For Consultation

PROPOSED APPROACH TO THE REGULATION OF CANNABIS

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PREFACE

On April 13, 2017, the Government of Canada introduced Bill C-45, *An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the Cannabis Act) in the House of Commons. The proposed Cannabis Act would implement the 2015 Speech from the Throne commitment to legalize, strictly regulate, and restrict access to cannabis.

The Government of Canada has indicated that it intends to bring the proposed Cannabis Act into force no later than July 2018, subject to the approval of Parliament and Royal Assent. To support implementation of the proposed Act, regulations would need to be enacted in a range of areas, such as cannabis product standards and packaging and labelling requirements, to ensure that the risks and harms of cannabis are appropriately addressed under the legal framework.

In many cases, Health Canada is proposing to build upon established regulatory requirements that have long been in place for current producers of cannabis for medical purposes or industrial hemp. Enacting many of the same types of strict regulatory controls for production under the proposed Cannabis Act would allow for legal and quality-controlled products to be available by July 2018 and immediately begin to address the public health and safety risks posed by illegally-produced cannabis.

The purpose of this consultation paper is to solicit public input and views on the approach to these regulations. To meet the government's commitment of bringing the proposed Cannabis Act into force no later than July 2018, the final regulations will need to be published in the *Canada Gazette*, Part II, as soon as possible following Royal Assent. As such, it is important that interested parties provide feedback on the regulatory proposals in this consultation paper, as draft regulations will not be pre-published. Instead, Health Canada intends to publish a summary of comments received, as well as a detailed outline of any changes to the regulatory proposal, which will continue to provide industry and stakeholders with as much information as possible on the proposed regulatory requirements.

Please note that references to the provisions of the proposed Cannabis Act made throughout this consultation paper reflect the version of the Act reported to the House of Commons by the Standing Committee on Health on October 5, 2017 [www.parl.ca/DocumentViewer/en/42-1/bill/C-45/second-reading], and therefore, do not reflect any amendments that may subsequently be made.

Regulatory proposals set out in this consultation paper have been made 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.

Health Canada thanks all stakeholders for the valuable contribution they have provided to date in the development of the proposed Cannabis Act and its supporting regulations, and for their continued participation in this next stage of consultations on regulatory proposals.

1 INTRODUCTION

1.1 Context

In the 2015 Speech from the Throne, the Government of Canada committed to introducing legislation to legalize, strictly regulate, and restrict access to cannabis. The Minister of Justice and Attorney General of Canada, the Minister of Public Safety and Emergency Preparedness, and the Minister of Health were mandated by the Prime Minister to implement this commitment.

To this end, in June 2016, the three Ministers established the Task Force on Cannabis Legalization and Regulation ("the Task Force") to consult broadly with Canadians and to provide advice on the design of a new legislative and regulatory framework. The Task Force engaged in extensive cross-country consultations with provincial, territorial and municipal governments, experts, patients, advocates, Indigenous organizations, youth, employers and industry. The Task Force also heard from many other Canadians, including many young people, who participated in an online public consultation that generated nearly 30,000 responses from individuals and organizations.

The Task Force delivered its final report, *A Framework for the Legalization and Regulation of Cannabis in Canada* [www.canada.ca/en/services/health/marijuana-cannabis/task-force-marijuana-legalization-regulation/framework-legalization-regulation-cannabis-in-canada.html], to the Ministers and the public on December 13, 2016. In it, the Task Force made 85 recommendations for the establishment of a comprehensive framework for the legalization and regulation of cannabis across five themes: minimizing harms of use; establishing a safe and responsible supply chain; enforcing public safety and protection; medical access; and implementation.

On April 13, 2017, the Government of Canada introduced Bill C-45, *an Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts* (the Cannabis Act) in the House of Commons. Based in large part on the advice provided by the Task Force, the proposed Cannabis Act would create a comprehensive national framework to provide restricted access to regulated cannabis, and to control its production, distribution, sale, import, export and possession. The proposed Act would also enable provinces and territories to oversee the distribution and retail aspects of the cannabis supply chain, and to tailor certain rules in their respective jurisdictions.

When the Government of Canada introduced Bill C-45, it signalled its intention to bring the Act into force no later than July 2018, subject to the approval of Parliament and Royal Assent.

1.2 Overview of the Proposed Cannabis Act[1]

The proposed Cannabis Act seeks to achieve the following objectives:

- restrict youth access to cannabis;
- protect young people from promotion or enticements to use cannabis;
- deter and reduce criminal activity by imposing serious criminal penalties for those breaking the law, especially those who import, export, or provide cannabis to youth;
- protect public health through strict product safety and quality requirements;
- reduce the burden on the criminal justice system;
- provide for the legal production of cannabis to reduce illegal activities;
- allow adults to possess and access regulated, quality-controlled legal cannabis; and
- enhance public awareness of the health risks associated with cannabis.

To achieve these objectives, the proposed Act would:

1. **Set the general control framework for cannabis**—The proposed Act would establish a general control framework for cannabis by establishing a series of criminal prohibitions, and then providing exceptions or authorizations to permit persons to engage in otherwise prohibited activities. For example, the proposed Act would prohibit any person from selling cannabis, unless explicitly authorized to do so under the Act or its regulations. The proposed Cannabis Act would also prohibit individuals aged 18 years or older from possessing more than 30 grams of dried cannabis or its equivalent in public. Provinces and territories, together with municipalities, could also tailor certain rules in their own jurisdiction (for example, setting a higher minimum age or more restrictive limits on possession or personal cultivation, including lowering the number of plants or restricting where it may be cultivated).
2. **Provide for the oversight and licensing of a legal cannabis supply chain**—The proposed Cannabis Act would, through the granting of a licence, permit or authorization, set parameters for the operation of a legal cannabis industry. Federal and provincial/territorial governments would share responsibility for the oversight and licensing of the cannabis supply chain. The federal Minister of Health[2] would be responsible for licensing, among other activities, the production of cannabis (cultivation and processing) and provincial/territorial governments would have the ability to use their legislative authority to authorize the distribution and retail sale of cannabis in their respective jurisdictions, should they choose to do so.

1 This section of the consultation paper is intended to provide a general, plain language overview of the proposed Cannabis Act. As a result, not all elements of the proposed legislation are reflected. As well, this overview reflects the version of the proposed Cannabis Act reported to the House of Commons by the Standing Committee on Health on October 5, 2017 [www.parl.ca/DocumentViewer/en/42-1/bill/C-45/second-reading], and therefore does not reflect any amendments that may be subsequently be made. A more detailed overview of Bill C-45 can be found at [www.justice.gc.ca/eng/cj-jp/marijuana/c45].

2 Throughout this paper, there are references to actions that would be taken by the Minister of Health under the proposed Cannabis Act or the regulations, often in the context of decision-making. In many cases, it is anticipated that the decision-making function would not be exercised personally by the Minister, but instead by an official in the Department of Health who is in a capacity appropriate to making the decision. This would be consistent with ministerial decision-making practices in many other contexts, and in accordance with the common law and the *Interpretation Act*.

3. **Establish national standards to protect public health and safety**—The proposed Act would set a number of clear legal requirements intended to protect against the public health and public safety risks associated with cannabis, in line with the government's objectives. For example, the proposed Act would prohibit the sale of products appealing to youth, and would set out a comprehensive framework to restrict promotion to protect young persons and others from inducements to use cannabis.

The proposed Cannabis Act would provide the Governor in Council with a broad suite of regulation-making powers that would allow for the development of the necessary regulatory frameworks to support the proposed Act. These authorities include regulations respecting areas such as licensing, importing or exporting, packaging and labelling, product quality and amending schedules of the proposed Act.

1.3 Transition from the Existing Legal Framework for Cannabis

1.3.1 EXISTING LEGAL FRAMEWORK

Currently, cannabis is primarily subject to the *Controlled Drugs and Substances Act* (CDSA) [http://laws-lois.justice.gc.ca/eng/acts/c-38.8/] and the *Food and Drugs Act* (FDA) [http://laws-lois.justice.gc.ca/eng/acts/f-27/].

The CDSA and its regulations set out Canada's framework for the control of substances that can alter mental processes and that may harm an individual or society when misused or diverted to an illegal market. Under the CDSA, cannabis is generally prohibited except as authorized under the regulations or through an exemption for medical or scientific purposes or if an exemption is otherwise in the public interest. Under the CDSA, the current *Access to Cannabis for Medical Purposes Regulations* (ACMPR) [http://laws.justice.gc.ca/eng/regulations/SOR-2016-230/] set out a framework to provide individuals with access to cannabis for medical purposes and the *Industrial Hemp Regulations* (IHR) [http://laws.justice.gc.ca/eng/regulations/SOR-98-156/index.html] establish the conditions under which certain cannabis plants (industrial hemp) may be produced for commercial purposes. As well, a number of other regulations under the CDSA, including the *Narcotic Control Regulations* (NCR) [http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/], the *New Classes of Practitioners Regulations* [http://laws-lois.justice.gc.ca/eng/regulations/SOR-2012-230/page-1.html] and the *Qualifications for Designations as Analysts Regulations* [http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-594/index.html] support the cannabis regulatory framework as it exists today. Similarly, the *Cannabis Exemption (Food and Drugs Act) Regulations* [http://laws-lois.justice.gc.ca/eng/regulations/SOR-2016-231/index.html] under the FDA play an important role in the framework.

The FDA applies to all food, drugs, natural health products, medical devices, and cosmetics. The Act and its regulations regulate the safety, efficacy and quality of health products, such as prescription or non-prescription drugs, natural health products, and medical devices. Health products are subject to a review process before they are authorized for sale with health claims. While there is no pre-market review or approval of cosmetics, all cosmetics in Canada must be safe to use.

Cannabis meets the definition of a drug under the FDA, which includes any substance intended to diagnose, treat, mitigate, or prevent health issues in humans or animals. Cannabis itself has not been authorized as a therapeutic product in Canada or in any other country. However, there are certain cannabis-based drugs that have undergone the market authorization process under the FDA, and as such are available for sale in Canada.

1.3.2 NEW LEGAL FRAMEWORK

Should the proposed Cannabis Act be approved by Parliament and receive Royal Assent, cannabis would be removed from the CDSA and would instead be subject to the Cannabis Act and its regulations. It is critical that there be a smooth transition between frameworks. To that end, the proposed Cannabis Act includes a number of transitional provisions to provide, for example, that licences issued under the ACMPR, NCR, or the IHR that are in force immediately before the day cannabis is repealed from the CDSA would remain in effect until such time as they expire or are revoked. As part of the transition, the intention is to enact new regulations under the Cannabis Act, addressing areas such as specific requirements for different types of licence holders, or packaging and labelling requirements for different types of cannabis products.

The existing regulations made under the CDSA that relate to cannabis provide a solid foundation for the new regulations. As a result, many of the regulatory proposals outlined in this consultation paper draw on existing regulations and the experience Health Canada has had in administering them, as well as on feedback and input already received from regulated parties and other stakeholders through various consultation forums since June 2016. That said, it is important to note that the purpose, objectives and structure of the proposed Cannabis Act are different in many regards from those of the CDSA. As a result, there are a number of regulatory proposals outlined in this consultation paper that represent a change from the status quo. These new regulatory proposals reflect that the proposed Cannabis Act was designed in the broader context of legalizing, regulating and restricting access to cannabis.

As cannabis will continue to meet the definition of a drug under the FDA, careful coordination will be required between the application of the FDA, the Cannabis Act, and both of the statutes' regulations, to ensure that health products containing cannabis that fall under the FDA can continue to be developed and sold subject to the appropriate rules and requirements. In addition, it is proposed that the *Cannabis Exemption (Food and Drugs Act) Regulations* [http://laws-lois.justice.gc.ca/eng/regulations/SOR-2016-231/index.html] would be updated to exempt the cannabis produced by individuals holding licences or other authorizations under the proposed Cannabis Act from the requirements of the *Food and Drug Regulations*.

It is also important to note that many of the recommendations made by the Task Force on Cannabis Legalization and Regulation related to potential regulatory requirements for the new cannabis framework. For example, the Task Force recommended that there be a regulatory requirement that all cannabis products intended for sale to the public include labels identifying levels of tetrahydrocannabinol (THC) and cannabidiol (CBD). The advice and recommendations of the Task Force were taken into account in the development of the proposals in this consultation paper.

Taken together, the regulatory proposals in this consultation paper have been developed based on the following principles:

1. **Consistent with the purpose of the proposed Cannabis Act**—Each regulatory proposal should clearly support the overarching purpose of protecting public health and public safety, and should be linked to one or more of the specific purposes set out in clause 7 of the proposed Act.
2. **Evidence-informed**—Each regulatory proposal should be informed by the best-available information or evidence. This includes experience regulating cannabis under the CDSA and the FDA, as well as other harmful substances at the federal level, such as tobacco, and the experience of other jurisdictions in regulating cannabis. Where relevant evidence is incomplete or inconclusive, a precautionary approach should be taken.
3. **Risk-based**—Regulatory proposals should be based on an assessment of the risks that regulated parties and activities may pose to achieving the government's objectives. For example, security requirements for regulated parties should be proportionate to the risk that their activities could pose to public health and public safety, including the risk of cannabis being diverted to illegal markets or activities.
4. **Balance**—Overall, the regulatory framework should seek to support all of the government's objectives for the legalization and regulation of cannabis. It should do so in a manner that seeks to minimize regulatory burden and facilitate compliance among regulated parties.

Consistent with the *Cabinet Directive on Regulatory Management*, this regulatory proposal aims, to the extent possible, to protect the health and safety of Canadians, while also seeking to maximize net benefits to Canadians and to minimize undue impacts on businesses. The feedback of all interested and affected parties, including Canada's Indigenous peoples, the provinces, territories, and municipalities, on this regulatory proposal will be actively sought and will be taken into consideration as Health Canada moves forward with the development of regulations.

1.4 Purpose and Scope of this Consultation

The purpose of this consultation paper is to solicit public feedback on an initial set of regulatory proposals that Health Canada is considering. It focuses on those regulations that would facilitate the coming into force of the proposed Cannabis Act by no later than July 2018, subject to parliamentary approval, and the transition from the current legal framework set out under the CDSA.

For example, it covers the rules and standards for the authorized production of the classes of products, namely dried cannabis, fresh cannabis, cannabis oil, seeds and plants, which would be permitted to be sold by an authorized person immediately upon coming into force of the proposed Cannabis Act. Regulatory proposals governing the production of other classes of cannabis for the purposes of sale, such as food-based cannabis products, known as "edibles," or concentrates or resins, such as hash, would be the subject of separate consultations at a later date, with a view to enabling the quality-controlled production and supply of these products after July 2018.

This consultation paper covers regulations that would be made by the Governor in Council on the recommendation of the Minister of Health and orders that would be made by the Minister of Health. It does not cover regulations made by the Governor in Council on the recommendation of the Minister of Public Safety and Emergency Preparedness (pertaining to law enforcement) or on the recommendation of the Attorney General of Canada (pertaining to tickets).

The Government intends to offset costs in relation to cannabis by collecting, for example, licensing and other fees. Proposals to establish fees or recover costs related to the administration of the proposed Cannabis Act are not within scope of the current consultation paper, but will instead be the subject of separate consultations.

Within this scope, the regulatory proposals set out in this consultation paper fall under the following themes:

- Licences, Permits and Authorizations;
- Security Clearances;
- Cannabis Tracking System;
- Cannabis Products;
- Packaging and Labelling;
- Cannabis for Medical Purposes;
- Health Products and Cosmetics Containing Cannabis; and
- Miscellaneous Issues.

The purpose of this consultation paper is to solicit public input and views on the approach to these regulations. The Government of Canada has indicated that it intends to bring the proposed Cannabis Act into force no later than July 2018, subject to the approval of Parliament. To meet this commitment, the final regulations will need to be published in the *Canada Gazette*, Part II, as soon as possible following Royal Assent. As such, it is important that stakeholders provide input on this consultation paper, as draft regulations will not be pre-published. Instead, Health Canada intends to publish a summary of the comments received, as well as a detailed outline of any changes to the regulatory proposal, in order to provide industry and stakeholders with as much information as possible on the proposed regulatory requirements.

2 LICENCES, PERMITS AND AUTHORIZATIONS

Health Canada is proposing a system of licences, permits, and authorizations that is intended to:

- Allow a range of different activities with cannabis (for example, cultivation, processing, 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.

To this end, it is proposed that the regulations would establish different types of authorizations, based on the activity being undertaken, and in some cases, the scale of the activity. The regulations would also establish rules and requirements for the different categories of authorized activities that would be proportional to the public health and safety risks posed by each category of activity.

The following types of authorizations are proposed:

- **Cultivation:** Standard cultivation, micro-cultivation, industrial hemp, and nurseries;
- **Processing:** Standard processing, and micro-processing;
- **Sale (federal level):** Sale for medical purposes, and sale for non-medical purposes to adults in provinces and territories that have not yet enacted a retail framework;
- **Analytical testing**;
- **Import/Export**; and
- **Research**.

2.1 Context

The proposed Cannabis Act sets out a general licensing and permitting scheme for the Minister of Health to authorize persons to conduct various activities with cannabis. The proposed Act would also enable wholesale distribution and retail sale of cannabis by persons authorized to sell cannabis under a provincial or territorial Act, subject to certain minimum legislative measures outlined in the proposed Act.

Under the proposed Act, the Minister of Health would have the authority to issue licences and permits to conduct certain activities involving cannabis, and to include any conditions on those licences and permits that the Minister considers appropriate. These authorities would include the ability to amend, renew, suspend, or revoke licences or permits when warranted. The proposed Act would set out grounds for refusing to issue a licence or permit, as well as grounds for suspending or revoking a licence or permit.

The proposed Act would provide the Minister of Health with the authority to set out the application process for the issuance, renewal or amendment of licences and permits, including the form and manner in which applications would be made, and the information that an applicant would be required to submit (which may include financial information).

Finally, the proposed Act would provide the Minister of Health with the authority to make an order setting out procedures and conditions for the processing of applications to issue and renew licences and permits.

To complement and support the Minister's authorities set out in the Act, the Governor in Council would be able to make regulations respecting a broad range of aspects related to licences, permits and authorizations. These authorities would include, for example, establishing classes of licences or permits and setting legal requirements applicable to the different classes.

2.2 Licences, Permits, and Authorizations

The licensing and permitting framework established under the proposed Act and related regulations will strongly influence the type of legal cannabis industry that establishes itself in Canada. The regulatory proposals set out in this section are intended to achieve the following:

1. **Enable a robust and responsible legal cannabis industry that is capable of outcompeting the entrenched illegal industry.** To achieve this, the licensing and permitting framework is intended to:
   a. Enable a diverse, competitive legal industry that is comprised of a range of market participants, including both small and large players in regions across the country.
   b. Allow a range of different activities with cannabis, enabling innovation while at the same time protecting public health and public safety.

c. Reduce the risk that individuals associated with organized crime infiltrate the legal industry and use their position to benefit, financially or otherwise, criminal organizations.

d. Require that legal cannabis products meet high standards for quality, are produced in clean and sanitary environments and are tested for contaminants and the presence of unauthorized pesticides prior to sale to consumers.

2. **Establish an appropriate regulatory framework for industrial hemp** that is risk-based and that allows cultivators of industrial hemp to sell the whole hemp plant to certain persons licensed under the proposed Cannabis Act.
3. **Maintain continued access to cannabis for medical purposes** by continuing to federally-license persons and organizations to sell cannabis directly to registered clients and hospitals.
4. **Facilitate research and development** by streamlining and rationalizing the process and requirements for cannabis-based research.

To achieve these objectives, it is proposed that the regulations set out the following categories of licensed activities:

- **Cultivation**
  - **Standard cultivation**, which would authorize the large-scale growing of cannabis plants and harvesting material from those plants, as well as associated activities
  - **Micro-cultivation**, which would authorize the small-scale growing of cannabis plants and harvesting material from those plants, as well as associated activities
  - **Industrial hemp**, which would authorize the growing of industrial hemp plants (those containing 0.3% THC or less) and associated activities
  - **Nursery**, which would authorize the growing of cannabis plants to produce starting material (seed and seedlings) and associated activities
- **Processing**
  - **Standard processing**, which would authorize the large-scale manufacturing, packaging and labelling of cannabis products destined for sale to consumers, and the intra-industry sale of these products, including to provincially/territorially authorized distributors, as well as associated activities
  - **Micro-processing**, which would authorize the small-scale manufacturing, packaging and labelling of cannabis products destined for sale to consumers, and the intra-industry sale of these products, including to provincially/territorially authorized distributors, as well as associated activities

- **Sale to the public**
  - **Medical purposes**, which would authorize the sale of cannabis products to registered clients for medical purposes
  - **Non-medical purposes**, which would authorize the sale of cannabis to adults in provinces/territories that have not yet enacted a framework for distribution and sale

In addition, it is proposed that the regulations provide for the Minister to issue authorizations for the following additional activities:

- **Analytical Testing**, which would authorize the possession of cannabis by independent, third-party laboratories for the purposes of analytical testing of cannabis to verify that it meets regulatory requirements for safety and quality
- **Import/Export**, which would authorize the import or export of cannabis for medical or scientific purposes, or in respect of industrial hemp
- **Research**, which would authorize activities with cannabis for the purposes of research and/or development by persons who are not otherwise permitted to conduct such activities under another licence or permit under the proposed Cannabis Act.

Additional details on each licensed activity are set out below, and a high-level overview of licensed activities is set out in Table 1. Each licensed activity would be subject to specific regulatory requirements tailored to the level of risk associated with the activity involved (discussed in sections 2.3 and 2.4 of this consultation paper).

In general, licence holders would be authorized to conduct core activities (for example, cultivation) as well as related, supplemental activities (for example, research and development related to the cultivation of cannabis).

In general, there would be no restriction on the ability of a single person (either an individual or organization) to be authorized to conduct multiple activities per site. For example, a person could be authorized to conduct one or more activities (for example, cultivation, processing and sale to the public). This would allow flexibility in the administration of licences and reduce overall administrative burden on applicants. Applicants would be free to choose whichever activity or combination of activities for which they wish to be licensed, and the licensing process would enable them to submit a single application should they wish to conduct multiple activities.

The regulations would set out general requirements for licensing and would be supported by guidance and policy documents that would provide more detail and clarity around specific requirements. This would allow for flexibility and change over time based on lessons learned as the market evolves, specific risks are better understood, and the performance of the regulated industry is established.

2.2.1 STANDARD CULTIVATION

It is proposed that a licence for standard cultivation would authorize the cultivation of any variety of cannabis and to produce cannabis seeds, cannabis plants, fresh cannabis and dried cannabis. A licence for standard cultivation would also authorize associated or supplemental activities related to these core activities, including possession, transportation, research and development, storage, and destruction. The intra-industry sale of seeds, plants, and harvested materials (e.g., fresh and dried cannabis in bulk or unfinished form) to other cultivators, processors, and holders of a research authorization would be allowed. The cultivation of industrial hemp plants would also be allowed. However, standard cultivators would not be able to package and label cannabis for sale to the public, nor to sell directly to the public or to federally-licensed or provincially- or territorially-authorized sellers.

It is proposed that the regulations would not prescribe a limit on the amount of cannabis that could be cultivated under a standard cultivation licence. However, the Minister of Health could establish a production limit as a condition of a licence if there were reasonable grounds to believe that a licensee was producing more cannabis than this licensee was able to sell, and that the excess inventory was at risk of being diverted to an illegal market or activity (for example, a licensed cultivator producing significantly more cannabis than this cultivator has supply arrangements to provide). In addition to the amount of unsold inventory, this approach would take into account factors such as the licence holder's compliance history, financial status, and planned future sales, when determining if there was a risk of diversion.

2.2.2 MICRO-CULTIVATION

The intent of this licence category is to enable the participation of small-scale growers in the legal cannabis industry. It is proposed that a licence for micro-cultivation would authorize the same activities as a licence for standard cultivation, but at a smaller scale.

It is proposed that the regulations would set out a threshold to define a micro-cultivator. Health Canada is considering a number of options for this threshold, such as plant count, size of growing area, total production, or gross revenue. Part of the purpose of this consultation is to solicit feedback from interested parties regarding the most appropriate basis for establishing this threshold, and what the threshold should be.

A micro-cultivation licence would authorize the cultivation of cannabis plants and to produce cannabis seeds, cannabis plants, fresh cannabis and dried cannabis. A licence for micro-cultivation would also authorize associated or supplemental activities related to these core activities, including possession, transportation, research and development, storage and destruction. The intra-industry sale of seeds, plants, and harvested materials (for example, fresh and dried cannabis) to other cultivators, processors, and holders of a research authorization would also be allowed. However, micro-cultivators would not be able to sell directly to the public or to federally-licensed or provincially- or territorially-authorized sellers.

As described further in section 2.3, below, certain regulatory requirements for micro-cultivation would be reduced as compared with regulatory requirements for standard cultivation, reflecting differences in the level of risk related to the scale of the operation.

2.2.3 NURSERY

The intent of this licence category is to enable a legal source of starting materials (both for commercial and personal cultivation), and the development of new varieties of high quality cannabis. It is proposed that a licence for a nursery would authorize the cultivation of any variety of cannabis plants (including industrial hemp), and to produce seeds and seedlings (including clones). A nursery licence would also authorize related activities, including possession, transportation, research and development, storage, and destruction. Nurseries would be permitted to sell live plants and seeds to other licensed cultivators, licensed processors, and holders of a research authorization. However, they would not be able to sell directly to the public or to federally-licensed or provincially- or territorially-authorized sellers. The harvest of other plant material and production of any other class of cannabis would be prohibited under this class of licence. This material would need to be destroyed.

As described further in section 2.3, below, certain regulatory requirements for nurseries would be reduced as compared with regulatory requirements for standard cultivation, reflecting differences in the level of risk related to the scale of the operation.

2.2.4 INDUSTRIAL HEMP

It is proposed that a licence for industrial hemp would authorize the cultivation of industrial hemp plants and the production and sale of seeds and grains (and their derivatives). It is proposed that the regulations would define industrial hemp as "cannabis plants whose leaves and flowering heads do not contain more than 0.3% THC." It should be noted that any part of the plant identified in Schedule 2 of the proposed Cannabis Act, such as a non-viable seed or mature stalk without any leaf, flower, seed or branch, would fall outside the scope of the proposed Act. As such, activities related to these plant parts (such as their processing or sale) would not require a licence under the proposed Act. Further, as is currently the case under the *Industrial Hemp Regulations,* a licence would not be required for the sale of derivatives of seed and grain that contain 10 micrograms per gram of THC or less.

An industrial hemp licence would also authorize related activities, including possession, transportation, research and development, consistent with other classes of licences. To improve upon the current regulatory requirements for industrial hemp producers, it is proposed that industrial hemp licences would authorize the intra-industry sale of leaves, flowers and branches (or the whole plant).

As is currently the case under the *Industrial Hemp Regulations*, industrial hemp licences would authorize the cultivation of approved industrial hemp varieties from pedigreed seeds. Since the THC content of plants produced from these seeds is consistently 0.3% or less, it is proposed that the current THC testing requirements with respect to these varieties grown for grain and fibre would be eliminated except for production of seeds. Requirements for THC testing would be maintained for the designation of new varieties of low THC cannabis (0.3% or less) as an approved cultivar of industrial hemp to be included in the *List of Approved Cultivars*.

As described further in section 2.3, below, certain regulatory requirements for cultivators of industrial hemp would be reduced as compared with regulatory requirements for standard cultivation, reflecting differences in the level of risk related to the scale of the operation.

2.2.5 STANDARD PROCESSING

It is proposed that a licence for standard processing would authorize the production and packaging and labelling of a range of cannabis products destined for sale to the public. Authorized activities would include manufacturing cannabis oil (and intermediary products such as cannabis resin), synthesizing phytocannabinoids, the manufacturing of other authorized products (for example, pre-filled cannabis oil capsules or oral sprays), and/or the packaging and labelling of products for sale to the public. Further information on the types of cannabis products that licensed processors would be able to produce is discussed in Part 5 of this consultation paper. A licence for standard processing would also authorize related activities, including possession, transportation, research and development, storage, destruction, and the intra-industry sale of cannabis to other federal licence holders or provincially- or territorially-authorized sellers. A separate authorization would be required for sales directly to the public (see sections 2.2.7 and 2.2.8 of this consultation paper).

2.2.6 MICRO-PROCESSING

The intent of this licence category is to enable the participation of small-scale processors in the legal cannabis industry. It is proposed that a licence for micro-processing would authorize the same activities as a licence for standard processing, but at a smaller scale.

It is proposed that the regulations would set out a threshold to define a micro-processor. Health Canada is considering a number of options for this threshold, such as limiting allowed activities to processing harvested product from a maximum number of micro-cultivators and nurseries, total production, on-site inventory, or gross revenue. Part of the purpose of this consultation is to solicit feedback from interested parties regarding the most appropriate basis for establishing this threshold, and what the threshold should be.

As with a licence for standard processing, a licence for micro-processing would authorize related activities, including possession, transportation, research and development, storage, destruction, and the intra-industry sale of products to other federal licence holders or to provincially- or territorially-authorized sellers. A separate authorization would be required for sales directly to the public (see sections 2.2.7 and 2.2.8 of this consultation paper).

2.2.7 SALE OF CANNABIS FOR MEDICAL PURPOSES

A licence for the sale of cannabis for medical purposes would authorize the sale of cannabis products obtained from a federally-licensed processor to registered clients (or to an individual who is responsible for a registered client) in a manner consistent with the current system established under the ACMPR (ordered over the phone, online or via written order, with secure delivery through the mail or by courier).

As with other licences, a licence for sale for medical purposes would authorize related activities, such as possession, transportation, research and development, storage, destruction, and the intra-industry sale of cannabis to other federal licence holders.

2.2.8 SALE OF CANNABIS FOR NON-MEDICAL PURPOSES

Under the proposed Cannabis Act, provinces and territories could licence and oversee the distribution and sale to adult consumers of cannabis for non-medical purposes. In the event that a province or territory has not established a retail environment with appropriate safeguards to enable the purchase of legal, regulated cannabis by July 2018, it is proposed that the regulations would enable the Minister to licence, potentially on a temporary basis, the sale of cannabis for non-medical purposes to adult consumers. This class of licence would authorize the sale of cannabis products obtained from a licensed processor to adult consumers in Canada (ordered over the phone, online or via written order, with secure delivery through the mail or by courier). As with other licences, a licence for sale for non-medical purposes would authorize related activities, such as possession, transportation, research and development, storage, destruction, and the intra-industry sale of cannabis to other federal licence holders.

As set out further in section 2.3, it is proposed that the regulations set strict controls to prevent illegal sales to youth and to prevent online sales by federally-licensed sellers in provinces and territories that have established their own distribution and sales systems (which may include online sales authorized at the provincial or territorial level).

2.2.9 ANALYTICAL TESTING

Under the ACMPR and *Narcotic Control Regulations*, respectively, both licensed producers and licensed dealers are authorized to test cannabis. Cannabis must be tested for microbial and chemical contaminants, residues of solvents, content of THC and CBD, and disintegration of capsules, using validated methods. In addition, on May 5, 2017, Health Canada announced that it would require all licensed producers to conduct mandatory testing of all cannabis products destined for sale for the presence of unauthorized pesticides (for more information, please see: www.canada.ca/en/health-canada/news/2017/05/statement_from_healthcanadaonmandatorytestingofmedicalcannabisfo.html).

Under the IHR, industrial hemp must be tested by a competent laboratory for THC content. Non-viable seeds must be tested by a laboratory accredited by the Canadian Food Inspection Agency.

As described in further detail in section 2.3.6 of this consultation paper, it is proposed that licensed processors would be required to conduct mandatory analytical testing, including mandatory testing for the presence of unauthorized pesticides, to verify that the regulatory requirements are met prior to packaging and labelling. For industrial hemp, it is proposed that mandatory testing only be required as set out in section 2.2.4 (i.e., for production of seeds and development of new varieties for designation as an approved cultivar).

Licensed processors could conduct their own, in-house analytical testing, however they would be required to demonstrate that they were using validated testing methodologies. Health Canada would require mandatory testing for the presence of unauthorized pesticides to be conducted by an independent third-party laboratory.

In general, all independent third-party laboratories conducting analytical testing of cannabis, including testing of microbial and chemical contaminants, residues of solvents, content of THC and CBD, disintegration of capsules, and testing for the presence of unauthorized pesticides, would be required to hold an analytical testing licence under the Cannabis Act. Such laboratories would also be required to demonstrate that they were using validated testing methodologies. With respect to industrial hemp, an analytical testing licence would not be required for private laboratories accredited by the Canadian Food Inspection Agency that conduct seed viability testing.

As with other licence types, a licence for analytical testing would authorize activities with cannabis such as possession, transportation, storage and destruction. A licence for analytical testing would also authorize research and development related to the analytical testing of cannabis (in particular the development and validation of testing methodologies), including industrial hemp. Licensed analytical testing laboratories would be required to destroy any cannabis or industrial hemp sent for analytical testing within 90 days of being tested.

2.2.10 IMPORT AND EXPORT

As is currently the case, the import or export of cannabis would require a permit from the Minister of Health. As set out in the proposed Act, import or export permits would only be available for medical or scientific purposes, or in respect of industrial hemp.

2.2.11 RESEARCH

It is proposed that a research authorization would enable activities with cannabis for the purpose of research by persons who do not hold any other type of licence issued under the Cannabis Act and whose activities would otherwise be prohibited under the Act (for example, they are involved in the possession of 30 grams of dried cannabis or its equivalent in public or distribution of more than 30 grams of dried cannabis or its equivalent, or possession by an organization). These activities would include possessing, cultivating, processing, storing, administering, and transporting cannabis. Authorized activities would not include the sale of cannabis—however, there would be provisions to enable the commercialization of novel research and development (for example, the sale of new plant genetics). Research authorization holders would generally be required to destroy all cannabis once the research activities are complete and/or upon the expiration or revocation of the authorization. However, exceptions to this requirement could be sought by those wishing to commercialize novel products of research and development (for example, new plant genetics) or for archival purposes (for example, a seed bank).

As described above, persons holding a federal licence to conduct activities with cannabis, such as cultivation or processing, would be authorized to conduct research and development under their existing licence, provided that the research is related to the core activities authorized under the licence. For example, an industrial hemp licence would authorize research with industrial hemp, but the holder of an industrial hemp licence would be required to seek a separate authorization to conduct research with other varieties of cannabis.

It should be noted that persons seeking to conduct clinical trials with cannabis would still be required to seek appropriate authorization under the FDA and its regulations.

Table 1: Summary of Licensed Activities

ACTIVITIES	CULTIVATION				PROCESSING		SALE	
	Standard	Micro	Nursery	Hemp	Standard	Micro	Medical	Non-medical
CORE ACTIVITIES								
Cultivation								
Cultivate cannabis with more than 0.3% THC	•		•					
Cultivate cannabis with more than 0.3% THC, **below** a certain threshold (to be established in the regulations)		•						
Cultivate cannabis containing 0.3% or less THC (hemp)	•	•	•	•				
Sell starting material (live plants and seeds) to cultivators or processors	•	•	•	•				
Sell harvested plant material (flower and trim) to processors	•	•		•				
Processing								
Manufacture cannabis products (for example, oil)					•			
Manufacture cannabis products, below a certain threshold (to be established in the regulations)						•		
Package and label products for sale to consumers					•	•		
Sell packaged products to federal or provincially- or territorially-authorized sellers					•	•		
Sell intermediary products (i.e. resin) to other processors					•	•		
Sale to the Public								
Sell products for medical purposes to registered clients							•	
Sell products to adult consumers in provinces and territories without a distribution and retail sale system								•
SUPPLEMENTAL ACTIVITIES								
Transportation	•	•	•	•	•	•	•	•
Storage	•	•	•	•	•	•	•	•
Destruction	•	•	•	•	•	•	•	•
Research and Development (within authorized core activities)	•	•	•	•	•	•	•	•

2.3 Licence Requirements

It is proposed that the regulations set out specific requirements by class of licence. As discussed in section 1.3, these requirements would be designed to achieve the purposes of the proposed Cannabis Act based on an objective assessment of risk that considers the following three factors: (i) the activities authorized to be undertaken and the resulting forms of cannabis that would be present on-site; (ii) the scale of activities authorized to be undertaken and the resulting quantity of cannabis that would be present on-site; and (iii) the proximity of authorized activities to the consumer-end of the supply chain. For each class of licence, it is proposed that the regulations would set, among others, requirements related to:

1. Notice to Local Authorities
2. Validity Period
3. Location
4. Physical Security
5. Personnel Security
6. Good Production Practices
7. Record Keeping and Reporting

A summary of these requirements by licence activity is set out in Table 2.

2.3.1 NOTICE TO LOCAL AUTHORITIES

It is proposed that the regulations would require notice be provided to local government, fire and policing authorities for all licence classes except industrial hemp, analytical testing, or for sale licences where cannabis is not stored on-site.

2.3.2 VALIDITY PERIOD

It is proposed that the regulations provide that all licences issued under the Cannabis Act be valid for a period of no more than five years.

2.3.3 LOCATION

It is proposed that the regulations would prohibit the conduct of any licensed activity in a dwelling-house.

It is proposed that the regulations would permit both outdoor and indoor cultivation of cannabis (under all four classes of cultivation licence: standard cultivation, micro-cultivation, nursery and industrial hemp).

For any indoor areas where cannabis is present (such as where it is cultivated or where it is dried or stored), it is proposed that the regulations would require reasonable measures to prevent the escape of odours and pollen. It is proposed that these restrictions would apply to all licences, except industrial hemp, analytical testing, and sale licences.

Under all licence classes, cannabis (with the exception of cannabis plants and industrial hemp) would need to be stored and processed indoors.

2.3.4 PHYSICAL SECURITY

Physical security requirements set out in the regulations would comprise one aspect of the overall approach to preventing legally produced cannabis from being diverted to an illegal market or activity, or from illegal cannabis being a source of supply for the legal industry. Other aspects would include personnel security requirements, record keeping and reporting, participation in the national cannabis tracking system, and facilities being subject to inspections.

Physical security requirements would be designed primarily to mitigate against the risk of cannabis being removed or stolen from a licensed site or during transit and diverted to an illegal market or activity. As a result, it is proposed that licences that authorize activities resulting in large quantities of high-value cannabis products being present on site would face proportionately higher physical security requirements compared to other licence classes. It is further proposed that the regulations would require all licence holders to take measures to safeguard cannabis in transit, including when transporting or shipping cannabis to another licence holder or when shipping cannabis to a provincially- or territorially-authorized seller.

For standard cultivation and standard processing licences, as well as for federal sale licences where cannabis is stored on-site (for medical purposes or non-medical purposes), it is proposed that the regulations require the following physical security requirements around the perimeter of the site:

- The perimeter must be secured in a manner that prevents unauthorized access, including physical barriers.
- The entire perimeter must be visually monitored at all times by a visual recording device. The visual recordings must be kept for one year after the day on which they were made.
- There must be an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to or movement in the site or tampering with the system.

In addition, for these same licence classes, it is proposed that the regulations require the following security measures for indoor areas where cannabis is present (excluding growing areas):

- Areas must include physical barriers that prevent unauthorized access.
- Areas must be secured by means of an intrusion detection system that operates at all times and that allows for the detection of any attempted or actual unauthorized access to the site or tampering with the system.
- Areas must be visually monitored at all times by visual recording devices. The visual recordings must be kept for one year after the day on which they were made.
- Access to areas where cannabis is present must be restricted to persons whose presence in those areas is required by their work responsibilities.
- For areas where cannabis is stored (but not where cannabis plants are cultivated or cannabis products are manufactured), the identity of the every person entering or exiting these areas must be recorded, in addition to the requirements above.

These physical security requirements are similar to those in place under the ACMPR, with four notable proposed changes. First, the proposed regulations would no longer require cannabis to be stored in accordance with the *Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances)* [www.canada.ca/en/health-canada/services/health-concerns/reports-publications/controlled-substances-precursor-chemicals/directive-physical-security-requirements-controlled-substances-licensed-dealers-security-requirements-storage.html]. Second, the proposed regulations would require visual recordings to be kept for one year, rather than for two years. Based on experience with the current program, this period of time is considered to be sufficient for compliance and enforcement purposes. Third, the proposed regulations would not require visual monitoring of areas where cannabis is grown. Considering the lower risk of theft of whole plants compared to processed material, other physical security requirements respecting cultivation areas (such as visual monitoring of the perimeter and points of entry) are considered to be sufficient mitigation against the risk of theft. Finally, the proposed regulations would no longer require the presence of a security-cleared individual, as will be discussed further in section 2.3.5, to be present when others are in an area where cannabis is present.

For micro-cultivation, nursery licences, and micro-processing licences, it is proposed that the regulations would require the following:

- That the perimeter be secured in a manner that prevents unauthorized access, including physical barriers.
- That indoor areas where cannabis is present be behind physical barriers that prevent unauthorized access.
- That access to areas where cannabis is present be restricted to persons whose presence in those areas is required by their work responsibilities.

For industrial hemp licences, it is proposed that the regulations not prescribe specific physical security requirements. As a result, the proposed regulations would remove the current requirement under the IHR, which requires that industrial hemp be stored in a locked container or locked location, or on premises to which only authorized persons have access. This approach would allow industrial hemp to be stored under the same conditions as other agricultural products.

For federal sale licences where cannabis is not stored on-site, it is proposed that the regulations would not prescribe specific physical security requirements.

For analytical testing licences, it is proposed that the regulations would require that:

- Cannabis be stored behind physical barriers that prevent unauthorized access;
- Access to areas where cannabis is present be restricted to persons whose presence in those areas is required by their work responsibilities and that the identity of every person entering or exiting these areas must be recorded; and
- Samples be destroyed within 90 days of the date of testing.

This proposed approach would be a change from the existing framework, and licensees conducting analytical testing of cannabis would no longer be required to adhere to the physical security requirements set out in the *Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances).*

2.3.5 PERSONNEL SECURITY

Personnel security requirements set out in the regulations would comprise a second element of the overall approach to preventing legally produced cannabis from being diverted to an illegal market or activity. Personnel security requirements would be designed primarily to mitigate against the risk that individuals associated with organized crime infiltrate licensed organizations and use their position to benefit, financially or otherwise, criminal organizations.

Under the proposed Act, the Minister of Health would have the authority to grant or refuse to grant a security clearance, or suspend or cancel a security clearance, with respect to individuals associated with a licence applicant or a licence holder. The proposed process for issuing security clearances is set out in section 3 of this consultation paper. This section sets out general requirements with respect to personnel security, and identifies specific persons associated with a licence that would be required to hold a valid security clearance issued by the Minister of Health.

It is proposed that the regulations would establish the following personnel security requirements for standard cultivation, micro-cultivation, nursery, standard processing, micro-processing, and federal sale (for both medical and non-medical purposes) licences, and in some instances for research authorizations. These requirements would not apply to industrial hemp or analytical testing licences.

- The creation and maintenance of an organizational security plan. The plan would need to set out, among other things, standard operating procedures to prevent cannabis from being diverted to an illegal market or activity, and from illegal cannabis being a source of supply for the organization's activities.
- The security plan would be required to include an organizational diagram that provides a description of the duties and responsibilities of senior positions within the organization. In particular, the security plan and organizational diagram would be required to designate the positions responsible for overall management and oversight, including the following ("key positions"):
  i. individual responsible for the licensed activities conducted by the organization;
  ii. chief of security;
  iii. for processing licences, a quality assurance person;
  iv. for cultivation licences, a master grower; and
  v. for licences to sell to the public, the head of client services.
- The security plan would be required to be submitted to the Minister of Health as part of a licence application, along with the identification of the individual occupying each key position.
- Nothing would prevent the same individual from occupying more than one key position (for example, the same person could be both the head of client services and the chief of security). However, only one individual could be responsible for any one position (for example, there could not be two different people designated as chief of security).

- A licence holder would be required to notify the Minister of Health of any change to the security plan, including any change in the individual occupying a key position.
- In addition to key positions, it is proposed that the regulations would require a licence applicant or licence holder to identify:
  i. all Directors and Officers of the organization and any parent company;
  ii. any shareholders that own more than 25% of the organization (if it is privately held) or more than 25% of a privately held parent company;
  iii. owner of the site, if different than the applicant, and in the case of a numbered company, the directors and officers; and
  iv. any individual that is in a position to legally bind the applicant or licence holder.
- It is proposed that the regulations would require any individual occupying a key position, or who are described above, to hold a valid security clearance issued by the Minister of Health. At least one individual holding a security clearance would be expected to be on site during normal business operations.
- Based on the security plan and an overall assessment of risk, it is also proposed that the regulations would provide the Minister of Health with the authority to identify additional positions and/or individuals in an organization who require a valid security clearance.

The proposed personnel security requirements represent a change from similar requirements currently in place under the ACMPR in two key respects. For current licensed producers, the ACMPR requires that a "responsible person in charge" or an "alternate person in charge" who holds a valid security clearance, be present whenever other employees are present in a room with cannabis. The proposed regulations would remove these requirements and instead require at least one individual holding a security clearance to be on site during normal business operations. Second, the proposed regulations would add new requirements for key positions to hold a valid security clearance—such as the quality assurance person, or the master grower. As well, the proposed regulations would require individuals in positions to direct or control the licensed organization—such as the directors and officers of a parent company or major shareholders—to also hold a valid security clearance.

For industrial hemp and analytical testing, it is proposed that the regulations not prescribe requirements for individuals to hold security clearances from the Minister.

2.3.6 GOOD PRODUCTION PRACTICES

Regulatory requirements with respect to good production practices would be the primary means by which the government would control the quality of cannabis through the legal supply chain. Good production practice requirements generally include rules related to the use of pesticides, chemicals and fertilizers; recall procedures; quality control/assurance activities; sampling and analytical testing protocols, as well as requirements pertaining to facilities, equipment and sanitation.

It is proposed that the regulations establish good production practice requirements for all classes of cultivation licences (standard, micro, nursery and industrial hemp) as well as for all classes of processing licences. It is proposed that the other classes of licences (analytical testing and sale licences) would not be subject to good production practice requirements, with the exception of those relating to recall and adverse reaction reporting.

Currently, the ACMPR set out a number of requirements with respect to good production practices. It is proposed that the regulations made under the proposed Cannabis Act establish requirements for good production practices based on those found in the ACMPR for standard cultivation, micro-cultivation, nursery and processing licences. Specific good production practices would only apply to a licence holder to the extent that they are applicable to the activities authorized under the licence. In general, the proposed regulations would establish the following requirements:

- Meet specific requirements with respect to:
  i. microbial and chemical contaminants (such as heavy metals);
  ii. maximum allowed limits of THC in cannabis oil (30 milligrams per millilitre);
  iii. the presence of solvents used during the preparation of cannabis products, or present in the final product;
  iv. the disintegration of capsules or other dosage forms; and
  v. the presence of unauthorized pesticides.
- Conduct mandatory analytical testing, including for unauthorized pesticides, to verify that requirements are met prior to packaging and labelling.
- Establish and maintain an appropriate sanitation program for indoor cultivation and processing.
- Maintain equipment, whether used in outdoor or indoor cultivation or processing, to prevent contamination of cannabis.
- Establish a system to recall every lot or batch of cannabis that has been made available for sale, and for processors, maintain a sample of product from every lot or batch made available for sale for 1 year following the date of availability for sale.

- Establish and maintain standard operating procedures to demonstrate that required good production practices applicable to the licence are properly implemented.
- For processing licences, employ a quality assurance person, with appropriate training, experience, and technical knowledge to approve the quality of cannabis products prior to making them available for sale.

For industrial hemp licences, it is proposed that the regulations require licence holders to implement the same good production practices required under the IHR and applicable provisions of the exemption issued pursuant to section 56 of the CDSA. These requirements would include, for example, that hemp producers be required to clean equipment to avoid the inadvertent dissemination of industrial hemp. As with the current circumstance, THC testing for most crops would not be required, while THC testing at the plant breeding and seed production levels would continue. Finally, it is proposed that the regulations not reference the *Industrial Hemp Technical Manual*, in favour of guidance that is aligned between requirements for hemp and other varieties of cannabis regulated under the proposed Cannabis Act. For parts of the hemp plant transferred to a licensed processor for further processing (for example, into cannabis oil) or for packaging and labelling for sale to consumers, the applicable good production practices set out above for all cannabis products would apply.

2.3.7 RECORD KEEPING AND REPORTING

Record keeping and reporting requirements set out in the regulations would help enable licensed persons to quickly and efficiently demonstrate that they are in compliance with their legal obligations under the proposed Act and its regulations. As well, record keeping and reporting requirements would help the Minister of Health protect public health—through measures such as the requirement to report details of product recalls or serious adverse reactions to specific cannabis products. Finally, record keeping and reporting requirements would enable the Minister of Health to monitor the evolution of the cannabis industry and track developments—such as the development of new types of products—to ensure that the regulatory framework is working effectively to support the objectives of the proposed Act.

To these ends, it is proposed that the regulations set out specific record keeping and reporting obligations for each class of licence. Reporting requirements with respect to the tracking of cannabis and cannabis products, including information such as production levels, inventory amounts, and sales volumes would be captured under the Cannabis Tracking System that would be established under Part 6 of the proposed Act, and are covered separately in section 4 of this consultation paper.

In general, it is proposed that the regulations require the following records be maintained by licensed persons, along with setting out the manner in which they must be maintained, and their retention period:

- Records required to demonstrate compliance with required good production practices. These records would include, for example:
  i. documents demonstrating that each batch or lot of product sold was produced, packaged and labeled in accordance with the requirements of the proposed Act and its regulations;
  ii. copies of standard operating procedures and the sanitation program;
  iii. the results of any required analytical testing and the methods used in the testing;
  iv. qualifications of the quality assurance person; or
  v. copies of complaints received, investigations undertaken and any resulting corrective action;
- Information respecting research and development undertaken by the licensed person, including information such as the purpose and description of the research and development activity, the type and amount of cannabis used, and the product or compound made as a result of the activity;
- Information respecting the system or controls established to enable the recall of cannabis, as well as information about recalls;
- Information respecting adverse reactions to any cannabis product that the licensed person becomes aware of, the maintenance of an annual summary report, as well as the reporting of serious adverse reactions to Health Canada within 15 days;
- Records related to physical and personnel security, including, for example, records of employees accessing areas where cannabis is present;
- Notices and communications sent to local authorities;
- Copies of import and export declarations and permits; and
- Information respecting promotional activities.

It is proposed that the regulations would provide the Minister of Health with the authority to specify the regular reporting of any of these records, including the form, manner and frequency of such reports. For example, this would include reporting by persons authorized to sell cannabis on voluntary recalls of cannabis products, including information such as:

- Details about the products being recalled (for example, name of product, lot or batch number, quantity produced and sold, list of licence holders to whom the product was sold, etc.);
- The reason for the recall;
- A risk evaluation identifying the level of risk to public health posed by the issue that led to the recall;

- Description of any action taken in respect of the recall and copies of communication with respect to the recall; and
- Outline of proposed actions to prevent a re-occurrence of the issue that led to the recall.

With respect to recalls, it is proposed that the regulations would require authorized sellers to report at three junctures: 1) within 24 hours of the decision to initiate a recall; 2) within 72 hours of initiating the recall; and 3) within 30 days after completion of the recall.

For sales licences, it is proposed that the regulations specify additional record keeping and reporting requirements.

For licences for sales for medical purposes, it is proposed that licensees would be subject to requirements consistent with current requirements set out under the ACMPR, including details on:

- Medical client registration information;
- Filling of orders and refusal to fill orders;
- Medical documents provided by clients; and
- Communications with provincial or territorial health care licensing authorities.

For licences for sale for non-medical purposes, it is proposed that licensees would be subject to the following additional record keeping and reporting requirements:

- Copies of standard operating procedures related to age verification and records demonstrating that the age of each purchaser has been verified as meeting the minimum age requirement in the province or territory to which the cannabis was shipped); and
- Copies of standard operating procedures related to geo-fencing (i.e., preventing sale to adult consumers in provinces and territories that have established their own systems) and records demonstrating compliance with a restriction to fill orders and make shipments to consumers in those provinces and territories.

Consistent with the current requirements under the IHR, industrial hemp licence holders would be required to keep records, samples or other documents proving that the seeds used are of pedigreed status, among other record keeping requirements.

Table 2: Summary of Licence Requirements by Activity

REQUIREMENTS	CULTIVATION				PROCESSING		SALE (medical and non-medical purposes)	
	Standard	Micro	Nursery	Hemp	Standard	Micro	Cannabis on-site	No cannabis on-site (for example, a call centre)
LOCATION								
Indoor	•	•	•	•	•	•	•	•
Outdoor	•	•	•	•				
PHYSICAL SECURITY								
Perimeter of the site								
Physical barriers (for example, walls or fences) to prevent unauthorized access	•	•	•		•	•	•	
Visual monitoring of the entire perimeter at all times	•				•		•	
Keep visual recordings for 1 year	•				•		•	
Alarm or other intrusion detection system	•				•		•	
Indoor areas on-site where cannabis is present, excluding growing areas								
Physical barriers (for example, walls, doors, locks) to prevent unauthorized access	•	•	•		•	•	•	
Alarm or other intrusion detection system	•				•		•	
Areas must be visually monitored at all times by visual recording devices	•				•		•	
Keep visual recordings for 1 year	•				•		•	
Access restricted to employees whose presence in those areas is required by their work responsibilities	•	•	•		•	•	•	
Additional requirement for areas where cannabis product (for example, dried, oil) is stored								
Identity of every person entering or exiting must be recorded	•				•		•	

REQUIREMENTS	CULTIVATION				PROCESSING		SALE (medical and non-medical purposes)	
	Standard	Micro	Nursery	Hemp	Standard	Micro	Cannabis on-site	No cannabis on-site (for example, a call centre)
PERSONNEL SECURITY CLEARANCE								
Specified employees must hold a valid security clearance issued by the Minister	•	•	•		•	•	•	•
GOOD PRODUCTION PRACTICES								
Clean equipment	•	•	•	•	•	•		
Sanitation of indoor areas	•	•	•		•	•		
Analytical Testing (microbial, contamination, heavy metals, unauthorized pesticides, THC, CBD) (limited requirements for hemp)*				•	•	•		
Quality Assurance Person					•	•		
REPORTING AND RECORD KEEPING								
Maintain records and report information that, for example, demonstrates compliance with good production practices, describes research and development activities, protocols for product recalls and adverse effects. The exact requirements vary per activity.	•	•	•	•	•	•	•	•
CANNABIS TRACKING SYSTEM								
Report information with respect to tracking cannabis, such as production levels, inventory amounts, and sales volume.	•	•	•	•	•	•	•	•

* Note: All cannabis will be tested prior to processing, packaging, and sale.

2.4 Permit and Authorization Requirements

2.4.1 IMPORT AND EXPORT PERMITS

Under the proposed Cannabis Act, the Minister of Health has the authority to issue import and export permits for medical or scientific purposes, or in respect of industrial hemp.

With respect to the import and export of cannabis for medical or scientific purposes, it is proposed that the regulations set out similar requirements to those found in the ACMPR and the *Narcotic Control Regulations*. This will enable persons licensed or permitted to conduct activities with cannabis to receive or send cannabis across international boundaries. Permits would be issued on a case-by-case basis and the validity period of a permit would be for a maximum of six months.

With respect to the import and export of industrial hemp, it is proposed that the regulations set out the same requirements as currently in place under the IHR, with the following modifications:

- Reference to the *List of Countries Approved for the Importation of Viable Grain* would be removed. Instead, importers would be required to provide the Minister of Health with documentation issued by a competent authority that establishes that the seed is of an approved cultivar or that grain is industrial hemp. This change would allow importers to import hemp seed or grain from a greater number of countries; and
- The validity period for import and export permits would be increased from a maximum of three months to a maximum of six months.

2.4.2 RESEARCH AUTHORIZATIONS

More research and development into cannabis will be critical in ensuring that public health and safety aspects are better understood and addressed. As well, the new cannabis industry will need to have the ability to develop and test new strains of cannabis, new product forms and new production methods to ensure they can compete with the illegal market. Finally, in its report, the Task Force emphasized the need for more research aimed at understanding, validating and approving cannabis-based medicines, and on the possible health benefits and harms of cannabis use.

Consistent with the overall principles of establishing regulatory requirements based on risk, it is proposed that the regulations establish a streamlined framework applying to activities with cannabis for the purpose of research, with security requirements based on the type of research being undertaken.

It is proposed that any person in Canada would be eligible to apply for an authorization to conduct research. This would include academic researchers, licence holders and industry. Based on the details of the research being undertaken, a research authorization could authorize any activity in relation to cannabis (including its possession, cultivation, processing, storage, administration, transportation, etc.), with the exception of its sale. However, there would be provisions to enable the commercialization of novel research and development (for example, the sale of new plant genetics).

Physical security requirements would be tailored to the level of risk of diversion associated with the specific research being conducted, consistent with requirements for the various classes of licences set out in part 2.3 of this consultation paper. For research involving the cultivation of cannabis, researchers would be subject to the same physical security requirements as with a cultivation licence (standard, micro or nursery), depending on the number of mature plants used in the research. For research activities involving the processing or manufacturing of cannabis products (for example, dried cannabis or cannabis oil), the physical security requirements applicable to an analytical testing licence would be required.

As well, it is proposed that the regulations provide the Minister with the authority to require individuals involved in the research to hold a valid security clearance, depending on the type of research being undertaken and the quantity and form of cannabis involved.

In addition, holders of research authorizations would be required to adhere to any reporting requirements specified by the Minister in issuing an authorization (consistent with the requirements respecting the record keeping and reporting of research and development activities undertaken by licensed organizations described in section 2.3.7 of this consultation paper). These requirements may include reporting into the Cannabis Tracking System discussed in section 4 of this consultation paper if the research activities involve high volumes of cannabis. As well, authorization holders would generally be required to destroy all cannabis once the research activities are complete and/or upon the expiration or revocation of their authorization.

2.5 Applications for Licences and Permits

2.5.1 APPLICATION REQUIREMENTS

The proposed Cannabis Act provides the Minister of Health with the authority to specify how applications must be submitted and what information must be provided in an application (including, financial information). It is proposed that the Minister would specify these requirements in an administrative document (such as an application guide, published on Health Canada's website).

2.5.2 GROUNDS FOR REFUSAL, SUSPENSION AND REVOCATION

The proposed Cannabis Act sets out the grounds upon which the Minister of Health may refuse to issue a licence or permit. These include, for example, that the applicant is under the age of 18, is not ordinarily resident in Canada, or that a security clearance in respect of the application has been refused or cancelled. In addition, the proposed Act specifies grounds under which the Minister may suspend or revoke a licence or permit.

The Governor in Council has the authority to specify additional grounds for refusal or revocation in regulations. It is proposed that the regulations add that the Minister may refuse to issue a licence, or revoke a licence, in the event that the applicant or licence holder fails to obtain or maintain other required federal licences or authorizations.

3 SECURITY CLEARANCES

It is proposed that select personnel associated with certain licences issued under the proposed Cannabis Act hold a valid security clearance issued by the Minister of Health. The regulations would enable the Minister to refuse to grant security clearances to individuals with associations to organized crime; or with past convictions for, or an association with, drug trafficking, corruption or violent offences. This is the approach in place today under existing regulations governing the licensed production of cannabis for medical purposes, which were designed to protect the integrity of the legal production system.

Health Canada acknowledges that there are individuals who have histories of non-violent, lower-risk criminal activity (for example, 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 on whether these individuals should be permitted to participate in the legal cannabis industry.

3.1 Context

As discussed in section 2.3.5 of this consultation paper, it is proposed that select personnel associated with certain licences issued under the proposed Cannabis Act hold a valid security clearance issued by the Minister of Health. The main purpose of these requirements is to mitigate against the risks that individuals associated with organized crime could infiltrate licensed organizations and use their position to conduct illegal activities with cannabis to the benefit of criminal organizations.

This section of the consultation paper sets out the proposed approach that the Minister of Health would follow for the issuance of security clearances under the Cannabis Act regulations.

3.2 Decision to Grant a Security Clearance

It is proposed that the regulations provide that the Minister of Health may issue security clearances to individuals who do not pose an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the proposed Act and its regulations.

The regulations would specifically enable the Minister to refuse to grant clearances to individuals associated with organized crime. The Minister would also have the ability to refuse to grant clearances to individuals with past convictions for, or an association with, drug trafficking (particularly trafficking to young persons); corruption (for example, money laundering or fraud); or violent offences (which may, among other risks, indicate a risk to the safety of Health Canada inspectors).

In making decisions, the Minister would take into account information provided by an applicant for a security clearance, as well as information resulting from a criminal record check and a law enforcement record check (for example, charges and/or convictions, circumstances related to same, frequency, date of last charge or conviction, any known affiliations or associations with organized crime, etc.). Each application for a security clearance would be assessed on its own merits.

Taken together, this proposed approach is consistent with the approach currently in place for the licensed production of cannabis for medical purposes under the ACMPR, which is designed to protect the integrity of the legal production system.

Health Canada acknowledges that there are individuals who have histories of non-violent, lower-risk criminal activity (for example, simple possession of cannabis, or small-scale cultivation of cannabis plants) who will 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 on whether these individuals should be permitted to participate in the legal cannabis industry.

3.3 Criminal Record and Law Enforcement Record Checks

It is proposed that the regulations would require the Minister of Health to conduct the following checks prior to making a determination whether to issue or refuse a security clearance:

- A criminal record check; and
- A check of the relevant files of law enforcement agencies, including intelligence gathered for law enforcement purposes.

As well, it is proposed that the regulations authorize the Minister to conduct these checks at any point after a security clearance has been issued (during the period in which it is valid) for the purpose of determining whether or not to suspend or cancel the clearance.

3.4 Validity Period

When granting a security clearance, it is proposed that the regulations would authorize the Minister to set a validity period and expiration date for the clearance. This would be based on the level of risk posed by the applicant, taking into consideration the information described in section 3.2. In all cases, it is proposed that the regulations would require that the expiry date be no more than five years after the day on which the clearance was granted. If a security clearance is initially granted for less than five years, it is proposed that the Minister would have the ability to extend the validity period of the clearance to a total of five years.

3.5 Portability of Security Clearances

Currently under the ACMPR, a licensee must notify the Minister if an individual holder of a security clearance no longer requires the clearance as part of his or her duties and responsibilities within the organization (for example, the individual leaves the organization to accept employment with another licensee). In these circumstances, the security clearance in respect of the individual would be cancelled.

The current requirement to cancel the security clearance is regarded as creating a barrier to the movement of employees within the industry and creates unnecessary administrative burden associated with the re-clearance of these individuals. As a result, it is proposed that the regulations would provide for individuals to maintain a valid security clearance when transferring employment between licensees. Licence holders would still be required to notify the Minister when there is a change in the individual occupying any key position that requires a valid security clearance (see section 2.3.5 of this consultation paper).

3.6 Refusal to Grant a Security Clearance

It is proposed that, in the event that the Minister decides to refuse an application for a security clearance, the regulations require the Minister to notify the applicant in writing. The notice would set out the basis for the Minister's decision, and the applicant would be provided with a reasonable period of time to make written representations in response to the refusal notice.

3.7 Suspension or Cancellation of a Security Clearance

It is proposed that the regulations would provide the Minister with the authority to suspend a security clearance upon receipt of information that the individual may represent an unacceptable risk to the integrity of the system, including information related to charges under federal statues such as the *Criminal Code,* as will be described further in section 3.8. In such an instance, the Minister would be required to provide notice to the holder of the security clearance, including the basis for the suspension, and provide the holder of the security clearance with a reasonable period of time to make written representations before making a decision to reinstate the security clearance or cancel it.

It is proposed that the regulations would provide the Minister with the authority to cancel a security clearance at any point where the Minister is of the opinion that the holder of the clearance poses an unacceptable risk to the integrity of the control of the production and distribution of cannabis under the proposed Act and its regulations, including the risk of cannabis being diverted to an illegal market or activity. In such a circumstance, the Minister would be required to notify the holder of the security clearance and inform the holder of the security clearance of the basis of the cancellation. The regulations would require that the Minister provide the clearance holder with a reasonable period of time to make written representations in response to the notice before the cancellation of the security clearance.

In the event that a security clearance is suspended or cancelled affecting a key position, or that the incumbent of a key position leaves the organization, it is proposed that the regulations would provide a reasonable period of time for an alternate individual to be identified and granted a security clearance.

3.8 Application for Security Clearance

It is proposed that the regulations limit those individuals who are eligible to apply for a security clearance to only those individuals who are required to hold a security clearance as described in section 2.3.5 of this consultation paper:

- Individuals occupying a "key position" in the organization.
- Directors and officers; any shareholders that own more than 25% of the organization (if it is privately held) or more than 25% of a privately held parent company; and individuals in a position to legally bind the licence applicant or holder.
- Individuals identified by the Minister of Health as requiring a security clearance based on the nature of their position and the level of risk associated with same.

The regulations would provide that an individual would not be eligible to apply for a security clearance if, in the preceding five years, the individual had been refused a security clearance or had their security clearance cancelled. It is also proposed that the holder of a valid security clearance be required to notify the Minister of Health if they are charged with any offence under the *Criminal Code*, the proposed Cannabis Act, the CDSA or the *Food and Drugs Act*. Based on this new information, the Minister of Health could suspend the security clearance (as set out in section 3.7). It is proposed that the Minister would specify the information that an individual would be required to submit in an application for a security clearance in an administrative document (such as an application guide, published on Health Canada's website). In general, it is proposed that the information required be consistent with the current requirements set out in the ACMPR. In addition, it is proposed an applicant would be required to provide information about any previous criminal charges, including those that did not result in a conviction.

4 CANNABIS TRACKING SYSTEM

The proposed Cannabis Act authorizes the Minister to establish and maintain a national Cannabis Tracking System. The purpose of this system would be to track cannabis throughout the supply chain to help prevent diversion of cannabis into, and out of, the legal market. A ministerial order would set out who would be required to report into the system, as well as the information that would need to be reported. It is proposed that any person authorized to conduct activities with cannabis (whether federally or at the provincial or territorial level) would be required to report into the Cannabis Tracking System.

4.1 Context

Part 6 of the proposed Cannabis Act authorizes the Minister of Health to establish and maintain a national Cannabis Tracking System (CTS) to enable the tracking of cannabis throughout the supply chain. Combined with the physical and personnel security requirements for licensees set out in section 2.3 of this consultation paper, the CTS would help prevent cannabis in the legal supply chain from being diverted to an illegal market or activity, as well as help to prevent illegal cannabis from being a source of supply in the legal market.

In order to establish and maintain the CTS, the proposed Act would provide the Minister of Health with the authority to make a ministerial order that would require certain persons named in the order to report specific information about their authorized activities with cannabis, in the form and manner specified by the Minister. In this context, the ministerial order would be similar to a regulation made by the Governor in Council, in that it would establish legal obligations that would need to be respected. The Minister of Health could not require the reporting of any personal information about consumers who purchase cannabis at the retail level.

The CTS would enable a single reporting platform to track the movement of cannabis throughout the supply chain that could be used by various government authorities to verify compliance or prevent non-compliance with other federal, provincial, or territorial laws respecting cannabis.

4.2 Persons Required to Report

It is proposed that the ministerial order would require any class of person authorized to conduct activities with cannabis, either through the proposed Cannabis Act or through provincial or territorial legislation, to report the information described in section 4.3 into the CTS.

4.3 Required Information

It is proposed that the ministerial order would require the reporting of all transactions involving all cannabis (with the exception of industrial hemp as defined in section 2.2.4 of this consultation paper). More specifically, this would include details (such as amounts by lot/batch) on:

- Cannabis sown, propagated and harvested;
- Cannabis obtained, returned, ordered, delivered, sent, and sold;
- Cannabis destroyed;
- Cannabis used at each stage of production (such as when it is transformed from one product class or form into another, or when it is chemically synthesized);
- Cannabis used in research and development; and
- Loss and theft.

Monthly tracking has been in place for current licensed producers since October 2013. This reporting mechanism provides Health Canada with data regarding cultivation and production, volumes of inventories and sales, number of shipments, and amount destroyed. This monthly tracking process represents the basis for what the ministerial order may require in terms of reporting. Health Canada will explore how the current monthly reporting requirements can be expanded to capture data at various points in the overall supply chain.

For industrial hemp, it is proposed that licence holders would only need to report transactions involving the transfer of leaves, flowers and branches to another licence holder (and they would not need to report the destruction of this material in the CTS should they choose not to sell it).

4.4 Frequency of Reporting

It is proposed that the CTS would be a data collection tool that would show, across the supply chain, both inventory and production levels, as well as high-level movements of cannabis (for example, from cultivator to processor, from processor to a provincial distributor, or from within the province or territory to retailer, etc.). The CTS would expand on the current reporting process used by licensed producers of cannabis for medical purposes under the ACMPR. Information would need to be reported on a monthly basis, with the exception of losses and thefts, which would be required to be reported within 10 days of detection.

4.5 Disclosure of Information

The proposed Cannabis Act would provide the Minister of Health with the authority to share information in the CTS with other government authorities under certain circumstances. These include, for example, disclosing information to a provincial or territorial government for the purpose of enforcing a provincial or territorial law authorizing the wholesale distribution or retail sale of cannabis.

The proposed Cannabis Act would provide the Governor in Council with the authority to specify additional circumstances under which the Minister of Health may disclose information in the CTS. It is proposed that the regulations specify that the Minister may disclose information to a provincial or territorial government for the purpose of administering cannabis-related public health programs or activities.

4.6 Submission of Information

The reporting process would include an online portal that would be accessible to federally-, provincially-, and territorially-regulated parties and would allow these parties to report their data online. The data would then be captured in a case management system, where Health Canada could verify, and analyze, as required, the data received.

5 CANNABIS PRODUCTS

It is proposed that the regulations would establish rules and standards for the production of cannabis products, and would seek 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 youth; and
- Reduce the risk of accidental consumption of cannabis by young persons.

The initial regulations would permit the sale to the public of: dried cannabis, cannabis oil, fresh cannabis, cannabis plants, and cannabis seeds. The sale of edibles and concentrates to the public would be enabled within one year following the coming into force of the proposed Act.

5.1 Context

Schedule 4 of the proposed Cannabis Act sets out the classes of cannabis that may be sold to the public. The sale of any class of cannabis not included in Schedule 4 would be prohibited. The proposed Act would provide the Governor in Council with the authority to develop regulations respecting the characteristics, composition, strength, concentration, potency, intended use, sensory attributes such as appearance and shape, purity, quality or any other property of any class of cannabis.

With a view to reducing their appeal to youth, the proposed Act would prohibit the sale of cannabis that has an appearance, shape or other sensory attribute for which there are reasonable grounds to believe could be appealing to youth.

The Government recognizes that cannabis products of all types are currently available in Canada through the illegal market. Cannabis products supplied through these means are unregulated and untested and may therefore pose a health risk if consumed, with no measures for recalls or product tracking. Part of the Government's strategy to displace the illegal market is to enable a legal industry that offers consumers a range of legal cannabis products that meet strict regulatory standards.

5.2 Classes of Cannabis under the proposed Cannabis Act

The proposed Cannabis Act would permit the sale of the following five classes of cannabis at the outset: dried cannabis, cannabis oil, fresh cannabis, cannabis plants, and cannabis seeds.

The proposed Act would provide the Minister with the ability to develop regulations to amend Schedule 4 to add other classes of cannabis. Edibles and concentrates would automatically be added to Schedule 4 one year following the coming into force of the Act, which would provide time for the Government to develop and consult on appropriate regulatory controls.

5.2.1 DRIED CANNABIS

The proposed Cannabis Act defines dried cannabis as "any part of a cannabis plant that has been subjected to a drying process, other than seeds." This is consistent with the definition of dried cannabis under the current *Access to Cannabis for Medical Purposes Regulations*.

5.2.2 CANNABIS OIL

It is proposed that cannabis oil would be defined as an oil-based solution that contains cannabis, and that is in liquid form at room temperature (22 +/-2 degrees Celsius), and does not contain more than 30 milligrams of THC per millilitre of oil.

5.2.3 CANNABIS PLANT SEEDS

It is proposed that cannabis seeds would be defined as a viable seed from a cannabis plant.

5.2.4 CANNABIS PLANTS

The proposed Cannabis Act *defines cannabis plants as* "a plant belonging to the genus Cannabis."

5.2.5 FRESH CANNABIS

It is proposed that fresh cannabis would be defined as freshly harvested parts of the cannabis plant that have not been subjected to a drying process, excluding seeds or other plant material that can be used to propagate cannabis. It is proposed that fresh cannabis must have a total water content of 50% or more, by weight.

5.2.6 EDIBLES CONTAINING CANNABIS

This class would include edible products, such as foods or beverages, that contain cannabis. A precise definition would be set out in a subsequent regulatory proposal.

5.2.7 CANNABIS CONCENTRATES

This class would include products such as hashish, wax, shatter and vaping solutions. A precise definition would be set out in a subsequent regulatory proposal.

5.3 Product Forms

Under the ACMPR, only cannabis oil is permitted to be sold in certain dosage forms (for example, capsules); dosage forms for dried and fresh cannabis are not permitted. Under the new regulatory framework, it is proposed that a range of product forms be enabled for dried and fresh cannabis, to help the legal industry displace the illegal market. Additional product forms could include, for example, pre-rolled cannabis and vaporization cartridges manufactured with dried cannabis. Product forms for cannabis oil, such as cannabis oil capsules, oral sprays, and cannabis oil intended for topical application, would continue to be permitted.

It is proposed that regulatory requirements respecting the maximum THC content per unit be based on how the product is represented to be consumed.

For dried cannabis products intended for inhalation, whether by smoking or by vaporization, single use product forms (such as pre-rolled cannabis) would not be able to contain more than one gram of dried cannabis.

Based on experience in U.S. jurisdictions that have legalized cannabis, as well as experience under the ACMPR regulating cannabis oil, it is proposed that for cannabis products intended for ingestion (including those comprised of dried cannabis, fresh cannabis or cannabis oil), a single unit would not contain more than 10 milligrams of THC. For example, no more than 10 milligrams of THC per capsule or no more than 10 milligrams of THC delivered per dose of a metered product, such as a spray, would be permitted.

As mentioned above, cannabis oil would be subject to a 30 milligrams per millilitre limit on THC concentration. Cannabis oil products intended for topical application would be subject to the same THC concentration limit and the label would need to clearly indicate that the product was not intended to be ingested.

5.4 Ingredients and Composition of Cannabis Products

The proposed Cannabis Act would prohibit the sale of any mixture of substances that contain cannabis and any prohibited substance listed in Schedule 5 of the Act. Currently, the prohibited substances listed in Schedule 5 are nicotine, caffeine and ethyl alcohol. The Minister of Health would have, by order, the authority to amend Schedule 5 (for example, to specify additional prohibited substances or to provide exemptions to permit the use of these substances in certain classes of cannabis). It is not proposed that Schedule 5 of the Act be amended at this time.

In addition to Schedule 5 of the Act, the Governor in Council would have the authority to make regulations respecting the composition of cannabis or any class of cannabis. It is proposed that processors would not be permitted to manufacture products containing more than one class of cannabis in a single product. For fresh and dried cannabis, it is proposed that additives would be prohibited, meaning that additional ingredients such as fillers, flavourings or colourants could not be added to a product in either of these two classes.

For cannabis oil, it is proposed that no additives aside from the carrier oil and those that are necessary to preserve quality or stability of the product would be permitted, meaning that no flavouring agents would be permitted (other than those naturally-occurring in the carrier oil). All additives used would be required to be suitable for their intended use (for example, suitable for ingestion or topical use), and would need to conform to the appropriate grade, such as pharmaceutical or food grade. If a cannabis oil product is intended for topical use, it could not contain known skin irritants or sensitizers. Additionally, no substance in the oil aside from cannabis could act to inhibit or enhance the effects of the natural cannabinoids.

6 PACKAGING AND LABELLING

It is proposed that the regulations would set out requirements pertaining to the packaging and labelling of cannabis products. The proposed packaging and labelling requirements would promote informed consumer choice and allow for the safe handling and transportation of cannabis. All cannabis products would need to be packaged in a manner that is tamper-evident and child-resistant.

Health Canada is proposing strict limits on the use of colours, graphics, and other special characteristics of packaging to curtail the appeal of products to youth. To ensure that consumers make informed decisions and to avoid misuse, products would be required to be labelled with specific information about the product, contain mandatory health warnings similar to tobacco products, and be marked with a clearly recognizable standardized cannabis symbol.

6.1 Context

Part 1 of the proposed Cannabis Act includes general prohibitions on the promotion, packaging and labelling, and the display of cannabis and cannabis accessories. The proposed Cannabis Act prohibits the sale of cannabis and cannabis accessories that, among other things, are packaged and labelled in a manner that is appealing to youth or includes elements intended to encourage consumption, such as lifestyle branding elements or testimonials.

The proposed Act would provide the Governor in Council with the authority to make regulations respecting the packaging and labelling of cannabis and cannabis accessories, including the information that must appear on packages and labels.

It is proposed that the regulations set out comprehensive packaging and labelling requirements that licensed processors would need to follow for classes of cannabis that are authorized for sale (dried cannabis, fresh cannabis, cannabis oil, plants and seeds). These requirements would not apply to industrial hemp, which would be subject to packaging and labelling requirements similar to those in place under the *Industrial Hemp Regulations*. Additional packaging and labelling requirements for products also regulated under the *Food and Drugs Act* are described in section 8 of this consultation paper.

6.2 Packaging

All cannabis products would need to be packaged in a manner that is tamper-evident, child-resistant, prevents contamination, and keeps cannabis dry, consistent with the requirements in the ACMPR. In addition, it is proposed that the regulations would enable both inner and outer packaging in order to accommodate new product forms, and require packaging to be opaque.

The maximum amount of cannabis in a single package would be 30 grams of dried cannabis, or the equivalent amount for other classes of cannabis, as outlined in Schedule 3 of the proposed Cannabis Act. For example, for cannabis oil, the maximum amount would be 2.1 litres (assuming a specific gravity of one gram per millilitre). These proposed maximum package amounts would be consistent with the amount of cannabis that the adults would be able to possess in public places upon coming into force of the proposed Cannabis Act.

6.3 Labelling

It is proposed that general labelling requirements would be the same for all cannabis products, regardless of whether the cannabis is sold for medical or non-medical purposes. However, additional client-specific information would be required to be affixed to the label of cannabis products intended for medical purposes, consistent with the current requirements set out in the ACMPR. Client-specific labels can be used to demonstrate to law enforcement that an individual is authorized to possess amounts that might be in excess of what is permitted under the proposed Act (for example, 30 grams of dried or equivalent in public).

Licensed processors would be required to label the package in which the cannabis product is contained, and do so in both official languages. It is proposed that the regulations would set out the following general labelling requirements:

- Name and contact information of the processor who packaged the product;
- Product description;
- Product lot number;
- Product weight or volume, depending on the product class;
- Packaging date (and expiry date, if one has been set);
- Recommended storage conditions;
- THC/CBD content (expressed as the percentage of THC/CBD the product could yield, and by unit or dose, if applicable); and
- Inclusion of the statement: “KEEP OUT OF THE REACH OF CHILDREN”.

Further, it is proposed that labels for cannabis oil products would be required, among other things, to list the type of carrier oil used and the name of certain allergens.

Finally, it is proposed that the regulations would require products containing dried cannabis, fresh cannabis or cannabis oil to carry (either as part of the product label, attached to the product container, or attached to an outer package) additional consumer information developed by Health Canada. This information would provide adult consumers with health and safety information, such as precautions and directions for use, and would be updated periodically to take into account new information about risks and effects.

Additional labelling requirements may be required for taxation purposes; these will be subject to a separate consultation on regulations under the authority of the Minister of Finance.

6.4 Health Warning Messages

To enhance public awareness of the health risks of cannabis use, it is proposed that, similar to what is done currently for tobacco products, rotating mandatory health warnings would be required on all product labels. In addition to messages about the health effects of cannabis use, it is proposed that health warning messages be developed for the following:

- Prevention of accidental ingestion;
- Risks associated with different methods of use;
- Risks associated with cannabis use during pregnancy;
- Dangers of impaired driving;
- Risks of combining cannabis with other substances, such as alcohol; and
- Impacts of cannabis use on mental health.

6.5 Standardized Cannabis Symbol

In order to prevent accidental ingestion, it is proposed that products intended for ingestion that contain more than 10 parts per million (10 ppm) THC (equivalent to 0.001% THC) be labelled with a clearly recognizable standardized cannabis symbol.

6.6 Appearance of Packaging

Use of colour, graphics, and font size on the product (package and label) would be strictly regulated in order to ensure that the key information, such as the standardized cannabis symbol and the health warning messages, would be the most prominently displayed elements. Potential measures may include:

- Limiting the use of colours on packaging;
- Standard font type, size, and colour for brand elements relative to other information displayed on the package; and/or
- Restrictions on the use of brand elements, including relative size, colour, and place on the package.

Further to this, text and graphics used in brand elements could not be appealing to youth and would be subject to the packaging and labelling restrictions in the proposed Cannabis Act. Health Canada is also considering establishing standards (such as limiting use of colour and size) of these brand elements.

7 CANNABIS FOR MEDICAL PURPOSES

Consistent with the advice of the Task Force on Cannabis Legalization and Regulation, a distinct system will be maintained to provide patients with reasonable access to cannabis for medical purposes. The proposed regulations would continue to enable individuals who have the support of their healthcare 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, if over the age of 18 (personal production); or
- Designating someone to grow cannabis on their behalf (designated production).

The proposed medical access regulatory 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.

7.1 Context

Consistent with the advice of the Task Force on Cannabis Legalization and Regulation, the Government of Canada has indicated that it intends to maintain a distinct framework under the proposed Cannabis Act to provide access to cannabis for medical purposes. The Task Force also recommended that the Government monitor and evaluate patients' reasonable access to cannabis for medical purposes during the implementation of the proposed Cannabis Act, and then evaluate the medical access framework within five years of implementation of the law, which the Government intends to do.

In developing the supporting regulations setting out the framework for providing access to cannabis for medical purposes under the proposed Cannabis Act, the government's objective is to ensure that rules surrounding patient access remain largely unchanged from the current framework. In particular, it is proposed that the following key features of the proposed framework would remain the same as the current system:

- Individuals with a medical need, and who have the support of their health care practitioner, would continue to be able to access cannabis for medical purposes in three ways:
  i. by registering with a federally-licensed seller of cannabis for medical purposes to purchase quality-controlled cannabis and to have it delivered by means of secure shipping;

ii. by registering with the Minister of Health to produce a limited amount for their own medical purposes; or

iii. by registering with the Minister of Health and designating someone to produce it on their behalf.

- There would continue to be no age restrictions. As is currently the case, individuals under the age of 18 could register to access cannabis for medical purposes, provided they have the support of their health care practitioner; however, they could not register to produce cannabis themselves.
- The possession limit, in a public place, for medical purposes would remain the lesser of either a 30-day supply (as authorized by a health care practitioner) or 150 grams of dried cannabis (or the equivalent amount of cannabis in another class, as outlined in Schedule 3 of the proposed Cannabis Act).

While it is proposed that these key features of the medical access framework would remain in place, certain improvements are being proposed for the new regulations with the goal of facilitating patient access to cannabis for medical purposes. These improvements are described further below.

7.2 Accessing Cannabis for Medical Purposes

It is proposed that the way in which individuals access cannabis for medical purposes would remain largely unchanged. In order to purchase or cultivate cannabis for medical purposes, individuals would need to have the support of an authorized health care practitioner, who would provide the patient with a medical document supporting access.

As is currently the case under the ACMPR, authorized health care practitioners would include physicians in all provinces and territories, as well as nurse practitioners in provinces and territories where supporting access to cannabis for medical purposes is included under their scope of practice or in legislation.

The medical document would continue to signify the health care practitioner's support for access to cannabis for medical purposes. As is currently the case, the medical document would indicate, among other things, the daily quantity of cannabis supported by the health care practitioner (in grams of dried cannabis). This medical document would continue to be required for an individual to register with a federally-licensed seller of cannabis for medical purposes or with Health Canada. The period of use—up to one year—would need to be indicated by the authorized health care practitioner.

7.2.1 PROPOSED CHANGES: IMPROVING PATIENT ACCESS

To facilitate patient access, it is proposed that individuals could request the return of their medical document from a federally-licensed seller or the transfer of a valid medical document to a different federally-licensed seller of cannabis for medical purposes. Should a federally-licensed seller of cannabis for medical purposes cancel a registration (if, for example, the desired strain of cannabis were no longer available), then the licensed seller must either return the medical document to the client or transfer the medical document to another licensed seller of cannabis for medical purposes of the patient's choosing. Also, in the event of mergers and acquisitions between licensed sellers of cannabis for medical purposes, the transfer of medical documents between licensed sellers would be possible, provided that clients provide their consent.

In addition, it is proposed that the period of use of a registration—whether the registration is with a federally-licensed seller of cannabis for medical purposes or with Health Canada—would begin on the date of initial registration, and not on the date that the medical document was signed by the health care practitioner, as is currently the case.

Given that it would be possible to return and transfer the medical document, it is proposed that federally-licensed sellers of cannabis for medical purposes would be required to date stamp the medical document when it is first used for registration so that the beginning of the period of use could be established.

It is also proposed that the regulations would remove the 30-day limitation period for the purchase for cannabis from a federally-licensed seller of cannabis for medical purposes—whereby a licensed seller cannot fill multiple orders within a 30-day period that would result in more than a 30-day supply of cannabis being provided to a client—be removed.

7.3 Health Care Practitioners

It is proposed that health care practitioners would continue to support the use of cannabis for medical purposes by completing a medical document. The medical document would contain similar information to that of a prescription. Specifically, the authorized health care practitioner would have to indicate his or her licence information, the name and date of birth of the patient, a period of use of up to one year, and a daily quantity expressed in grams of dried cannabis.

A health care practitioner could continue to transfer cannabis to a person under his or her professional care or to an individual who is responsible for that person. The proposed framework would maintain provisions related to the administration of cannabis in hospital settings.

7.3.1 PROPOSED CHANGES: HEALTH CARE PRACTITIONERS

Currently, the *Narcotic Control Regulations* (NCR) under the CDSA require Health Canada to issue notices related to certain health care practitioners who have contravened a rule of conduct or been found guilty of a designated drug offence under the NCR or the ACMPR. These notices advise licensed producers and pharmacists not to fill orders for cannabis on the basis of a medical document provided by the practitioner. It is proposed that similar provisions would be included within the new regulatory framework under the proposed Cannabis Act.

7.4 Personal and Designated Production

As is currently the case under the ACMPR, individuals who register with the Minister of Health to produce a limited amount of cannabis for their own medical purposes, or who designate someone to produce on their behalf, would continue to receive a registration certificate upon successful registration. If applicable, a document containing information relating to the production would be sent to the designated person. The registration certificate would provide the individual with the necessary information to understand the activities they have been authorized to conduct.

Currently, an individual can produce under a maximum of two registrations, and a maximum of four registrations per production site is permitted. It is proposed that these limits would continue.

It is proposed that registrations could be cancelled by the Minister of Health for reasons such as:

- ineligibility of the registered person or designated producer;
- the registration was issued on the basis of false or misleading information;
- the registration is to produce at a site where there is already production under four registrations;
- the health care practitioner no longer supports the individual's use of dried cannabis for clinical reasons; or
- the registered person dies or ceases to be ordinarily resident in Canada.

These proposed grounds for cancellation are consistent with those under the ACMPR. The Minister of Health would continue to give the registered person written notice of the reasons for the proposed cancellation and an opportunity for the registered person to be heard.

7.4.1 PROPOSED CHANGES: PERSONAL AND DESIGNATED PRODUCTION

Currently, the ACMPR provide that the Minister must register an individual to produce cannabis for their own medical needs, or to designate someone to produce it for them, if they meet the requirements under the regulations. The ACMPR outline a limited number of reasons why an application for a registration may be refused:

- ineligibility of the applicant or designated person (not an adult, not ordinarily resident of Canada, having been convicted of certain types of criminal offences, etc.);
- that the individual who signed the medical document is not authorized (for example, is not a healthcare practitioner);
- that the applicant information on the medical document does not match the information on the application;
- the health care practitioner no longer supports the use of cannabis for clinical reasons; or
- any information submitted in the application is false or misleading.

The refusal provisions of the ACMPR do not include any discretionary grounds for refusal based on risks to public health or safety.

It is proposed that a provision be added to the regulations that would provide the Minister the ability to refuse the issuance, renewal or amendment of the registration if the issuance, renewal or amendment would likely create a risk to public health or public safety, including the risk of cannabis being diverted to an illegal market or use.

7.5 Production Limits and Storage Requirements

It is proposed that the regulations would continue to use established formulas for converting the daily quantity of dried cannabis indicated in the medical document into a maximum number of plants that may be in production under the registration. A registered person would continue to be able to access starting materials (i.e., seeds or plants) and/or interim supply from a licensed retailer of cannabis for medical purposes.

7.5.1 PROPOSED CHANGE: STORAGE OF CANNABIS BY PERSONAL AND DESIGNATED PRODUCERS

It is proposed that personal and designated producers would continue to be required to attest to securely storing cannabis, but there would no longer be limits on where and how much cannabis could be stored, as no such limits are outlined in the proposed Cannabis Act pertaining to the possession of cannabis (other than the limit of possessing no more than 30 grams of dried cannabis or its equivalent in public).

7.6 Sharing of Information with Law Enforcement, Licensing Authorities, and Licensed Sellers

It is proposed that the Minister of Health would continue to be able to share certain information with law enforcement, provincial and territorial health care licensing bodies and federally-licensed sellers of cannabis for medical purposes.

7.6.1 SHARING OF INFORMATION WITH LAW ENFORCEMENT

Consistent with the information sharing provisions currently in place under the ACMPR, under the proposed regulations, the Minister of Health would be able to share limited information with police in the context of an investigation. This would include information, such as whether an individual is a registered or designated person, the address of the production site, the plant limit, and the possession limit. Health Canada currently provides support to law enforcement for this purpose 24 hours per day, 7 days a week.

7.6.2 SHARING OF INFORMATION WITH PROFESSIONAL LICENSING AUTHORITIES

Under the proposed regulations, the Minister of Health would continue to be required to provide provincial and territorial health care licensing authorities with information about a health care practitioner obtained under the Cannabis Act and its regulations, when requested by a licensing authority in specific circumstances (such as to support a professional investigation). The Minister would also continue to have the authority to proactively share certain information with provincial and territorial health care licensing authorities about health care practitioners who provided a medical document in support of a registration.

8 HEALTH PRODUCTS AND COSMETICS WITH CANNABIS

In keeping with the objectives of the proposed Cannabis Act to legalize and strictly regulate cannabis, and the health and safety mandate of the *Food and Drugs Act*, Health Canada is proposing a scientific, evidence-based approach for the oversight of health products with cannabis that are approved with health claims, including prescription and non-prescription drugs, natural health products, veterinary drugs and veterinary health products, and medical devices. Market access would be maintained for previously approved health products with cannabis, including prescription drugs that have been approved for the treatment of serious conditions. The use of cannabis-derived ingredients (other than certain hemp seed derivatives containing no more than 10 parts per million THC) in cosmetics is currently prohibited; moving forward, it is proposed that cosmetics containing cannabis-derived ingredients would be subject to provisions of the proposed Cannabis Act.

8.1 Context: current legislative framework

Under the current legislative framework, the CDSA and the FDA work together to establish strict parameters for the sale of health products and cosmetics containing controlled substances, such as cannabis, which might affect a person's mental processes (for example, create a "high" or other form of impairment).

Currently, cannabis is listed as a controlled substance under the CDSA. It is also subject to the FDA because it meets the definition of a drug, which includes any substance sold to modify organic function in humans or animals, or to treat, mitigate, or prevent health issues.

The FDA aims to protect and promote the health of Canadians by regulating the safety, efficacy and quality of health products that are approved with health claims, such as prescription and non-prescription drug products for human and veterinary use, natural health products (NHPs), veterinary health products (VHPs), and medical devices. These health products can only be sold if they have been approved by Health Canada following a scientific review. The FDA also sets out regulations for cosmetics, but there is no pre-market review or approval of cosmetics in Canada. However, all cosmetics sold in Canada must be safe to use and must meet the requirements of the FDA and the *Cosmetics Regulations*.

8.2 Currently-approved health products with cannabis

Should the proposed Cannabis Act receive Royal Assent, steps would need to be taken to ensure ongoing access to existing health products with cannabis (including prescription health products, NHPs, VHPs, and medical devices) and a pathway to market for new products.

Currently, drugs containing cannabis, authorized under the FDA, are restricted to prescription-only access because cannabis is a controlled substance under the CDSA.

The current cannabis listing under the CDSA (as well as the definition of cannabis under the proposed Cannabis Act) excludes some cannabis parts (i.e., non-viable cannabis seeds, with the exception of its derivatives, and mature cannabis stalks that do not include leaves, flowers, seeds or branches, and fibre derived from such stalks). Furthermore, the *Industrial Hemp Regulations* exclude hemp seed derivatives (e.g., hemp seed oil) and products made from those derivatives from the application of the CDSA for certain activities such as their retail sale, provided they meet certain conditions and contain no more than 10 micrograms of THC per gram (equivalent to 10 parts per million, or ppm). These cannabis parts have been included in NHPs and VHPs that make health claims; this has been permitted provided they contain no more than 10 ppm THC and no other controlled substances. The 10 ppm limit is generally recognized as safe because there is very little risk of psychoactivity.

Devices used for the consumption of cannabis for medical purposes can be authorized as medical devices under the FDA, subject to the medical device licensing process.

Within the existing regulatory framework, the following health products with cannabis have been approved:

- **Prescription drugs with cannabis:** Two (2) approved for serious conditions
  - Sativex contains THC and CBD for treating spasticity and neuropathic pain from multiple sclerosis
  - Marinol contains THC for AIDS-related anorexia and nausea and vomiting from chemotherapy (this product was voluntarily withdrawn from the market by its manufacturer)
- **NHPs and VHPs containing parts of the cannabis plant permitted for sale, and no more than 10 ppm THC:**
  - Approximately 220 NHPs are marketed with minor claims, largely related to antioxidants as a source of protein
  - Nine (9) VHPs marketed for cats, dogs, and non-food horses

- **Medical Devices:** Two (2) vaporizers for delivery of cannabis for medical purposes
  - Volcano Medic is a table-top unit with balloon for inhalation
  - Mighty Medic is a handheld device for inhalation

In addition, prescription health products containing the synthetic cannabinoid nabilone (used to treat nausea and vomiting from chemotherapy) have been approved. Nabilone, a synthetic cannabinoid which does not exist in nature, does not meet the definition of cannabis under the proposed Cannabis Act (the proposed definition of cannabis includes synthetic phytocannabinoids, i.e., cannabinoids produced by the cannabis plant, such as THC, but does not include other synthetic cannabinoids). Nabilone will remain available under its current CDSA controls (i.e., by prescription only).

8.3 Health Products under the proposed Cannabis Act

In keeping with the objectives of the proposed Cannabis Act to legalize and strictly regulate cannabis, and the health and safety mandate of the FDA, Health Canada will maintain a scientific, evidence-based approach for health products with cannabis that are approved with health claims. These products will be subject to the requirements of the FDA and applicable regulations, including requirements for safety, efficacy and quality.

To address the uncertainties around the health benefits and potential risks of cannabis related to non-medical use, addiction potential or neurological harm (for example, risks to the developing brain), any manufacturer of health products with cannabis would be required to demonstrate robust safety and efficacy evidence prior to being authorized for sale in Canada. The evidence would need to specifically address these potential risks, in addition to other relevant quality information required as part of the review process. Further detail of Health Canada's evidence expectations will be clarified in policy guidance.

Operating under this strict health and safety framework, Health Canada proposes that a number of provisions of the proposed Cannabis Act would apply to health products with cannabis. Where necessary to allow for health products in the appropriate formats, exemptions to certain provisions are also proposed. Subsections 8.3.1 to 8.3.7 explain the proposed pathways to market for different types of health products, followed by an explanation of how the proposed Cannabis Act would apply to them.

8.4 Prescription Health Products

In Canada, health products are only authorized for sale once they have successfully gone through Health Canada's drug review process. This process is the means by which applications are reviewed by scientists at Health Canada to assess the safety, efficacy and quality of a drug. The drug would be evaluated based, among other things, on its specific use, dose, route of administration, and target population. Without successfully completing this process, health products cannot be sold or make a health claim (for example, for temporary relief of the symptoms of colds). Throughout the review, the safety and well-being of Canadians is the paramount concern.

As part of its review, Health Canada considers the need for the oversight of a healthcare practitioner, including the level of uncertainty respecting the drug and its potential harms or risks to human or animal health. Products with indications requiring practitioner oversight (for example, if a drug has dependence and/or addiction potential), are added to the Prescription Drug List (PDL). Substances included on the PDL are limited to sale by prescription only.

8.4.1 PROPOSAL FOR CURRENTLY-APPROVED PRESCRIPTION HEALTH PRODUCTS WITH CANNABIS

Currently-approved health products (i.e., Sativex and Marinol) are restricted to prescription-only access because they contain cannabis, a controlled substance under the CDSA. As these health products were never considered for listing on the PDL because of their controlled status, Health Canada proposes to review their prescription status. Given their indications for the treatment of health conditions that require practitioner supervision, the Department expects that the dosage, route of administration and conditions of use of THC and CBD included in these health products would be listed on the PDL. This would maintain their current prescription-only access.

8.4.2 PROPOSAL FOR NEW PRESCRIPTION HEALTH PRODUCTS

Any submission for a new drug with cannabis would be examined through the usual review process. If any of the criteria for physician oversight are met, the product would be available by prescription only.

8.4.3 PROPOSED ACCESS AND PROMOTIONAL CONTROLS UNDER THE CANNABIS ACT

For currently-approved prescription health products, and any that may be approved in the future, it is proposed that no additional access restrictions (for example, place of sale) under the proposed Cannabis Act be imposed. This is because access to prescription health products that have been reviewed against robust safety, quality, and efficacy evidence are well controlled under the oversight of a healthcare practitioner.

8.5 Non-Prescription Health Products

It is anticipated that Health Canada will receive submissions for new health products containing cannabis with lower levels of THC and CBD than found in currently-approved prescription health products, and with less serious health claims. Health Canada would review these submissions through its usual drug review process. If the drug were found to be safe and effective for use without the oversight of a healthcare practitioner, it would be available as a non-prescription product. This would represent a new pathway to market for non-prescription health products with cannabis.

8.6 Natural Health Products

NHPs are also subject to Health Canada's requirements for safety, efficacy, and quality. The evidence requirements are based on the risk profile of the product.

8.6.1 PROPOSED FRAMEWORK FOR NHPS WITH CANNABIS

The approximately 220 NHPs with cannabis that are currently authorized for sale will continue to be available to Canadians. These NHPs contain parts of the cannabis plant that fall outside of the legal definition of cannabis in the CDSA (or are exempted from the CDSA by virtue of the *Industrial Hemp Regulations*) and contain no more than 10 ppm THC. It is proposed that new NHPs similar to these would also be permitted under the Cannabis Act and its regulations if authorized by Health Canada.

A new pathway is proposed for NHP submissions containing parts of the cannabis plant subject to the proposed Cannabis Act, such as products derived from cannabis flowers containing cannabinoids such as CBD. To minimize the risk of psychoactivity, the same 10 ppm THC limit would be applied to such products. These submissions would be required to demonstrate robust safety and efficacy evidence under the NHP regulatory framework.

The 10 ppm THC limit applicable to all NHPs with cannabis would be established in the *Natural Health Product Regulations.*

8.7 Medical Devices

Medical devices, as defined in the FDA, cover a wide range of instruments used in the treatment, mitigation, diagnosis, or prevention of health issues. Medical devices cannot be sold in Canada without complying with the safety, effectiveness and quality requirements of the *Medical Devices Regulations.* The two medical devices that are currently authorized for sale for the consumption of cannabis for medical purposes were subject to the medical device licensing process.

8.7.1 PROPOSAL FOR MEDICAL DEVICES USED FOR CONSUMING MEDICAL CANNABIS

Any submission for a new medical device for the consumption of cannabis for medical purposes would be examined through the usual review process. As these devices could potentially be used by youth to consume cannabis for non-medical purposes, it is proposed that further precautions be put in place, in addition to the requirements under the FDA. This could include requiring the support of a healthcare practitioner for sales to young persons.

8.7.2 PROPOSAL FOR COMBINATION PRODUCTS

Medical devices can also be combined with drugs or NHPs for therapeutic purposes (for example, bandages with a drug for pain relief). These combination products would be subject to the same requirements as the drugs or NHPs they contain.

8.7.3 PROPOSAL FOR TEST KITS

Test kits used in laboratories for identifying cannabis in patient samples are regulated as medical devices. Some of these contain small amounts of cannabis for calibration, and their sale is limited to professional laboratories. Unless exempted, any test kit that contains cannabis would be subject to the proposed Cannabis Act. As these devices are not publicly available, they present an insignificant risk of diversion. Therefore, Health Canada proposes to maintain their current availability in professional laboratories. Test kits are also discussed in section 9.1.

8.8 Veterinary Drugs

Similar to drugs for human use, veterinary drugs must undergo Health Canada's drug review process before they can be sold. As part of the review process to ensure they are safe, effective, and of high quality for their intended animal use, applications are reviewed against the factors for requiring health practitioner oversight. Any submission for a new veterinary drug with cannabis would be examined through this review process.

8.9 Veterinary Health Products

Veterinary health products are used to maintain or promote the health and welfare of animals. They are low-risk drugs in dosage form, such as vitamins, minerals, and traditional medicines. Like NHPs for humans, VHPs can contain ingredients such as hemp seed derivatives containing no more than 10 ppm THC, which will be exempt from the proposed Cannabis Act. These products will remain available as they are now, limited to a maximum of 10 ppm THC.

8.10 Application of Cannabis Act provisions and other measures for health products

All health products with cannabis would need to comply with the FDA and its regulations, including requirements for manufacturing, distribution, advertising and sale. In addition, to maintain strict controls around the production of cannabis and its sale to youth, certain provisions of the proposed Cannabis Act would apply to health products with cannabis, including:

- **Processing and research licences:** In addition to the licensing requirements under the FDA, health product manufacturers would have to comply with certain licensing requirements under the proposed Cannabis Act, such as those for security, good production practices, or record keeping and reporting purposes.
- **Promotion, packaging and labelling:** All health products would be subject to the provisions that control against practices that may appeal to youth, or the use of testimonials, real or fictional characters or animals, or lifestyle branding. Tamper-evident and child-resistant packaging requirements would also apply.

Further precautions are also being explored for implementation in partnership with the provinces and territories to meet the proposed Cannabis Act's objective of restricting youth access to cannabis, particularly for those health products with cannabis that would not require the oversight of a healthcare practitioner (i.e., non-prescription drugs and natural health products for humans or animals, and medical devices for consuming cannabis for medical purposes). Specifically, Health Canada proposes to work with the provinces and territories and the National Association of Pharmacy Regulatory Authorities (NAPRA) on options to control the sale and display of these health products to youth. This could be achieved, for example, by controlling them behind the counter at pharmacies, or by utilizing the provincially-regulated distribution system.

8.11 Exemptions from the proposed Cannabis Act for all health products

To allow for health products in the appropriate formats, the following exemptions are proposed for all health products:

- **Limitations on classes and forms of cannabis:** As described in section 5 of this consultation paper, the limitations to classes that could be sold would not apply to health products with cannabis because the precise dosage, route of administration and conditions of use of each of these products would be subject to Health Canada's review of each product.

- **Appeal to youth:** To allow for pediatric formulations that could be purchased by responsible adults for children under their care, an exemption is proposed to the controls around the sale of cannabis or cannabis accessories with traits that appeal to youth.
- **Possession limits:** Given that health products would be regulated under strict conditions of sale, it is proposed that possession limits and package size restrictions under the Cannabis Act would not apply to these products.

8.12 Cosmetics under the proposed Cannabis Act

As mentioned above, cosmetics are regulated under the FDA and the *Cosmetic Regulations* (CR), but are not subject to pre-market review or approval. The FDA states that no person shall sell a cosmetic that may injure the health of the user, when the cosmetic is used according to its customary method (the general prohibition). The Cosmetic Ingredient Hotlist (hereafter the Hotlist) is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition in the FDA, may contravene one or more provisions of the CR, or may otherwise be inappropriate for use in cosmetics.

Cannabis is addressed in three separate entries on the Hotlist: "*Cannabis sativa* seed oil", "Hydrolyzed Hemp seed protein" and "Narcotics, natural and synthetic". Existing restrictions for *Cannabis sativa* seed oil and hydrolyzed hemp seed protein (permitted in cosmetics as long as they contain no more than 10 micrograms per gram of THC, which is equivalent to 10 ppm) would not be affected by the proposed Cannabis Act and would remain.

Cannabis-derived ingredients currently captured under the "narcotics" entry (for example, cannabis oil) would fall within the scope of the proposed Cannabis Act. Such products would be subject to provisions of the proposed Cannabis Act, including those pertaining to licensing, product classes and forms, place of sale, packaging and labelling, promotion, and possession.

Table 3: Summary of the Proposed Application of Cannabis Act Provisions for Health Products with Cannabis

PRODUCT LINES	PROVISIONS OF THE PROPOSED CANNABIS ACT*					
	Classes for sale	**Maximum possession limits**	**Sales and display to young persons**	**Promotional practices** (e.g. those that may appeal to youth, or use testimonials, fictional characters, or lifestyle branding)	**Packaging and labelling practices** (e.g. those that may appeal to youth or use testimonials, fictional characters, or lifestyle branding)	**Processing licence requirements** (e.g. those for security, good production practices, or record keeping)
Natural Health Products**	X	X	C	✓	✓	✓
Non-Prescription Drugs	X	X	C	✓	✓	✓
Non-Prescription Veterinary Drugs	X	X	C	✓	✓	✓
Prescription Drugs	X	X	X	✓	✓	✓
Prescription Veterinary Drugs	X	X	X	✓	✓	✓
Medical Devices for consuming cannabis for medical purposes	N/A	N/A	C	✓	✓	N/A

* Important note: This chart illustrates, in general terms, the application of key sections of the proposed Cannabis Act. It is not intended to be an exhaustive list of all provisions that may or may not apply.

** There are approximately 220 Natural Health Products that have been licensed and 9 Veterinary Health Products that have been approved; these contain no more than 10ppm THC (and no other identified cannabinoids). The ingredients of these products will not be controlled under the proposed Cannabis Act; they will remain available as they are now, subject to existing NHPR and FDR requirements.

Legend

- X Proposed that the Cannabis Act provision would not apply (i.e. health products with cannabis would not be subject to this provision)
- ✓ Proposed that the Cannabis Act provision would apply (i.e. health products with cannabis would be subject to this provision)
- C Proposed to work with the provinces and territories on options to control sales to young persons

9 MISCELLANEOUS ISSUES

9.1 Amendments to the *Narcotic Control Regulations*

The *Narcotic Control Regulations* (NCR) under the CDSA describe the circumstances and requirements in which persons (including businesses), pharmacists, practitioners and hospitals may conduct regulated activities including possession, sale, distribution, importation and exportation, and production, of substances listed in the Schedule to the NCR, including cannabis. Should the proposed Cannabis Act become law, the NCR would be amended to delete relevant references to cannabis, its preparations and derivatives. Associated terms (for example, marihuana), and references to the ACMPR, former *Marihuana for Medical Purposes Regulations*, and former *Marihuana Medical Access Regulations*, would also be deleted as necessary.

Currently, the regulatory framework for cannabis for medical purposes includes provisions under both the ACMPR and the NCR. An example of where the NCR set out requirements pertaining to cannabis that are not covered in the ACMPR is with respect to licensed dealers. Becoming a licensed dealer under the NCR could permit the licensee to conduct certain activities with cannabis. Currently, there are a number of laboratories permitted to conduct analytical testing of cannabis by virtue of the fact that they hold a valid dealer's licence under the NCR. As detailed earlier in this consultation paper, it is proposed that such laboratories would no longer need to maintain their status as a licensed dealer under the NCR in order to conduct activities with cannabis, but would instead apply for an analytical testing licence under the proposed cannabis framework.

Other examples of requirements pertaining to cannabis that are currently covered in the NCR and that would be reflected in the new framework are with respect to the registration of test kits containing cannabis and provisions related to obtaining and handling reference standards.

9.2 *Qualifications for Designations as Analysts Regulations*

The Qualifications for Designations as Analysts Regulations *under the Controlled Drugs and Substances Act* establish the qualifications of individuals involved in analyzing suspected controlled substances seized by peace officers, including Canadian police forces and inspectors. It is proposed that similar regulations would be established, setting out the qualifications of analysts involved in the administration and enforcement of the proposed Cannabis Act.

9.3 Amendments to the *New Classes of Practitioners Regulations*

The *New Classes of Practitioners Regulations* under the *Controlled Drugs and Substances Act* provide a means of authorizing midwives, nurse practitioners and podiatrists to prescribe, administer and provide controlled substances, provided they are already authorized to prescribe controlled substances under provincial or territorial legislation.

Currently, both physicians and nurse practitioners can support the use of cannabis for medical purposes, since they are authorized to do so under provincial or territorial legislation. Proposed regulations under the Cannabis Act would continue to allow for both physicians and nurse practitioners to do so, provided they are authorized under provincial or territorial legislation.

ANNEX 1: CONSULTATION QUESTIONS

Health Canada encourages all interested parties to provide feedback online. For more information regarding the public consultation process, please see: www.canada.ca/en/health-canada/programs/consultation-proposed-approach-regulation-cannabis.html.

To safeguard privacy, you should ensure that any written comments you may provide are sufficiently general that you cannot be identified as the author and that individual identities are not disclosed.

Alternatively, written submissions (Microsoft Word or Adobe PDF) may be sent electronically to: cannabis@canada.ca, or in hard-copy format by mail to:

Cannabis Legalization and Regulation Secretariat
Address locator 0602E
Health Canada
Ottawa, Ontario
K1A 0K9

Those who may choose to provide written submissions are encouraged to use the following questions as a guide.

The deadline to provide written comments and responses is January 20, 2018.

1. What do you think about the different types of proposed licences (i.e., cultivation, processing, etc.)? Will they achieve the objective of enabling a diverse, competitive legal industry that is comprised of both large and small players in regions across the country?

2. What do you think would be an appropriate threshold to distinguish between a micro-cultivator and a standard cultivator, taking into account the reduced physical security requirements for a micro-cultivator? Should the threshold be based on the number of plants, size of growing area, total production, gross revenue, or some other criteria? What should the threshold be?

3. What do you think would be an appropriate threshold to distinguish between a micro-processor and a standard processor, taking into account the reduced physical security requirements for a micro-processor? Should the threshold be based on total production, on-site inventory, gross revenue, or some other criteria? What should the threshold be?

4. What do you think of the proposed rules and requirements (i.e., physical security, good production practices, etc.) for the different categories of authorized activity? Do you think that the requirements are proportional to the public health and safety risks posed by each category of activity?

5. What do you think about the proposed requirements for certain individuals associated with a licensed organization to hold a security clearance issued by the Minister of Health? Do you think the proposal appropriately addresses positions of greatest risk?

6. What do you think of the proposed criteria for determining whether or not an individual is eligible to hold a security clearance? Do you think that the proposed approach should permit individuals with a history of non-violent, lower-risk activity (such as simple possession or small-scale cultivation of cannabis plants) to obtain a security clearance and participate in the legal cannabis industry?

7. What do you think about the proposal not to restrict the types of product forms that industry will be able to manufacture and sell (for example, pre-rolled dried cannabis, or cannabis oil capsules and oral sprays)? Are there any specific product forms that you think should be prohibited?

8. What do you think about the proposed THC limits based how a product is represented to be consumed (i.e., by inhalation or by ingestion)? What do you think about the proposed limits on a unit or serving basis?

9. What do you think about the proposed rules for the packaging and labelling of cannabis products? Do you think additional information should be provided on the label?

10. What do you think about the proposed approach to providing cannabis for medical purposes? Do you think there should be any specific additional changes?

11. What do you think about the proposed restrictions on the sale of health products containing cannabis authorized by Health Canada? Do they strike an appropriate balance between facilitating access to safe, effective and high quality health products, and deterring illegal activities and youth access?

12. What do you think about the overall regulatory proposal? Is there any additional feedback that you would like to share on the proposed approach to the regulation of cannabis?