Canada

Proposed Approach to the Regulation of Cannabis

An Overview of Health Canada's Fall 2017 Regulatory Consultation

Overview and Purpose

- On April 13, 2017, the Government of Canada introduced Bill C-45, the proposed Cannabis Act, to implement its commitment to legalize, strictly regulate, and restrict access to cannabis.
- The Government of Canada intends to bring the proposed Cannabis Act into force no later than July 2018, subject to the approval of Parliament.
- To support implementation, a series of regulations and ministerial orders will be required.
- Health Canada is actively seeking public views and comments on the proposed approach to these regulations.
- The purpose of this presentation is to provide an overview of specific regulatory proposals that Health Canada is considering and is seeking feedback on.
- Proposals set out in this presentation are for consultation purposes only, and should not be interpreted as representing the final views of the Governor in Council, the Minister of Health or the Government of Canada.

Policy Principles for Regulations under the Cannabis Act

- Regulatory proposals have been developed based on the following principles:

1. **Consistent with the purpose of the proposed Cannabis Act**
   - Proposals support overarching purpose of protecting public health and safety, and are linked to one or more specific purposes of the Act.

2. **Evidence-informed**
   - Proposals are informed by the best-available information, including Canadian and international experience regulating cannabis and other substances (e.g. tobacco).

3. **Risk-based**
   - Proposals are based on an assessment of the risks that regulated parties and activities pose to achieving the government's objectives.

4. **Balance**
   - The proposed framework should support the government's objectives, in a manner that minimizes regulatory burden and facilitates compliance.

To a large extent, proposals are based on existing regulations (e.g., medical or hemp), with strategic improvements to help achieve the Government's objectives

Required Elements of the New Regulatory Framework

A. Licences, Permits, and Authorizations

– Establish system to authorize otherwise prohibited activities with cannabis and set associated rules and requirements.

B. Security Clearances

– Establish rules for the issuance of security clearances to certain personnel working in federally-licensed organizations.

C. Cannabis Tracking System

– Establish requirements for industry-wide reporting to enable the tracking of cannabis throughout the supply chain.

D. Cannabis Products

– Establish rules and standards for the production of cannabis products, including packaging and labelling requirements.

E. Cannabis for Medical Purposes

– Maintain distinct system to provide patients with access to cannabis for medical purposes.

F. Health Products and Cosmetics Containing Cannabis

– Clarify how the use of cannabis in health products (e.g. prescription drugs, natural health products) and cosmetics would be regulated.

A. Licences and Permits

System to authorize otherwise prohibited activities with cannabis and set associated rules and requirements

- The proposed system of licences, permits, and authorizations is intended to:
  - Allow a range of different activities with cannabis (e.g. cultivation, sale, research);
  - Enable a diverse, competitive legal industry comprised of both large and small players in regions across the country;
  - Reduce the risk that organized crime will infiltrate the legal industry; and
  - Ensure that legal cannabis products meet high quality standards.

- As a result, it is proposed that the regulations:
  - Establish different types of authorizations, based on the activity being undertaken, and in some cases, the scale of the activity; and
  - Establish rules and requirements for authorized activities that are proportional to the public health and safety risks posed.

A. Licences and Permits – Types

Cultivation

- **Standard cultivation** – Large-scale growing of cannabis plants.
- **Micro-cultivation** – Small-scale growing of cannabis plants.
- **Industrial hemp** – Growing of industrial hemp plants (containing 0.3% THC or less).
- **Nursery** – Growing of cannabis plants to produce starting material (seeds and seedlings).

Processing

- **Standard processing** – Large-scale manufacturing, packaging and labelling of cannabis products destined for sale to the public.
- **Micro-processing** – Small-scale manufacturing, packaging and labelling of cannabis products destined for sale to the public.

Sale (Federal level)

- **Medical purposes** – Sale of cannabis for medical purposes to registered patients.
- **Non-medical purposes** – Sale of cannabis to adults in provinces/territories that have not yet enacted a retail framework (temporary, online only).

A. Licences and Permits – Types (cont'd)

Analytical Testing

- Analytical testing of cannabis (including industrial hemp) to verify that it meets regulatory requirements for health, safety and quality.

Import/Export

- **Medical or scientific purposes** – Import or export of cannabis for medical or scientific purposes.
- **Industrial hemp** – Import or export of industrial hemp.

Research

- This would authorize research and development activities with cannabis by persons who do not hold any other type of federal licence (such as academic researchers).

A. Licences and Permits – Rules and Requirements

General Provisions

- Licensees would be authorized to conduct associated activities related to the core activity of the licence (e.g. research and development, transportation, storage).
- All activities must take place at an approved site (with the exception of transportation).
- In general, a person could be licensed to conduct multiple activities at multiple sites.

Physical Security

- Licensees that have large quantities of higher-value cannabis products on-site would be required to have higher physical security relative to other licensees.

Personnel Security

- Specified persons would be required to hold a valid security clearance for all cultivation, processing or retail sale licences – with the exception of industrial hemp.
- Security clearances would be required for employees that hold key positions with access to sensitive security or business information, as well Directors and Officers of the organization, major shareholders, and individuals in a position to legally bind the licence holder.

A. Licences and Permits – Rules and Requirements (cont'd)

Good Production Practices

- All licensees engaged in cultivation and processing of cannabis would be required to meet good production practice requirements, such as rules related to the use of pesticides and fertilizers; standard operating procedures; a sanitation program; and establishing a product recall system.
- Licensees engaged in processing would be required to conduct analytical testing of cannabis products for potency, pesticides, and microbial and heavy metal contamination.
- Processors would also be required to have a Quality Assurance Person.

Record Keeping and Reporting

- All licensees would be required to maintain records in order to demonstrate compliance with the Act and regulations (e.g., analytical test results), which would be verified during inspections.
- All licensees would be required to report certain information to Health Canada within a specified timeframe (e.g., serious adverse reaction reports, products being recalled).
- These reporting requirements would be separate and apart from any requirements to report information into the Cannabis Tracking System.

B. Security Clearances

Rules for the issuance of security clearances to certain personnel working in federally-licensed organizations

- As proposed on slide 8, select personnel associated with certain licences would be required to hold a valid security clearance issued by the Minister of Health.
- The main purpose of these requirements is to mitigate against the risks that organized crime may infiltrate licensed organizations and use them to benefit criminal activity.
- Based on information provided by law enforcement, it is proposed that the regulations would enable the Minister to refuse a security clearance to any individual:
  - With an association with organized crime; or
  - With past convictions for, or an association with, drug trafficking (particularly to youth); corruption (e.g. money laundering or fraud); or violent offences.
- Health Canada acknowledges that there are individuals who have histories of non-violent, lower-risk criminal activity (e.g. simple possession of cannabis, or small-scale cultivation of cannabis plants) who may seek to obtain a security clearance so they can participate in the legal cannabis industry.
- Part of the purpose of this consultation is to solicit feedback from interested parties regarding the degree to which these individuals should be permitted to participate in the legal cannabis industry.

C. Cannabis Tracking System

Establish requirements for industry-wide reporting to enable the tracking of cannabis throughout the supply chain

- Part 6 of the proposed Act would authorize the Minister to establish and maintain a national Cannabis Tracking System.
- The purpose of the system is to track cannabis throughout the supply chain to help prevent diversion of cannabis into, and out of, the legal market.
- It is proposed that any person authorized to conduct activities with cannabis (federally or provincially/territorially) be required to report into the system.
  - Exceptions would be provided for industrial hemp and certain (lower risk) research and development activities.
- The tracking system would be a data collection tool that will show across the supply chain:
  - Inventory and production levels; and
  - High-level movements of cannabis (e.g. from cultivator to processor, from processor to a provincial/territorial distributor, from within the province or territory to retailer etc.).

D. Cannabis Products

Establish rules and standards for the production of cannabis products, including packaging and labelling requirements

- The regulations respecting cannabis products are intended to:
  - Provide adults with access to quality-controlled cannabis products of known potency;
  - Enable a range of product forms to help the legal industry displace the illegal market;
  - Reduce the appeal of cannabis products to young persons; and
  - Reduce the risk of accidental consumption of cannabis by children.
- Dried and fresh cannabis, cannabis oil, cannabis seeds and plants permitted initially, with edibles and concentrates permitted within the following 12 months.
- It is proposed that the regulations would:
  - Establish rules and standards for the production of cannabis products, including product forms and unit sizes; and
  - Set out packaging and labelling requirements, such as the use of child-resistant, tamper-evident packaging, a standardized cannabis symbol, standardized health warning messages, as well as limits and restrictions on the size, colour, and shape of packaging.

D. Cannabis Products – Rules and Requirements

Product Rules and Standards

- Define classes of cannabis permitted for retail sale:
  - Dried cannabis, fresh cannabis, cannabis oil, cannabis plants, and cannabis seeds would be permitted at coming into force;
  - Edibles containing cannabis and cannabis concentrates would be permitted within 12 months, and defined in a future regulatory proposal
- Enable the manufacturing of various product forms, including ready-to-use forms such as:
  - For dried cannabis, pre-rolled cannabis and vaporization cartridges (new); and
  - For cannabis oil, pre-filled capsules, oral sprays, and topical oils (status quo).
- Establish a maximum unit-size based on how the product is represented to be consumed
  - Inhalation – no more than 1 gram of dried cannabis per unit (e.g. pre-rolled); and
  - Ingestion – no more than 10 mg of THC per unit (e.g. oil capsule).
- No additives, such as colours, flavourings or fillers, would be allowed in dried or fresh cannabis products.
- For cannabis oil, no more than 30 mg of THC per ml of oil; and no additives aside from the carrier oil and those necessary to preserve quality or stability would be allowed.

D. Cannabis Products – Rules and Requirements (cont'd)

Packaging and Labelling

- Require child-resistant, tamper-evident packaging that prevents product contamination.
- Inner and outer packaging permitted.
- Maximum amount of cannabis per package of 30 grams of dried cannabis (or equivalent).
- Required bilingual information on inner and outer package:
  - Would include: THC/CBD content (including amount of THC per serving if applicable), product weight or volume, product lot number, name and contact information;
  - For cannabis oil, the carrier oil used and any known allergens;
  - Statement: "KEEP OUT OF THE REACH OF CHILDREN"; and
  - Standardized cannabis symbol for products that contain >0.001% THC.
- Standardized health warning messages (developed by Health Canada) on all inner and outer packages.
  - Would address topics such as: health effects of cannabis use and the dangers of drug-impaired driving.
- Limits and restrictions on the size, colour, shape and other characteristics of packaging; permitted display of brand elements on the package.
- Informational insert (to be developed by Health Canada) to be included with all products sold to consumers, providing additional health and safety information.

E. Access to Cannabis for Medical Purposes

Maintain distinct system to provide patients with access to cannabis for medical purposes

- The proposed regulations would continue to enable individuals that have the support of their health care practitioner (including those under 18 years of age) to access cannabis for medical purposes by:
  - Purchasing from a federally licensed seller of cannabis for medical purposes;
  - Cultivating their own cannabis (personal production); or
  - Designating someone to grow cannabis on their behalf (designated production).

- The medical access framework would remain substantively the same as it currently exists with proposed adjustments to:
  - Create consistency with rules for non-medical use;
  - Improve patient access; and
  - Reduce the risk of abuse of the system.

E. Access to Cannabis for Medical Purposes

Consistent Rules

- Eliminate storage limits for personal and designated production.

Improve Patient Access

- Facilitate greater choice and mobility for patients by allowing them to request the return or transfer of their medical document to another federally licensed producer.
- Reduce burden on patients by beginning period of use for a registration on the date of initial registration (not the date signed by the medical practitioner).

Reduce Risk of Abuse

- Enable the Minister to refuse personal or designated production if there are reasonable grounds to believe that it would create a risk to public health or safety.

F. Health Products and Cosmetics

Clarify how the use of cannabis in health products and cosmetics would be regulated

- Proposal will clarify rules for the use of cannabis in health products (e.g. prescription drugs) and cosmetics regulated under the *Food and Drugs Act.*
- Given history of cannabis as a controlled substance and the uncertainty about risks of abuse, addiction, and neurological effects, rigorous evidence of safety and efficacy would be required as part of any pre-market application.
  - Manufacturers are currently allowed (and would continue to be allowed) to file new drug submissions for prescription drugs containing cannabis.
  - The use of cannabis in non-prescription drugs and natural health products (NHPs) would be permitted.
    - For NHPs, a THC limit would be established to minimize the potential for psychoactive effects / abuse of these products.
    - Health Canada would work with the provinces and territories on options to prevent sale to youth by, for example, controlling access behind the counter.
  - The use of cannabis-derived ingredients in cosmetics is currently prohibited; it is expected that it would continue to be prohibited moving forward.

F. Health Products and Cosmetics – Drugs

Prescription and Non-prescription Drugs

- New drug submissions with cannabis can be filed, subject to rigorous evidence standards to ensure safety, efficacy and quality.
- Submissions also reviewed against prescription drug criteria.
- Products with indications requiring practitioner oversight, or with serious abuse or addiction potential, would be prescription only.
- For non-prescription drugs, it is proposed that Health Canada work with the provinces and territories on options to prevent sale to youth (e.g. behind the counter).

Veterinary Drugs

- Similar to approach for human drugs, new drug submissions for veterinary drugs would require robust evidence of safety, efficacy, and quality.
- Submissions also reviewed against prescription drug criteria; products with serious abuse potential would be prescription only.
- Similar measures to prevent sale to youth will also be identified in partnership with the provinces and territories.

F. Health Products and Cosmetics – NHPs

Natural Health Products

- Currently, NHPs may contain certain parts of the cannabis plant, provided that they are excluded from the *Controlled Drugs and Substances Act* (e.g. industrial hemp) and contain no more than 0.001% (10 parts per million) THC.
    - This pathway will remain unchanged as these same ingredients would also be excluded from the proposed Cannabis Act.
- In addition, it is proposed that it will also be possible to make new NHP submissions with cannabis ingredients that are subject to the Cannabis Act (e.g. non-hemp ingredients).
- For all NHPs, it is proposed that a limit of no more than 0.001% THC be established in the *Natural Health Products Regulations* to minimize the potential for psychoactive effects / abuse of these products.
- For NHPs that contain cannabis ingredients subject to the Cannabis Act, it is proposed that the same precautions be taken as with non-prescription drugs – including working with the provinces and territories to prevent sale to youth.

F. Health Products and Cosmetics – Medical Devices and Cosmetics

Medical Devices

- Medical devices sold for the purpose of consuming cannabis (e.g. vaporizers) for therapeutic purposes could also be considered a "cannabis accessory" under the Cannabis Act.
  - Existing approval process under the *Food and Drugs Act* would remain unchanged; however, Cannabis Act measures to prevent non-medical use by youth may apply.
- Medical devices could also be combined with cannabis drugs or NHPs for therapeutic purposes (e.g. bandages with cannabis for pain relief); these combination products would be subject to the same evidence standards and access restrictions as drugs or NHPs.

Cosmetics

- Cosmetics are not subject to pre-market review or approval, but must meet the requirements of the *Food and Drugs Act* and *Cosmetics Regulations.*
- The Cosmetic Ingredient Hotlist is a list of substances whose use is either restricted or prohibited. The Hotlist restricts cannabis seed oil and hemp seed proteins at certain limits (consistent with the 0.001% THC limit for NHPs). It is proposed that these restrictions would be maintained.
- The use of any other cannabis-derived ingredients in cosmetics is currently prohibited under the "narcotics" entry on the Hotlist. It is proposed that going forward, cosmetics containing these ingredients would be subject to the requirements of the proposed Cannabis Act.

Public Consultation

- A Consultation Paper, which provides greater detail on the proposed regulations, is on Health Canada's website: https://www.canada.ca/en/health-canada/programs/consultation-proposed-approach-regulation-cannabis.html.
- Health Canada encourages all interested parties to provide feedback by completing an online questionnaire available at the above link.
- Alternatively, written submissions can be sent by:
  - Email to: cannabis@canada.ca
  - Mail to: Cannabis Legalization and Regulation Secretariat
    Address locator 0602E
    Health Canada
    Ottawa, Ontario K1A 0K9
- The 60-day public consultation period will end on January 20, 2018.