Consultation on Potential Amendments to the Cannabis Regulations

# **Introduction**

Health Canada is seeking feedback and comments on potential amendments to the Cannabis Regulations that aim to:

* Streamline and clarify existing requirements,
* Eliminate inefficiencies in the regulations such as duplications between requirements, and
* Reduce administrative and regulatory burdens where possible, while continuing to meet the public health and public safety objectives in the Cannabis Act.

While our response will address operational and administrative efficiencies for Cannabis Act licence holders, we will also take a step back and revisit one of the key objectives of cannabis legalization – displacing the illicit market. Maximizing operational and administrative efficiency means little if we cannot effectively communicate with consumers to sell them products they want to buy and create the purchase experience they desire.

While public health and safety is paramount, it cannot be considered through the narrow lens of the regulated market only. It must also take into account the reality of the still-pervasive unregulated market. Public health and safety will only be optimized once the regulated industry has succeeded in displacing the illicit market.

We must equip licence holders with the tools needed to convince legacy market consumers to buy from a regulated source.

# **1. Licensing**

## *Are there any activities with cannabis that are not currently authorized under existing licences that could be authorized? What specific activities, for which classes of cannabis, and for what classes and subclasses of licences? How would such changes streamline the regulations or lead to greater efficiencies?*

* **Permit the promotion of consumer education on cannabis products through samples at age-gated trade shows, events etc. that are prohibitive to minors**, and through pamphlets, inserts, information guides, allowing consumers to be better educated on the different product types and product attributes
	+ This should be authorized under licences for processing and for sale and distribution activities.
	+ This should be authorized for all classes of cannabis destined for sale and distribution.
* Currently, only holders of a licence for research are authorized to administer and distribute cannabis to a research subject. **Organoleptic and sensory activities should be authorized under licences that are authorized to produce, sell, and distribute cannabis products** as it is beneficial to the consumer, and to the manufacturer, to have products evaluated for sensory attributes. This would lead to better quality products in the market, as well as a reduction in complaints received by licence holders due to sensory attributes.
	+ This should be authorized for all types of consumable cannabis classes under standard processing and micro-processing licences, in addition to the current standalone research licence.
	+ Sensory testing should be permitted outside of the licensed site for panelists wishing to conduct sensory evaluations in the safety of their own homes or private space.
	+ In-process sensory evaluations should be permitted to ensure the product is meeting product quality expectations at key steps during production.

## *Are there any activities with cannabis that organizations should be able to carry out, without the need to hold a licence or permit (for example, the possession of small amounts of licit cannabis for the purpose of laboratory research)? What specific activities and for what classes of cannabis? What measures, including regulatory requirements, should apply to mitigate public health and public safety risks?*

* **Research labs and analytical labs should be able to possess small amounts of licit cannabis without a research licence**. These products are intended for research and testing purposes only, not for sale or distribution to the general public.

## *What measures could be taken to increase flexibility for licensed cannabis processors and to reduce the burden on the Quality Assurance Person (QAP)?*

* **Permit all approved individuals (QAP and aQAPS) to conduct all activities** required by a QAP at any given time. Eliminate the requirement for there to be one acting QAP at a time. These individuals have been hired and approved to fulfill this designation and so should be allowed to operate as such at all times.
* **Extend the current requirement of up to 3 QAPs** (1 QAP and 2 alternates) associated with a licensed site. Allow an unlimited number of QAPs based on experience, training, and education, to carry out the duties of a QAP at any given time. The current limit of one QAP and two alternates is insufficient given the duties and responsibilities outlined in the GPP guidelines for a QAP to execute efficiently.
* **Eliminate the requirement for QAPs to be linked to any given site**. If an individual has been granted approval by Health Canada to act as a QAP, this individual should be permitted to act as QAP at any site he/she is employed at, without the need for further notification and updating in the CTLS.

# **2. Personnel and physical security measures**

## *Are there personnel security requirements that could be changed without increasing the risk of diversion or inversion of cannabis? What specific requirements, and for what classes and subclasses of licences? Why or why not?*

* **Security-cleared personnel should not be required to be on-site when activities with cannabis are being conducted**. This presents operational constraints due to limited resources and availability of security cleared individuals. Licence holders should be permitted to hire and designate representatives for activities related to cannabis at their own discretion. Visual monitoring devices and secure access to the facilities and designated areas within the facility are in place which assist in monitoring and controlling activity.
	+ This should be removed for all licences.
* **Security clearance requirements should be removed from the following activities for all licences:**
* **Waste destruction**
* **On-site movement of cannabis**
* **Off-site anti-microbial treatment**

Current security clearance requirements cause significant operational constraints due to limited availability of security cleared personnel, unique staffing resources to complete these required activities, and ensuring these individuals have the available time to dedicate to these tasks. This creates constraints and pressure on regular business functions and operations as these individuals would need to shift away from their primary focus and have no ability to delegate these tasks outside of a small designated group. The risk of cannabis diversion is mitigated by video monitoring and full inventory traceability by record keeping and monthly reporting. Removing this requirement would streamline operations and allow for more flexibility in scheduling and management of operations.

There should be no requirement for a security cleared individual, or any individual employed by the associated licence holder, to be present at an anti-microbial treatment facility. These individuals are not required to be within the facility nor are they required to accompany the shipment; the cannabis is packaged, sealed, and reconciled; and carriers are vetted and approved by the licence holders. The risk of cannabis diversion is mitigated by secured shipments and full inventory traceability and recorded chain of custody. This is putting the individual at an increased cost and risk to safety due to unnecessary travel.

* **Security clearances should not be required for individuals that do not hold key roles associated with the site’s licence due to the operational constraints outlined above.** Further evaluation is required for the necessity and objective of security clearances for individuals that do hold key roles. Commitment to timing of issuance of security clearances is also requested.

## *Are there physical security requirements that could be changed without posing a risk to public safety (for example, no visual monitoring during “off-season” for outdoor cultivation)? What specific requirements, and for what classes and subclasses of licences? Why or why not?*

* Currently, under Section 73, a visual recording must be kept for at least one year after the day on which it was made. However, it presents additional challenges with respect to storage of footage, resources, and cost. Visual recording retention should be reduced from **12 to at least 6 months**.
* Visual monitoring devices should only be used to detect and confirm illicit conduct within a reasonable timeframe. This further leads to the recommendation that visual monitoring devices should not be required to be operational when an area is not in use.

# **3. Production requirements for cannabis products**

## *Are there any changes to the current production requirements that could create efficiencies for holders of a micro-cultivation or micro-processing licence?*

* **Packaging date**: Extend permanently the COVID restriction which provide +/- 4 days window for the use of the same packaging date on the same batch.
* **Packaging room changeovers**: Reduce requirements for room cleaning between batches, especially when between THC to THC strains.
* **Dedicated Health Canada agents for licence holders**: Providing a singular point of contact for LPs (such as CRA and other governmental agencies) provides increased clarity, reduces volume of emails and operational delays, and creates efficiencies in information sharing efforts. It also helps internal operational knowledge within Health Canada which can aid in the identification of ongoing issues or potential regulatory improvements.

**NOTE**: Changes for micros should be available to LPs of all sizes. A level playing field for all reduces administrative requirements for all. Quantity/output restrictions do not change GPP requirements that relate to safety and quality of the products produced. Our position is that if there are efficiencies that can be applied to micros, they can also be applied to all LPs without risk to safety or quality of products.

## *Are there regulatory requirements from other relevant control frameworks, such as those for food, vaping products, or cosmetics, that Health Canada should consider? Why or why not? For which classes of cannabis?*

* **Natural health product monographs**
	+ Monographs for approved products, uses ets.
	+ Many similarities with formulated products containing cannabis extract where we can draw from
	+ Standardized test methodology and specifications for both input materials and finished products
	+ Guidance on risk based reduced testing schedules, supported by scientific rationale
	+ Guidance related to supplier management and confirmatory testing that would support the evolving cannabis supply chain
	+ Personnel and QA requirements that define a QAP but allow the organization flexibility to assign this internally and allow delegation of tasks within the QA unit.
* **Natural health product ‘self care framework’** : This includes aiming to help consumers make more informed choices and support the safe use of these products by improved labeling that is clear and easy to understand, as well as establishing risk-based rules to reduce the regulatory burden and associated costs to industry.
* **Reduce/reform GPP requirements based on activity**: Subdivide production activities and align to classes as defined by GPP framework.
* **Risk classification guide for drug GMP observations** which was established to help ensure consistency among inspectors and informs industry of situations that may result in noncompliance
* **Management of sub-lots of batches**: Look at how other industry control requirements related to sub-lots of batches to identify additional administrative efficiencies.

## *Are there certain production requirements that could be changed or eliminated for licensed processors that are limited in what activities with cannabis they are authorized to undertake (for example only authorized to store cannabis products)? Which requirements, and under what circumstances?*

* **Cannabis material in cultivation rooms**: Permit cannabis leaf debris to accumulate on the floor of cultivation rooms, with leaf waste being removed at the end of the plant’s life cycle at harvest rather than having to sweep the floors of these rooms daily.
* **Reduce/reform GPP requirements based on activity**: Subdivide production activities and align to classes as defined by GPP framework.
* **Discuss better subdivision under processing** to tease out work with dried cannabis, extraction, and further formulation activities; combine with sales activity to remove additional amendment applications required for sale of 2.0 products
* There is a significant opportunity to reduce the regulatory burden for sites conducting **limited “low risk” activities** such as storage of retail-ready product. The GPP requirements for the activity of storage would be limited to maintain a clean, safe and secure environment for cannabis products and would eliminate all GPP requirements applicable to cultivation and sanitation for production processing, allowing licence holders to focus on environmental controls and physical security for the site. The ability to license sites for the activity of storage only would support complex logistics and supply chain models and would offer opportunities for supply chain maturation in cannabis, further strengthening the industry.
* **The addition of “testing” as a licensable activity** is our proposal to address the current challenges around unstandardized testing. We propose that any licence holder engaging in testing of cannabis for release or labeling would require the activity of testing on their licence, compared to the current situation where both licensed processors and holders of analytical testing licences can conduct testing activities. By establishing testing as a licensable activity, Health Canada would gain visibility and oversight over licence holders conducting testing of cannabis products. Testing as a licensable activity will be a useful tool for Health Canada in establishing specific testing requirements and executing compliance promotion and enforcement actions where necessary.

## *Should the limits on the maximum quantity of delta-9-THC that can be contained in a cannabis product (by container and ingestible unit) apply to the sum total of all intoxicating cannabinoids found in the product? Why or why not? How could such a requirement be established in an efficient manner that is simple to comply with?*

## Yes, but…

## Clear definitions, scope & guidelines are needed to avoid added complexity,

## More research also needed in the area of intoxication for minor cannabinoids.

## Need better communication to consumers via product label, which should list all minor cannabinoids

* **Definition of “intoxicating”:** Health Canada must provide a clear definition of what is considered to be intoxicating and provide formal classification of all potential cannabinoids to be reported on which falls into this definition.
* **Definition of “sum total”:** Health Canada must standardize the calculation for "total intoxicating cannabinoids" so it is replicable and provides consistency in reporting across all product categories.
* **Minimal thresholds for intoxicating cannabinoids**: Health Canada must establish minimal thresholds (i.e. mg/g or % potency) for which intoxicating cannabinoids must be reported on a label.
* **Fully synthetic, bio-synthetic or ‘semi-synthetic’ (extracted and chemical conversion), and naturally derived minor cannabinoids,** including delta-8-THC, provided they are phyto-identical cannabinoids, should be regulated in the same manner.

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# **4. Packaging and labeling requirements for cannabis products**

## *Should Health Canada consider amending packaging requirements for dried and fresh cannabis?*

The requirement for child-resistant packaging of dried and fresh cannabis products should be removed. Unlike edible cannabis and cannabis extracts, dried and fresh cannabis products are non-intoxicating in their packaged form. They must be heated in order to undergo decarboxylation, which converts the THCA present in the product into intoxicating delta-9-THC. Until these products are decarboxylated, they pose no threat to one’s health if consumed as is. Furthermore, the taste and appearance of dried and fresh cannabis is unappealing to children.

The child-resistant packaging requirement adds 20% to packaging costs. With 56% of the cannabis products sold in Canada (by unit) being dried cannabis (<https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/research-data/market.html>), the child-resistant packaging requirement on dried cannabis products significantly increases costs for licence holders without enhancing public health or safety.

## *Are there labelling requirements that could be changed without public health or public safety impacts? What required information should remain, and what information could be removed? Why or why not?*

**Evidence-based information about the attributes and effects of cannabis products should be permitted on product labels**. Public health and safety is enhanced when consumers are provided with clear and easily understood information regarding how to consume the product and the types of effects that can be expected (including on-set time, duration, and intensity) with consumption. Providing consumers with information about the quality measures taken to produce the product will assist with illicit product differentiation.

**Arbitrary packaging and labelling restrictions which have no clear connection to public health or safety should be lifted.** These include the single uniform colour requirement, smooth texture requirement, hidden features restriction, prohibition on use of images, etc. The power of brands is undeniable, and brand-building will be an important part of converting consumers who continue to purchase cannabis from the unregulated market to a regulated source. The perceived commoditization of ‘government weed’ has stifled the displacement of the illicit market. Packaging is an important part of telling a brand story. Providing licence holders with significantly more liberty in packaging and labelling will assist with brand-building, which will enhance product legitimacy in the eyes of consumers.

## *Do you have any suggestions to simplify the requirements to include delta-9-THC and CBD content information on product labels?*

Permit delta-9-THC and CBD content to be stated on the product label with larger font and in a prominent location which stands out for consumers.

Permit the cannabinoid concentration of any products in liquid form to be stated in terms of mg/ml (as opposed to mg/g).

## *Should the requirement to include delta-9-THC content information on product labels apply to the total of all intoxicating cannabinoids, such as delta-8-THC? Why or why not? How could such a requirement be established in an efficient manner that is simple to comply with?*

Yes, but this must also be accompanied by an increase in the permissible amount of delta-9-THC (or equivalent intoxicating cannabinoid) per package of edible cannabis from 10mg to 100mg.

The public health risk to children from the accidental consumption of edible cannabis products is coming from the illicit market; not from regulated products. Public health and safety can only be achieved in this area through much more effective displacement of the illicit market for edible cannabis. The regulated cannabis industry must be permitted to sell edible cannabis products which are competitive with the illicit market.

The current restriction on delta-9-THC per package has limited the market share for edible cannabis products and left room for the sale of illicit edible cannabis products (often containing >100mg delta-9-THC per package) to flourish. It is estimated that $250 Million in sales of edible cannabis products are lost to the illicit market each year in Canada.

The increased cost of having to purchase multiple product units to achieve a desired effect pushes many consumers to the illicit market.

The restriction also comes at a cost to the environment, with consumers being forced to purchase multiple packages of edible cannabis to achieve the effect they could obtain from one edible cannabis product from the illicit market.

## *Are there other packaging and labelling requirements that Health Canada should consider for a regulatory amendment? Why and what is the current impact of these requirements on licence holders and consumers?*

None to add.

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# **5. Record keeping and reporting for cannabis licence holders**

## *Are there record-keeping or reporting requirements for micro-class licence holders that could be reduced without affecting public health and public safety? If so, which requirements and why? What is the current impact of these requirements on micro-class licence holders?*

* **Leverage inter-governmental reporting data:** Currently it takes up to 10 days of personnel time to compile monthly reporting for Health Canada. Health Canada could leverage reports submitted to other governmental bodies (e.g. CRA) to reduce administrative burden, and/or limit reporting to what is needed over and above what has already been submitted to bodies.
* **Reduce complexity of record-keeping**: Simplify detail required to help streamline reporting and operations. (e.g. Tracking weight of seeds and number of seeds sold/bought/germinated is enormously laborious, especially for larger facilities)
* **Reduce reporting frequency to quarterly**
* **Digitize the reporting process**

**NOTE**: Data security concerns, LPs provide Health Canada sensitive information about their operations. Given the increase in recent data attacks, LPs would appreciate it if Health Canada could assure the security of the information they are reporting.

**NOTE**: Changes for micros should be available to LPs of all sizes. A level playing field for all reduces administrative requirements for all.

## *Should Health Canada remove the requirement to provide a promotion expenditure report to Health Canada? Why or why not?*

Yes, Health Canada should remove the requirement to provide a promotion expenditure report. It is unclear to LPs what Health Canada does with the information they collect on promotional expenditures. Given that LPs are already required to maintain samples of promotional materials and track our financial expenditures, it would be much easier for Health Canada to conduct random audits of LPs as required. Alternatively, upon renewal of their licences, LPs could be required to provide a high-level summary of our marketing expenditures.

## *Should Health Canada remove the requirement to maintain a record of key investors? Why or why not?*

Yes, Health Canada should remove the requirement to maintain records of key investors for publicly-traded companies specifically: These companies should be exempt based on financial reporting requirements. Would avoid duplication of efforts.

## *Do you have any suggestions to improve the efficiency of the requirement for licensed processors to provide Health Canada with advance notice of a new cannabis product?*

* **Redesign process to provide product approvals**: The current NNCP system of notification does not provide a clear approval, which results in LPs making multiple submissions for a single product, assuming submissions are approved and bringing products to market that are at risk of being recalled or revised completely.
* **Streamline existing process & allow for changes:**
	+ **Ability to revise submissions**: The system lacks the ability to edit prior submissions, and requires a full resubmission even for minor changes to a product specification. This results in LPs filing multiple submissions unnecessarily, which could be substantially reduced.
	+ **Remove or make non-critical product details be editable without resubmission** (e.g. date of expected sale, net weight/volume, number of units per container, ingredients, sensory attributes).
	+ Support new strains/varieties, new pack sizes, formulation updates
* **Visibility of completed submissions:** Currently, one cannot see all the information that was included in past submission, only a portion of the submission is visible.
* **Reduce waiting period from 60 days to 30 days**
* **Create broader NNCP product categories** that allow multiple strains or varieties under a single product. Also combine size within the critical product attributes
* **Differentiate notification for dried cannabis and 2.0 products**
	+ Remove waiting period for new dried cannabis products (there is nothing new about them)
	+ Redesign the NNCP information for extracts to allow for product potency ranges and combination of different strains and varieties
	+ Incorporate the RMI requests into the submission process to reduce the post-notification administrative burden. (Vit E Acetate attestation, composition of the product, supplier info, ingredient classification and compositions, terpene compositions)
* Associate with **Master Product Records** that the licence holder keeps updated with information about products associated under each NNCP, like a CPID certified product information document from drugs for example.

## *Are there other requirements that could be adjusted for record keeping and reporting?*

* **Revise inventory ID requirements**: Remove the requirement that internal inventory IDs match naming on inventory schedules submitted to Health Canada. This is not necessary, as LPs are already required to maintain full batch traceability in their systems.
* **Risk-based approach**: Overall, LPs and Health Canada would greatly reduce administrative and operational burden by moving from a preventative regulatory record keeping and reporting model to a risk-based approach, by which Health Canada assumes LPs to abide by requirements and subject them to periodic audits as required.

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# **6. Additional Input**

## *Health Canada is also interested in feedback on regulatory measures that may be duplicative, redundant, or particularly onerous, and where there are opportunities to promote efficiencies. Please provide a rationale and/or evidence wherever possible, including the expected impact on the legal cannabis industry, consumers, and public health and public safety. These responses will help inform and prioritize items for regulatory development and will be reviewed carefully by Health Canada.*

* **Retail stores (window coverings restrictions)** : The existing restrictions prohibit cannabis products, accessories or any other cannabis-related item or material from being visible from the exterior of the premises. Similar to the direction taken by AGLC’s Board to lift these restrictions (which inadvertently contribute to targeting these retail locations due to a lack of visibility into the site).
	+ The prohibitions in the federal Cannabis Act and Cannabis Regulations for display remain in place and continue to apply (no outward facing promotion or advertising is permitted).
* **Validation & standardization on testing methodologies**
* **Elimination of annual regulatory fee**