The Cannabis Act and Regulations

OVERVIEW

- The Cannabis Act and Regulations come into force on October 17, 2018 and replaces the Access to Cannabis for Medical Purposes Regulations (ACMPR), and any mention of Cannabis and Marihuana in the Narcotics Control Regulations (NCR) and Controlled Drug and Substance Act. The Cannabis Act and Regulations cover recreational, medical, and industrial hemp cannabis products. This QuickNote focuses on the requirements for cannabis related activities, including:
  - Licensing
  - Security
  - Quality Assurance

WHO DOES THIS APPLY TO?

- Existing Licensed Producers and Licensed Dealers of medical cannabis in its various forms, i.e., dried marihuana, cannabis oil, fresh marihuana, seeds, plants

- Current Producers Licence applicants for medical cannabis in its various forms, i.e., dried marihuana, cannabis oil, fresh marihuana, seeds, plants

- Those who want to provide goods and services to the Cannabis Industry (e.g., security firms, packaging and labelling component suppliers, device manufacturers, etc.)

- Prospective new applicants who want to:
  - Grow cannabis
  - Make cannabis products
  - Sell cannabis for medical and/or recreational purposes
  - Perform testing of cannabis
  - Perform research with cannabis
  - Produce drugs containing cannabis
KEY POINTS

- Health Canada now regulates cannabis under the Cannabis Act
- Edible cannabis products, cannabis infused drinks and cannabis concentrates are not within the scope of the Cannabis Act and cannot be sold legally. Health Canada is currently reviewing these types of products.

<table>
<thead>
<tr>
<th>Licence Class</th>
<th>Sub-classes</th>
<th>Allowed Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Licence for Cultivation</td>
<td>Standard Cultivation</td>
<td>Produce dried and fresh cannabis, and cannabis plants and seeds*</td>
</tr>
<tr>
<td></td>
<td>Micro-Cultivation (smaller than 200m²)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nursery</td>
<td>Produce plants, and seeds in area up to 50m²*</td>
</tr>
<tr>
<td>Licence for Processing</td>
<td>Standard Processing</td>
<td>Manufacture cannabis products (i.e., dried cannabis, cannabis oils, packaging of cannabis, etc.)*</td>
</tr>
<tr>
<td></td>
<td>Micro-Processing (less than 600kg of dried cannabis, or equivalent, per year)</td>
<td></td>
</tr>
<tr>
<td>Licence for Sale for Medical Purposes</td>
<td></td>
<td>Sell cannabis to registered clients</td>
</tr>
<tr>
<td>Licence for Analytical Testing</td>
<td></td>
<td>Any testing of a cannabis product (i.e., providing third party testing services)</td>
</tr>
<tr>
<td>Licence for Research</td>
<td></td>
<td>Perform any research and development activities with cannabis</td>
</tr>
<tr>
<td>Cannabis Drug Licence</td>
<td></td>
<td>Produce and sell cannabis as a drug, with Drug Identification Number (DIN)</td>
</tr>
<tr>
<td>Industrial Hemp Licence</td>
<td></td>
<td>Cultivate, process and sell hemp</td>
</tr>
</tbody>
</table>

*These licences include other activities including sale, and are outlined in the regulations

** An individual who is registered with a licence holder, on the basis of a medical document for cannabis
• Health Canada licence requirements for medical and recreational cannabis include the following areas:
  o Security
  o Qualified personnel, such as Quality Assurance Person (QAP), responsible person (RP), Head of Security, etc.
  o Defined quality system, such as Good Production Practices (GPP), Good Agricultural Collection Practices (GACP), Good Manufacturing Practices (GMP), etc.
  o Facility/Site design
• Quality Assurance
  o A QAP, who meets required qualifications, and is responsible for GPP quality oversight at processing sites including:
    ▪ Approval of facility design, focusing on:
      ✓ Flow of material and personnel
      ✓ Equipment & utilities
      ✓ Material of construction
    ▪ Approval of quality assurance system, which must include:
      ✓ Procedures, quality records, record keeping via electronic systems
      ✓ Finished product specifications
      ✓ Validated analytical methods
    ▪ Approval of every lot or batch of substances before it is made available for sale
• Only use pesticides approved as per the Pest Control Products Act. Note, a pesticide used for food may not be acceptable for medical cannabis
• Security
  o You must design your facility security to prevent unauthorized access
  o A Head of Security is required, except for analytical and research licence holders
• Packaging and Labelling
  o All information on the label must be in both English and French.
  o Product label must contain:
    ▪ THC and CBD content in % w/w.
    ▪ Brand name
    ▪ Lot number
    ▪ Warning messages
    ▪ Standardized cannabis label (as seen below)

• Advertising activities are very limited; the regulations specify allowed activities.

WHAT DO I NEED TO DO?

• Develop your business strategy
• Apply for the applicable Health Canada cannabis licences
• Design, build and qualify your facility
• Establish and maintain a compliant GPP quality system
• Prepare for your Health Canada inspections
## DEFINITIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACMPR</td>
<td>Access to Cannabis for Medical Purposes Regulations.</td>
</tr>
<tr>
<td>CBD</td>
<td>Cannabidiol. A main cannabinoid present in cannabis.</td>
</tr>
<tr>
<td>DIN</td>
<td>Drug Identification Number.</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices. Health Canada regulations that apply to pharmaceuticals, natural health products, and APIs that are approved for therapeutic use.</td>
</tr>
<tr>
<td>GPP</td>
<td>Good Production Practices. The quality system required by the Cannabis Regulations.</td>
</tr>
<tr>
<td>Head of Security</td>
<td>A specified individual who is responsible for the licensed facility's organizational security plan and physical security measures.</td>
</tr>
<tr>
<td>Head of Laboratory</td>
<td>The individual who is responsible for the testing of cannabis for a Licence for Analytical Testing holder.</td>
</tr>
<tr>
<td>Licensed Producer</td>
<td>The holder of a licence, under the ACMPR, that permits possession, production, sale/provision, shipping, transportation, delivery, and destruction of cannabis. Now superseded by new Cannabis licence classes.</td>
</tr>
<tr>
<td>Marihuana</td>
<td>The substance referred to as “Cannabis (Marihuana)”. Also known as “Marijuana”.</td>
</tr>
<tr>
<td>Master Grower</td>
<td>The individual responsible for the cultivation, propagation and harvesting of cannabis.</td>
</tr>
<tr>
<td>QAP</td>
<td>Quality Assurance Person.</td>
</tr>
<tr>
<td>RP</td>
<td>Responsible Person.</td>
</tr>
<tr>
<td>RPIC</td>
<td>Responsible Person In Charge.</td>
</tr>
<tr>
<td>SPIC</td>
<td>Senior Person In Charge. Now superseded by RP.</td>
</tr>
<tr>
<td>THC</td>
<td>Tetrahydrocannabinol. A main cannabinoid present in cannabis.</td>
</tr>
<tr>
<td>% w/w (unit of measure)</td>
<td>The ratio of the mass of a substance to the total mass of the whole product, represented as a percentage (e.g., the ratio of mass of THC to total mass of the cannabis product).</td>
</tr>
</tbody>
</table>
RELATED DOCUMENTS

Regulations

- Cannabis Regulations
- Pest Control Products Act and Regulations

Security

- Directive On Physical Security Requirements For Controlled Substances And Drugs Containing Cannabis

FAQ

Licensing:

1. **What will change as of October 17th, 2018?**

   The sale of recreational cannabis will become legal in Canada, and the Cannabis Act and Regulations will come into force.

2. **What happened to the ACMPR regulations?**

   The Cannabis Act and Regulations (SOR/2018-144) will replace the ACMPR as of October 17, 2018.

3. **How do I apply for a licence?**

   The application for a licence under the Cannabis Act is done through the online Cannabis Tracking and Licensing System (CTLS).

   Your application must demonstrate how the security, record keeping, inventory control measures, and GPP at the facility meet all the regulatory requirements.

4. **Why is a Dealer’s Licence no longer needed for cannabis drugs and/or R&D?**

   Health Canada will regulate cannabis under the Cannabis Act and cannabis will no longer be regulated under the Controlled Drug and Substance Act. Under the new Cannabis Act all activities previously permitted under the Dealer’s Licence will be covered by one or more of the 7 new licence classes.
5. **What do I need to do if I have already applied or already am a Licensed Producer or Licensed Dealer?**

Health Canada will transition all current Licensed Producers and Licensed Dealer’s to licences under the Cannabis Act; Health Canada will contact you directly.

6. **What licences do I need if I am servicing the recreational market only?**

All licences, except for the sale for medical purposes and cannabis drug licences, are applicable to the recreational markets.

7. **Can I import/export cannabis to and from Canada?**

Only import/export of cannabis for medical and scientific purposes is allowed. It is possible to import/export, if you have the applicable cannabis licence, and are granted an import/export permit by Health Canada. Approval of import/export permits is dependent on the foreign country’s laws around cannabis.

**Quality Systems:**

8. **What is the difference between the previous ACMPR and the new Cannabis Regulations?**

The main differences between the previous ACMPR and the new Cannabis Regulations are as follows:

- The Senior Person In Charge (SPIC) role will be removed and existing SPIC’s will be transitioned into the RP role, which replaces the previous Responsible Person In Charge (RPIC) role.
- The RP does not have to be physically present when activities are conducted in the operations and storage areas.
- Security requirements remain; however, vary by licence type.
- Master Grower, Head of Security, and Head of Laboratory roles have been added.
- The previous QAP role will only required for processing licence holders.
- Key investors will have to be identified on the licence application.
- The new Cannabis Regulations will allow outdoor growing of cannabis.
9. **Is GPP the same as GMP?**

No, GPP is the quality system required by the Cannabis Regulations. GMP is the quality system required by Health Canada’s Food and Drug Regulations for drug products. GPP does not include GMP critical processes, such as system validation, product stability, self-inspection, Annual Product Quality Reviews, quality agreement requirements, and formalized change control processes.

10. **Do I need to meet Health Canada GMPs for medicinal products/drugs?**

If you wish to export to a foreign market, you may need to comply with GMP standards based on the applicable regulations of the foreign country.

11. **Will Health Canada inspect my Canadian licensed cannabis facility to GMP standards?**

No Health Canada is not inspecting cannabis facilities to drug GMP standards at this time.

12. **My cannabis product has a DIN. Do I need to comply with the Cannabis Regulations?**

Yes, you must follow both drug and cannabis regulations.

13. **Is a stability program required for medical cannabis products sold in Canada?**

It depends. Stability is not required if you do not have an expiration date on your cannabis product label. If you do state an expiration date on your product label, you must have stability study data to support your claim.

14. **Can I grow cannabis outdoors?**

Yes, outdoor activities are limited to cultivating, harvesting and propagating under the cultivation licences.

15. **Can I legally produce edible cannabis products or cannabis concentrates?**

No, this is currently out of the scope of the Cannabis Act and Regulations. Health Canada is reviewing edibles and concentrates at this time.