Cannabis Council of Canada | Conseil du cannabis canadien

January 11, 2021

Mr. John Clare
Director General
Strategic Policy, Cannabis
Controlled Substances and Cannabis Branch

Delivered via email to john.clare@canada.ca and cannabis.consultation@canada.ca

Department of Health – Cannabis Act - Notice of Intent – Consultation on the Cannabis Regulations: Cannabis research and other regulatory issues

PART 1: Proposed regulations amending the Cannabis Regulations and associated regulations to facilitate non-therapeutic cannabis research involving human participants and cannabis testing

The Cannabis Council of Canada ('**C3'**) welcomes the recognition that non-therapeutic cannabis research activities involving human participants are critical to generating high-quality evidence. We are very pleased to see that Health Canada has responded to our concerns about the threats to cannabis research, and we have appreciated the open and ongoing dialogue on this issue over many months.

Health Canada's further recognition that the research would yield necessary knowledge to assist adult Canadians in making informed decisions on cannabis consumption and risks should, in our view, go further to indicate that benefits could emerge from non-therapeutic cannabis research.

We understand the underlying precautionary principle that guides Health Canada as the regulator. In our view, the precautionary principle can operate in alignment with the principle of harm reduction so that research may consider the health implications of cannabis in contrast to other therapies.

C3 has discussed several impediments to Canada's global leading role in cannabis research with Health Canada. In particular, we have raised concerns that newfound study requirements for research that do not anticipate the pursuit of a DIN have posed a significant threat to research viability. Accompanying this regulatory regime is the requirement that all cannabis studies involving humans, regardless of whether or not the study's purpose is for drug development, use cannabis produced in GMP-certified facilities, despite the lack of such certification being the norm for cannabis produced in Canada. The result here, intended or not, is that the bulk of cannabis products that Canadians consume could not be used for these clinical trials.

We believe that the current regime poses a threat to a wide variety of non-DIN related studies including many initiated by or funded by government bodies (including CIHR) with very important public health considerations at hand. The research community has identified the requirement for pre-clinical data as a barrier to the development of necessary clinical evidence. The viability of the cannabis research grant review process is under threat due to the challenges of timely approvals.

Non-therapeutic research (Question 2)

The Cannabis Council of Canada believes that the requirements for non-therapeutic cannabis research involving humans under the CR should be significantly different than those that apply to clinical trials under the FDR. By now, our members would have communicated clearly to Health Canada that they intend to conduct a broad array of these studies, whether they occur in Canada or elsewhere.

Fundamentally, we believe that the requirements for extensive safety studies – including animal studies – for products legally and broadly available, is the imposition of a standard developed for clinical trials for DIN-seeking products.

Furthermore, the costs that the above-noted studies impose seriously impair the prospects for independent research and hamper the prospects for many kinds of research that could yield benefits to society.

On numerous points in the "Notice of Intent", C3 looks forward to hearing the views of the research community and on commenting on the Regulation when it is posted to the Canada Gazette.

Analytical Testing (Question 7)

We are supportive of the proposal to expand participants in the production, distribution and sale of cannabis reference standards and test kits. Enhanced domestic production is a desirable proposed outcome that the Cannabis Council of Canada supports.

Head of Laboratory (Question 8)

No concerns about the current requirements for the "head of laboratory" have been brought to the attention of C3.

Part 2: Feedback on additional regulatory issues

Public Possession Limits

Based on the results of the research and public opinion polling completed by Health Canada (***"Health Canada Focus Testing"***), the possession statement was consistently misunderstood. Further, no participant possessed knowledge of the 30-gram public possession limit. Rather, this information was misinterpreted as either providing a guide of product strength or as a benchmark for an easier cost comparison to determine the product's cost per gram. Therefore, we submit that cannabis product labels should indicate the contribution of individual units towards their public possession "allowance".

Public Possession Statement on Cannabis Labels (Question 9).

As we seek to address social justice implications associated with past cannabis possession criminal convictions for Black, Brown, and Indigenous Canadians, we must reduce the risk that compliance with possession limits emerges as a new social justice irritant.

That said, the current possession limit information is conveyed confusingly and is likely impairing compliance with the regulation's intent. This lack of clarity, coupled with the very high equivalency count attached to cannabis beverages, further enhances the risk that one will unwittingly contravene the law. More than half of respondents in C3's *Consumer Survey on Cannabis* indicated that they have never noticed the public possession statement on their products.

Fundamentally, our industry believes that it would be prudent to increase possession limits so long as supporting evidence in terms of public acceptance, rates of youth participation and illicit market elimination are demonstrated to be achieving the goals of the *Cannabis Act*. Based upon our preliminary analysis, we believe that the circumstances associated with adult recreational legalization lend themselves to increasing possession limits.

We recognize that current possession limits disadvantage those who do not have the mechanisms to place online orders due to a lack of a regular address, credit card or computer. During the pandemic, member-companies have encouraged others to buy online, or if going to the store, to limits trips and even buy for others who are higher risk (elderly, immune compromised etc.). Increased possession limits might also assist in this regard.

During our October 6, 2020, bilateral meeting with Health Canada, we identified the trend towards the purchase of larger format dry flower and the impact on the price for growers. We should be mindful that in the current environment where large format dry flower cannabis has achieved relative price parity with so-called black market or illicit cannabis; keeping in mind that such a move would likely lead to even larger formats of dry cannabis in the marketplace. This could have a further impact on the price per gram, creating more challenging conditions for some licensees.

In addition to increasing individual possession limits, the Cannabis Council of Canada proposes that Health Canada change the current labelling regime as discussed below, to improve the communications surrounding public possession limits and to help clarify the contribution each product makes to an individual's limit.

Beverage Equivalency (Question 11)

C3 believes that the current equivalency formula has a serious flaw related to cannabis-infused liquids and we appreciate the opportunity to address this point further to our most recent discussion of this topic during our October 6, 2020, Bilateral Meeting.

With consideration of the added social justice risks noted above, our organization firmly supports the prompt promulgation of a regulation that would address the inadequacies of the current beverage equivalency formula.

Results from C3's *Budtender Survey on Cannabis* illustrated a clear consensus among budtenders that the current cannabis beverage equivalency rules encourage consumers to purchase and consume higher potency products, creating a misalignment with public health objectives. Overall, 3 in 4 respondents noted that the current rules are not sensible. Results of the *Budtender Survey on Cannabis* will be published on C3's website in the coming days.

C3 has formed a Beverage Caucus including Member and Affiliate Member companies. Separately, we submitted a detailed document proposing a solution for a beverage equivalency that establishes a ratio of one (1) gram of dry flower to 0.625g in beverages. This would produce a practical equivalency whereby 30 grams of dry flower would be deemed equivalent to (48) units of 355 ml cans of cannabis-infused beverages.

Equating these models with the state of Colorado, where the equivalency formula considers one (1) gram of dried flower equivalent to 28.57mg of THC. Colorado's legal possession limit is 28 grams, and consumers may possess up to 800 mg of THC content in their cannabis beverages. By contrast, our proposed model would permit consumers to possess up to 480 mg of THC content (10 mg x 48 units) in their cannabis beverages.

Health Canada has noted that, "The equivalencies across classes of cannabis products draw on lessons learned from, and the limits established by, U.S. jurisdictions that have legalized and regulated cannabis." With this considered, C3 posits that the solution it has posed to the issue of beverage equivalencies marries the public health imperative at the heart of the Canadian legalization effort and alignment with relevant U.S. jurisdictions.

While C3 has made the issue of beverage equivalency a significant priority, it must be noted that other equivalency anomalies do exist and warrant ongoing dialogue between the cannabis industry and Health Canada.

Product Labelling (Questions 12 and 13)

When C3 met with Minister Hajdu on March 9, 2020, our Board Chair demonstrated that the current labelling regime, for instance, does nothing to differentiate between two products with a wide variance of THC levels.

Findings from **Health Canada Focus Testing** show that additional information may be needed to help improve public understanding and comprehension of cannabis products. Participants in the focus testing found some of the information displayed on cannabis product labels difficult to understand. In examining package labelling, both cannabis users and non-users were unable to easily identify the product type or its intended use. Also, most participants were unsure how to interpret the tetrahydrocannabinol (THC) and cannabidiol (CBD) content and were generally unable to put those numbers in context – this was also strongly identified as a shortcoming in C3's *Consumer Survey*.

On the matter of the difficulties in communicating more than just numbers to describe our products, we feel that these limitations impact the development of higher-value products which is an essential survival strategy of all cultivators regardless of their size. Ultimately, if cannabis continues a trend towards

differentiation based on potency and price alone, that is going to have a negative implication on the sustainability of every cannabis business since we are impaired in our ability to build value in categories offering value-added products. As the market matures and the array of emerging 2.0 products increases demand from cannabis consumers for clear information will no doubt increase as well.

When considering what information is the most essential on a cannabis product, results from the **Health Canada Focus Testing** show that displaying the product type, product strength, intended use, recommended dosage, and potential side effects are deemed the most important information. Inclusion of health warning messages are appreciated and desired, however, it was felt that priority could be placed on warnings related to the specific product's immediate use (e.g., may cause drowsiness). The sophistication of the Canadian cannabis consumer was reflected in C3's *Consumer Survey,* where a strong sentiment expressed was the desire for terpene profiles on labels.

The conversation about product labelling is often characterized as part of a discussion about so-called branding and advertising and is therefore seen to be motivated by commercial objectives. Budtenders frequently reported not being able to answer questions about cannabis products from consumers. C3 would say that it is not just a means of achieving commercial objectives, but a matter of the survival of our Canadian cannabis industry. Particularly given that the current labelling regime does not provide space to (educate consumers) and build value-added products.

The perception that our industry is protected by our first-mover advantage and sheltered marketplace must be replaced with a clear understanding of the pressure that will come from an increasingly large adult recreational marketplace in the United States. This market development is on our doorstep and if the Canadian regulatory market does not adapt, it will diminish considerably. We have an opportunity here to model exemplary tactics and behaviours rather than be overtaken by larger markets with fewer public policy objectives.

We request that a comprehensive conversation be initiated relating to the means and measures of the cannabis sector's ability to communicate with clients about our product attributes, including the potential for harm reduction.

Furthermore, we encourage Health Canada to implement a Certification Stamp regime that would permit companies to communicate key product attributes (ex. Gluten-free, Halal, Kosher, etc.) through the introduction of approved Certification Symbols. C3 supports a move toward a simplified collection of iconographies to better equip a broad swath of consumers with relevant product knowledge.

Health Canada has significant experience defining such regimes, but we recommend consideration of a System that would allow for symbols such as Organic or Vegan. For future consideration, C3 also supports an approved certification symbols for Sustainability commitments.

Overall, as there seems to be a consensus that the current labelling regime could be improved, the Cannabis Council of Canada calls for the creation of a working group constituted between industry and Health Canada to tackle this complicated and essential element of the *Cannabis Act*.

Micro Class and Nursery Licences

The Cannabis Council of Canada wishes to acknowledge HC's recognition of challenges facing micro-scaled participants in Canada's cannabis landscape. The premise of the question seems to have created the impression that cultivators are either Micros, with a modest defined footprint, or large growers who have captured the benefits of "economies of scale". It is well-known and there is quite a bit of evidence that profitability is a sector-wide challenge, and many Standard Cultivation licensees are only somewhat larger than micro cultivators.

We do wish to make the point that no matter the size of a cultivator licensed under the *Cannabis Act* the pathway to that licence and the licence to sell product is arduous, born of great investments of cash, blood, sweat, tears, and rigour. Having undergone the compliance-heavy licensing process should provide significant confidence about the calibre of our licensees. Regulatory compliance data compiled by Health Canada reiterates the point about the calibre of our operators.

To that end, we would seek to harness all goodwill possible to proactively address the burden, cost of regulation, and risks that such costs pose to achieving the objectives of the Cannabis Act. Micros and other licensees have critically ingrained relationships and should be thought of as unique yet integral elements of the cannabis sector.

During our last Bilateral meeting, we signalled our strong interest in engaging Health Canada in an ongoing dialogue about industry economics. We recognize that it is atypical for Health Canada to consider the economic realities of the parties it regulates. However, it cannot be ignored that achieving the key public policy objectives of the Cannabis Act requires a collection of successful private sector partners.

We presented information at that time that demonstrated serious business challenges stemming from a pronounced decline in the price of dry flower since legalization. We commented at length on the trend towards high potency, low-cost cannabis differentiating the marketplace.

We are facing quite a few headwinds despite good trends in overall sales. Product returns and write-downs have been exacerbated by the arbitrary imposition of product best before dates threatening another cycle of returns and write-downs.

We also presented information that shows that even if the cost of goods were reduced to zero, the end cost to the consumer for regulation, packaging, excise taxes, markups, and provincial taxes would amount to a lot. That amount is the competitive advantage that our industry is staking to illicit players.

Not only do we wish to bring attention to the regulatory and packaging cost, but especially to the implication of markups and HST being applied on top of the original application of the excise tax. These are not only costs to participants in the cannabis sector, industry, and consumers, but also manifests in terms of jobs, investment, potential growth, and research/development opportunities. In the long run, the costs seem to far outweigh the benefits.

We were encouraged by the acknowledgement of concern about economic conditions reflected in the consultation documents and we reiterate our formal request for a follow-up and ongoing dialogue about industry economics. We need companies that are poised to supply products that can meet the needs of Canadians who will otherwise obtain products from illicit streams – which would negatively impact a key pillar of the legalization framework.

Beyond the similarities that all licence holders face, Micro Cultivators and Processors operate within a model that provides for a more modest security regime as well as relief from regulatory fees in the application process. These reduced barriers have been designed to ease the transition of legacy participants into the legal framework. C3 continues to support this important public policy objective recognizing that the elimination of unnecessary regulation benefits everyone.

We are glad that Health Canada is aware that many standard LPs operate on a modest scale. Micro Cultivators have told us that one concern is the lack of space for cultivar hosting. Health Canada may wish to consider adding a proportion of space to allow, for instance, the hosting of proprietary cultivars.

While there is progress being made in the transition of cannabis consumers from legacy markets, we must be fully aware that the cannabis production landscape is currently characterized by overcapacity and significant inventory excesses.

Furthermore, we believe that it is critical for Health Canada to address the noteworthy vulnerabilities of personal grow licenses as commented upon by the Ontario Provincial Police most recently.

From a standard licensing perspective, the marketplace is very well populated. Geographic representation of cultivators is widespread throughout Canada's regions and license holders are incorporating a range of business models including community-held, privately-held, and publicly-traded.

With respect to standard licensees, the Cannabis Council of Canada requests Health Canada remain attentive to needs amongst companies for amendments and updates of licences going forward and to accommodate likely emerging pressures stemming from mergers and acquisitions.

Health Canada should consider appropriate policy alternatives to enhance the participation of Indigenous applicants considering the current dramatic under-representation of Canada's founding peoples.

COVID – 19 Measures

We have been clear in acknowledging the benefit of the flexibility provided to companies at the outset of COVID – 19. Sadly, nearly one year later, it continues to be difficult to predict a return to normal. Cannabis workplaces continue to operate under models revised with paramount concern for the safety of member employees in light of the risks.

Concerning the continuance of the measures, it is very important to acknowledge that Health Canada reserves the power to re-impose any measure we might refer to here as "permanent."

We would strongly request that Health Canada consider re-instating flexibility regarding the emergency deployment of pre-Security Cleared individuals, with notice to Health Canada. Numerous examples of the

benefit that this provided to companies adapting operating models have been brought to the attention of C3. Due to the continued grip of COVID – 19, workplaces continue to operate at high alert just as the rest of the Canadian economy does.

Additionally, the current environment for public companies includes Board evolution to accommodate gender and racial diversity and some flexibility to navigate the wait times of the security clearance process, which can be a catalyst for change.

We have made a priority of the need for a globally competitive Export permitting process and we have made some suggestions for improvement. We are glad to know that Health Canada is open to engaging in a discussion about beneficial process changes going forward. In the meantime, given the extreme ongoing interruptions to global air cargo routes, many companies would benefit from the restored flexibility to adjust and inform Health Canada on unanticipated changes to Port of Export. It goes without saying that the overall improvement of efficiencies in export permitting will significantly improve Canada's ability to compete internationally. The reality is that there are several examples of global players entering this economic space and that the immediate future looks nothing like the market of 2018.

With regard to the COVID-19 measures currently offering flexibility, we would hope that the best evidence in favour of their continuance is the absence of evidence that they have compromised the regulatory underpinnings of the Cannabis Act. One hoped-for unintended consequence of COVID – 19 could be to accomplish our mutual responsibilities more efficiently. To that end, we would encourage Health Canada to maintain the current regulatory flexibility as "permanent" and to work with the Cannabis industry to establish a focused task group to monitor for emerging risks and also to highlight opportunities to achieve the objectives of the Cannabis Act as efficiently as possible.

We thank you for the opportunity to participate in this process.

Board of Directors, Cannabis Council of Canada

Rick Savone
Chair
Cannabis Council of Canada
rick.savone@auroramj.com
416 725 1450

George Smitherman
President and CEO
Cannabis Council of Canada
george@cannabis-council.ca
416 816 7118