly on developing new genetics.

  In every consumer industry, these small craft producers first connect with many of their customers through their labeling. They share their story, brand, and differentiators on their packaging, and consumers that care about quality take the time to find something that really matches their values. With today's CR framework, small producers are unable to connect with a substantial portion of their market niche due to their inability to share these critical pieces of information.

  Large producers generally do not produce cannabis with the level of care and quality that small producers do, nor do they have differentiators that connoisseurs care about. They accordingly benefit from the labeling restrictions, as they do not lose sales that they would if small producers could share their stories (though we are certain that they too are otherwise negatively impacted by their inability to tell their stories). Additionally, large producers have massive marketing budgets, so they are able to creatively market their products despite these restrictions in a manner that small producers simply do not have the budget for.

Micro cultivator issues

- The upper volume restriction on micro cultivators is too limiting their options for achieving economies of scale for financial success.

- The upper volume restriction on micro cultivators makes it challenging to meet minimum product batch size requirements from processors, retailers.
- Micro cultivators are discouraged from growing small batches of specialized cultivars due to the testing costs per batch and processor batch minimums.
- Micro cultivators have to compete against a trend of lowering prices while being limited in their ability and resources to differentiate their product from larger producers.
- A micro-cultivator licence needs to allow the producer to package their product in order to facilitate farm to store / consumer sales, such as are planned for British Columbia in 2022.

- The current zero tolerance for microbials is a significant barrier for small scale producers.
  - Adopt a science-based approach to microbial limits for pathogenic microbials rather than a blanket prohibition that necessitates processes that destroy beneficial microbials. Existing models can be found in Washington and California as well as others. These jurisdictions do not have a generic aerobic bacteria test, but rather focus on pathogenic testing.[1]
  - Small scale producers put a lot of time and care into growing the highest quality cannabis that they can. Many craft growers use permaculture practices, growing organically and using living soil. This inevitably leads to a higher level of microbial life, but it is beneficial microbial life. The current limits defined in the regulations require these growers to irradiate their flower in order to legally sell their product. Since they are growing high quality craft cannabis, this now-necessary irradiation greatly reduces the quality of their final product, and significantly diminishes one of their primary differentiators from large scale enterprises.
  - A properly cured product will have beneficial microbials, whether it be cured meat, cheese, or cannabis. To meet the product quality and characteristic goals of many of the legacy growers, particularly those growing in living soil and following organic practices, beneficial microbials must be present.

Micro processor issues

[1] These USA jurisdictions solely target pathogens: Alaska, Arizona, Arkansas, California, Colorado, Florida, Louisiana, Michigan, Missouri, Montana, Nevada, New York, Oklahoma, Oregon, Washington. Links to a few example jurisdictions' government data on microbial limits:
Washington: https://apps.leg.wa.gov/wac/default.aspx?cite=314-55-102
California: https://www.bcc.ca.gov/about_us/documents/17-261_required_testing_chart.pdf
Oregon: https://www.oregon.gov/oha/PH/PreventionWellness/marijuana/Documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf

- If holding a license for processing only, they are restricted to processing <600kg, while a dual license holder (cultivation, processing) is limited by their volume of production. This causes a disadvantage for those who want to specialize in processing.
- There are related disadvantages for standard license holders:
  - Exponentially higher cost for facility development due to stricter regulations.
  - Micro cultivators can be stuck at the micro level as they are not able to make a competitive leap into the higher production levels of the standard category. There is a large gap in facility and production sizes with no differentiation between those with hundreds of meters in production and those with thousands or millions. There needs to be a licence and appropriately scaled requirements for production larger than micro but much smaller than most large standard licence holders.
- Health Canada would do well to consider adding one or two more levels of license classification. A 'small' license could be structured to have lower costs than the standard operator running a larger footprint. This would open up the industry to those who operate on the lower side of standard production, but without the large jump in costs incurred by a standard operator. A 'large' license could apply to those in the highest range of square footage. This would help level the field in terms of operators incurring expenses that are more appropriate to their income potential, and would encourage more innovation and diversity in the cultivation industry overall. It would also likely bring more legacy businesses into the regulated system as it makes more financial and competitive sense.

COVID-19 MEASURES

Health Canada has put in place measures to support cannabis licence holders with operational and logistical difficulties that they may be facing due to the COVID-19 pandemic. These include, among others, accepting a packaging date that is within four (4) days of the printed packaging date on the label (provided appropriate records are kept), enabling the destruction of cannabis to be witnessed virtually and simplifying the requirements for the presence of a security cleared person accompanying cannabis being treated at an external destruction or irradiation facility. These measures were put in place in April 2020 and are in place until March 31, 2021.

16. Are there any measures that should be made permanent? What would be the impact if these measures were not continued? Are there any risks of making a measure permanent and how should they be mitigated?

- Remotely viewed destruction and security pre-clearances allows people to take up a designated role while the application is being reviewed. It also accommodates micro cultivators who are single operator with no employees. This should be made permanent.
- Extend and maintain the policy that allows virtual witness destruction for micros; if the head of security has passed all screening and is responsible for the overall security of the site they should be trusted to follow the regulations when it comes to destruction.

- Consider restricting the requirement for witnessed destruction "bud", not trimmed/pruned leaves or plants that are not viable.

ADDITIONAL CONCERNS

Environmental

- The Council feels there are excessive packaging requirements for products that are already under strict management at the retail level in terms of restricting access by youth and children. The result is an unnecessary increase in waste streams from multi-layered product packaging
- Sustainable, climate friendly, and regenerative production practices need to be privileged and supported through pro-active policy
- The cannabis sector, like all other sectors in Canada, needs to be part of the climate solution so policy should pro-actively support practices that reduce the need for nitrogen fertilizer, fossil fuels and other high GHG emissions practices.

Regulatory & Licensing

- where possible, guidance and best practices for the sector should be the default, rather than prescriptive policy that is harder to change when necessary and tends to privilege large scale
- Provide clear Cannabis Inspection (audit) expectations so that producers / processors can best prepare
- Provide clear definitions of what constitutes a minor, major or critical infraction, combined with options for a pathway to resolution
- Establish and facilitate fast track conversion of ACMPR license holders applying for Micro-cultivation licenses.
- Maintain and make publicly accessible service standards for licensing and for answering questions in order to expedite licencing and revenue generation for producers and processors.
- Re-classify CBD as a natural health product
- Establish a sliding scale for excise tax that reflects the revenue generating potential of each scale and does not unduly burden micro and small licence holders.
- Make a portion of the excise tax available to local government to enable them to support the sector and off-set their respective costs of oversight.

Sector Development

- The financial requirements to enter the market are far too high. The cannabis industry is denied or restricted access to many banking and other professional services. With limited ability to secure deep financial backing and the high costs incurred, micros potentially have a higher risk of failure, due to the cost of entry, lengthy licence turnaround times, and limited ability to market.
- Work with other relevant departments to establish financial incentives and programs to support shovel-ready value-added processing.
- Work with other federal departments to develop programs for producers through agencies such as Western Economic Diversification Canada and Farm Credit Canada, in order to enable access to financing for start-ups and those wishing to expand who are blocked out of conventional financing institutions.

Regulatory & Industry Fit

- Other jurisdictions have delegated oversight of the cannabis sector to agricultural agencies. Restricting HC oversight to the strictly health-related aspects of regulation may result in a more successful transition for legacy producers, while not compromising on the health oversight where it is warranted.
- small scale cannabis production and licensing managed and overseen by Agriculture and Agri-Food Canada would enable the sector to benefit from the programs that are offered at a national and provincial / territorial level and which that target and seek to increase the success of small-scale farmers, of which cannabis is but one sector.
- We encourage Health Canada to consider restricting its oversight to the creation of new cannabis products using chemical products that introduce a higher risk of danger for human consumption.

Thank you for considering this submission. Please do not hesitate to contact us for further information, as necessary.

On behalf of the Council,

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