

Report to Committee

To:

General Purposes Committee

Date:

December 19, 2017

From:

Cecilia Achiam, MCIP, BCSLA

General Manager, Community Safety

File:

12-8000-01/2017-Vol

01

Re:

Update on Cannabis Regulation within the City of Richmond and Health

Canada Proposed Approach to Regulation of Non-Medical Cannabis

Staff Recommendation

1. That the status update and process details for site-specific rezoning applications for medical marihuana production facilities be received for information; and

2. That the responses summarized in the staff report titled "Health Canada Proposed Approach to Regulation of Cannabis", dated December 19, 2017, from the General Manager, Community Safety be approved for submission to Health Canada.

Cecilia Achiam, MCIP, BCSLA General Manager, Community Safety (604-276-4122)

Att. 6

REPORT CONCURR	ENCE
ROUTED TO:	CONCURRENCE
Law Policy Planning	
REVIEWED BY STAFF REPORT / AGENDA REVIEW SUBCOMMITTEE	Initials:
APPROVED BY CAO	

Staff Report

Origin

This report provides an overview of the existing medical cannabis regulatory framework and information regarding past and existing applications. In addition, on November 22, 2017 Health Canada published a proposed approach to the regulation of cannabis and requested written comments be submitted by January 20, 2018. The following report outlines:

Part 1: The existing medical cannabis regulatory framework and information on past and existing applications; and

Part 2: The recommended City of Richmond response to the proposed framework presented by Health Canada.

This report supports Council's 2014-2018 Term Goal #1 A Safe Community:

Maintain emphasis on community safety to ensure Richmond continues to be a safe community.

This report supports Council's 2014-2018 Term Goal #3 A Well-Planned Community:

Adhere to effective planning and growth management practices to maintain and enhance the livability, sustainability and desirability of our City and its neighbourhoods, and to ensure the results match the intentions of our policies and bylaws.

Part 1: The existing medical cannabis regulatory framework and information on past and existing applications.

Land Use Regulations Regarding Cannabis Production and Retail

Since 2013, Council has adopted a number of amendments to the Official Community Plan and the Richmond Zoning Bylaw 8500 to regulate medical marihuana in Richmond.

Previous Bylaw Amendments Regulating Medical Marihuana

On June 26, 2013, an application was submitted by 1348 Productions Incorporated to rezone the property at 11320 Horseshoe Way to allow an indoor medical marihuana production and research facility. This application was submitted in response to the 2013 changes to the Federal Marihuana for Medical Purposes (MMPR) legislation regarding the production of medical marihuana.

In response to this application, staff prepared an amendment to the Official Community Plan and a number of amendments to the Richmond Zoning Bylaw 8500 to regulate the use. Council adopted the OCP amendments in 2013, and these are summarized below:

• If Council receives requests to approve medical marihuana production facilities and medical marihuana research and development facilities, to protect the City's interests, Council may consider such proposed facilities, on a case-by-case basis, subject to

meeting rigorous social, community safety, land use, transportation, infrastructure, environmental and financial planning, zoning and other City policies and requirements.

- Limit medical marihuana production facilities and medical marihuana research and development facilities, through the rezoning process, to one facility in an OCP designated Mixed Employment or Industrial area.
- Any future proposals for a medical marihuana production facility or a medical marihuana research and development facility may be considered on a case-by-case basis and may require additional OCP amendments.

The relevant section of the Richmond Official Community Plan is provided in Attachment 5.

Concurrently with these 2013 Official Community Plan amendments, the Richmond Zoning Bylaw 8500 was also amended as follows:

- New definitions for *medical marihuana production facilty* and *medical marihuana research and development facility* were added. These definitions were developed in response to the application submitted for the property at 11320 Horseshoe Way.
- The definition of farm business was amended to state that a permitted farm business does not include a *medical marihuana production facilty* and *medical marihuana research and development facility*.
- The Richmond Zoning Bylaw 8500 was also amended to state that a *medical marihuana* research and development facility was not considered an office use.

On February 20, 2017 Council adopted bylaw amendments to the Richmond Zoning Bylaw 8500 to create a new definition of *Marihuana Dispensary*, and added the use to the list of uses prohibited in any zone. This change was adopted in response to on-going issues with an illegal marihuana dispensary in the City Centre.

The adopted definition of *Marihuana Dispensary* is broadly worded, and captures the retail sale of any type of cannabis-related products (both medical or recreational cannabis).

A summary of all the relevant sections of Richmond Zoning Bylaw 8500 that relate to the regulation of medical marihuna is provided in Attachment 6.

Rezoning Applications and Review Process for Medical Marihuana Production

Current and Historical Rezoning Applications

To date, there have been three applications to amend the Richmond Zoning Bylaw 8500 to allow a medical marihuana production and or research facility. These applications are summarized in the table below:

Application Number	Site Address	Current Status
RZ 13 - 639815	11320 Horseshoe Way	Application closed and Bylaw abandoned by Council July 25, 2016
RZ 14 -665028	5960 No. 6 Road	Public Hearing September 6, 2016 Bylaw at 3 rd Reading
RZ 17 -769785	13751 Garden City Road	Staff review

The first application for the facility at 11320 Horseshoe Way received 3rd reading following the Public Hearing on March 17, 2014. However, the applicant did not proceed with the project, and Council abandoned the rezoning bylaw on July 25, 2016.

The application for the property at 5960 No. 6 Road is consistent with the OCP policy adopted by Council, and is currently at 3rd reading, and the applicant is working on conditions of rezoning adoption, including confirmation of licensing from Health Canada.

The application for the property at 13751 Garden City Road does not comply with the OCP policy, and is currently under staff review. A staff report on the application will be presented to Planning Committee and Council in due course.

Current Rezoning Process

In order to allow a medical marihuana production or research facility, an application to amend the Richmond Zoning Bylaw 8500 is required, and a bylaw must be adopted by Council. The zoning amendment bylaw would be drafted to allow the proposed use on a site-specific basis only. As per the Official Community Plan, Council has directed staff to review applications for cannabis production on a case-by-case basis.

The application review process includes confirmation of RCMP review, Richmond Fire Rescue review, and proof of licensing from Health Canada. Principal staff review of an application focusses on the conformance of the application to Council's adopted OCP policy. A bylaw would not be presented to Council for consideration until all technical issues have been resolved.

Future Bylaw Amendments

At the current time, the regulatory framework of the Official Community Plan and the Richmond Zoning Bylaw 8500 has focussed on medical marihuana production facilities and medical marihuana research and development facilities. There are no current zoning regulations which

would apply to the production or processing of cannabis for recreational purposes. As noted earlier in this report, the retail sale of cannabis is currently prohibited.

Should Council wish staff to explore regulations in advance of the Federal and Provincial framework for legal cannabis sales, it would be in order for Council to endorse a third recommendation to this report:

That staff report back to Council with bylaw amendments for the regulation of production, processing and sale of cannabis (medical and recreational) in the City.

Part 2: The recommended City of Richmond response to the proposed framework presented by Health Canada

The federal government intends to pass the proposed Cannabis Act (the Act) by July 2018. The stated objectives of the Act are to restrict youth access to cannabis, protect public health through strict product safety, permit legal production and allow adults to possess and access legal cannabis products.

On November 22, 2017, Health Canada published a discussion paper titled "Proposed Approach to the Regulation of Cannabis" (Attachment 1) and is seeking public and stakeholder input by January 20, 2018. The focus of this framework is on federal responsibilities related to the commercial cultivation, manufacturing, setting industry-wide rules and standards, tracking, packaging and labeling of cannabis. The federal regulatory framework seeks to supplement provincial legislation on the retail sale and distribution of cannabis.

The online consultation identified 12 questions (Attachment 2) that requests input on cultivation and process licencing, permitting and authorizations, security clearance, researching and selling cannabis products. The framework also includes regulations for tracking cannabis producers, rules and standards for cannabis products, requirements for packaging and labeling cannabis products and regulations for alternative forms of cannabis such as medicinal cannabis, health products and cosmetics.

The current consultation pertains only to dried and fresh cannabis, cannabis oil, seeds and plants. Following the enactment of the Cannabis Act, the federal government will develop regulations to permit the sale of cannabis edible products (i.e. beverages, baked goods). At this time, not many details are available on the cannabis regulatory framework, both at the federal and provincial level. As such, responses provided in this report are focused on the potential impacts to local governments and highlights issues that overlap with provincial jurisdictions.

The discussion paper, published by Health Canada, contains information on licence types and the general regulatory framework that the federal government is proposing. Based on the federal criteria provided in the discussion paper, the City's response is aligned with previous Council resolutions – to strictly regulate the legalization of non-medical cannabis use. Once the regulatory model in Canada and British Columbia has been established, reviews will be conducted to determine the impact to the City.

City staff is in regular contact with Vancouver Coastal Health regarding the cannabis legalization and other emerging issues. Vancouver Coastal Health confirmed they will be submitting a separate response to the Health Canada consultation survey.

The following responses, if endorsed by Council, will be provided to Health Canada.

City of Richmond Response to the Health Canada Consultation on Regulation of Cannabis

Question 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

competitive legal industry that is comprised of both large and small players in regions across the country?

For additional information, refer to the discussion paper Section 2.2 "Licences, Permits and Authorizations."

City Response:

In general, the City acknowledges the licencing scheme as identified in the discussion paper. Nonetheless, the City has comments in regards to local government control on land-use, uses on agricultural farmlands and the Microcultivation and Micro-processing licences. The ability for local government to control the location, activity and production is important in city planning.

To effectively manage cannabis cultivation, processing, sale, analytical testing, research and import/export activities in local communities, it is critically important for local governments to maintain authority over regulation of land use, zoning and business operations as it pertains to all cannabis-related activities. Furthermore, local governments should be granted authority to impose stricter and/or specific regulations on cannabis-related activities as needed, in order to respond to local context or conditions.

Another concern the City has with the licencing scheme is with respect to agricultural lands and farmland use. To ensure farmland areas are prioritized for soil-based agricultural activities, with minimal requirements for buildings and modification of land, it is critically important for local governments to maintain authority over regulation of land use, zoning and business operations as it pertains to cannabis cultivation (including nurseries), processing, sale, analytical testing, research and import/export activities on farmland.

The discussion paper outlines various cultivation and processing licences but did not clearly define "Micro" cultivation and "Micro" processing licences. Based on the limited information available, the City assumes the "Micro" class of licences to be similar to the current illegal "home-grown" style of cannabis production. Therefore, the City does not support having Micro-cultivation and Micro-processing licences for the following reasons:

First, "micro producers" face many of the same risks such as theft, break-in and fire risk. As outlined in the discussion paper, the Micro-cultivation/processing

licence has fewer requirements for premise and building security. The security risks with Micro-cultivation/processing licensed premises is concerning and will have impacts to community safety, such as increased crime.

Second, the legalization of cannabis in Canada is a new endeavour. It is unknown how the industry will respond to the large scale legalization and deregulation at the national level. It is prudent to observe the effects (such as compliance, security, prices, impact of organized crime, etc.) of legalization before allowing Micro-cultivation and Micro-processing licences.

Third, Micro-cultivation and Micro-processing licences could lead to the proliferation of cannabis production that would impact local government land-use planning and bylaws enforcement. This represents a community safety concern, particularly if the Micro-cultivation and Micro-processing are located in areas (i.e. near schools) or buildings (i.e. residential) that are unfit or unsuitable.

For the reasons listed above, the City does not support Micro-cultivation and Micro-processing licences as outlined in the discussion paper. It is imperative that the City has the authority to restrict the location and operating standards (such as ventilation, noise, etc.) through land-use, zoning and business licencing bylaws.

Question 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?

For additional information, refer to the discussion paper Subsection 2.2.2 "Micro-cultivation."

City Response:

The discussion paper has not provided a clear definition between "Standard" and "Micro" cultivation and processing activities, therefore, the City does not support Micro-cultivation or Micro-processing of cannabis for reasons provided in the response to question 1.

If Micro-cultivation and Micro-processing of cannabis are allowed, then all regulations, facility, security and licence requirements shall be the same as Standard Cultivation and Standard Processing licence. Again, to effectively manage cannabis cultivation and processing it is important for local governments to maintain authority over regulation of land use, zoning and business operations as it pertains to all cannabis-related activities.

Specifically, the security requirements for Micro-cultivation and Micro-processing are to have all of the following attributes:

- Physical barriers at the perimeter and inside of the building;
- Visual monitoring of the entire perimeter at all times;

- Keep a record of visual recordings for one year;
- Alarm or other intrusion detection system;
- Access restricted to employees whose presence in those areas as required by their work responsibilities; and
- Keep a record of the identity of every person entering or existing the perimeter.

In terms of metric to distinguish an appropriate threshold between "Standard" and "Micro" cultivation/processing, the City recommends that the size or floor area of the building be used. This is a measure that can approximate the overall amount of production. Nevertheless, the yield may change as technology and innovation progressed in this field.

Question 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?

For additional information, refer to the discussion paper Subsection 2.2.6 "Micro-processing ."

City

Please see response to question 2.

Response:

Question 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?

For additional information, refer to the discussion paper Section 2.3 "Licence Requirements."

City Response:

To effectively manage cannabis cultivation, processing, sale, analytical testing, research and import/export activities in local communities, it is critically important for local governments to maintain authority over regulation of land use, zoning and business operations as it pertains to all cannabis-related activities. Furthermore, local governments should be able to impose stricter and/or specific regulations on cannabis-related activities as needed, in order to respond to local context and/or conditions.

The City has the following comments regarding Section 2 of the discussion paper:

<u>2.3.1 Notice to Local Authorities:</u> The notice to local governments should be provided for all licence types – including hemp, analytical testing and sale licence not stored on-site. Notification alone is not sufficient and that all federally licensed operations should be required to adhere to local government bylaws.

Further, the applicant should be required to demonstrate compliance with all municipal bylaws and obtain City issued business licence prior to being granted any federal licence.

- <u>2.3.2 Validity Period:</u> All licences under the Cannabis Act should be valid for only one year (instead of five) and local governments input should be considered for the renewal process.
- 2.3.3 Location: To ensure farmlands are prioritized for soil-based agricultural activities, with minimal requirements for buildings and modification of land, it is critically important for local governments to maintain authority over regulation of land use, zoning and business operations as it pertains to cannabis cultivation (including nurseries), processing, sale, analytical testing, research and import/export activities on farmland. It is imperative that the City has the authority to implement operating standards (such as ventilation, noise, etc.) and compliance with locational criteria through land-use, zoning and business licencing bylaws.
- <u>2.3.4 Physical Security:</u> The physical security requirements should be the same for Standard-cultivation/processing and Micro-cultivation/processing licences. Additionally, the security plans and building plans should be submitted to local governments and shared with local law enforcement and fire-rescue.
- <u>2.3.6 Good Production Practices</u>: The City should have authority over production operating standards (e.g. exhaust filtration, gas recirculation, noise, etc.) to prevent fumes and other odorous gasses from being released into the environment and impacting the livability of local residents.
- <u>2.3.7 Record Keeping and Reporting:</u> Similar to the British Columbia report on liquor sales, summary data reports (from the Cannabis Tracking System) of dollar value and quantity should be provided to the general public on a monthly basis. Such summary reports should contain production, inventory levels and sales volumes; with classification by licence type and/or product type for provinces, territories and municipalities.
- 2.5.1 Application Requirements: Local governments must maintain authority over regulation of land use, zoning and business operations as it pertains to all cannabis-related activities. Furthermore, local governments must be able to impose stricter and/or specific regulations on cannabis-related activities as needed, in order to respond to local context or conditions. The federal licencing application process should require confirmation from local governments that any proposed operation meets local zoning and business licencing bylaws.
- 2.5.2 Grounds for Refusal, Suspension and Revocation: Administrative procedures should be created to include resolutions from local government councils for the refusal, suspension and revocation of any licence issued/applied

under the Cannabis Act.

Question 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 identifies positions

of greatest risk?

For additional information, refer to the discussion paper Subsection 3.8 "Application for Security Clearance."

City Response:

The City acknowledges that security clearances be extended to all "key positions" of the applying organization, such as but not limited to:

- Individuals responsible for the licence activities conducted by the organization;
- Chief of security;
- For processing licences, quality assurance person;
- For cultivation licences, master grower; and
- For licence to sell to the public, head of client services.

The City also acknowledges the security clearance requirements for directors and officers. Further, the City recommends that any shareholders that own more than 10 per cent (instead of the proposed 25%) of the organization, if it is privately held, or more than 10 per cent of a privately held parent company, be required to have a security clearance. The 10 per cent threshold is consistent with British Columbia liquor licencing requirements.

Question 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 smallscale cultivation of cannabis plants) to obtain a security clearance and participate in the legal cannabis industry?

For additional information, refer to the discussion paper Subsection 3.2 "Decision to Grant a Security Clearance."

City Response:

The City acknowledges the proposed structure on how security clearances would be issued. In the interest of public safety, any persons with a violent offence, associated with organized crime, corruption and drug trafficking offences be denied a security clearance under the Cannabis Act.

In addition, the City recommends establishing administrative procedures for local government's input to identify individuals requiring a security clearance based on the concurrence with local law enforcement agencies.

Question 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 the government should prohibit?

For additional information, refer to the discussion paper Subsection 5.3 "Product Forms."

City Response:

The City acknowledges the proposal set out in Section 5 Product Form of the discussion paper with the exception of 5.2.7 Cannabis Concentrates. The City does not support the sale of non-medical cannabis products of high concentrate such as hashish, hash oil, shatter, budder, wax, honeycomb and rosin, etc.

The City believes the goals of the Cannabis Act can be achieved without the introduction of high concentrate cannabis derivatives. Limiting access to high potency cannabis products and derivatives is consistent in protecting public health. As well, local governments should be able to impose stricter and/or more specific regulations on cannabis-related products as needed, in order to respond to local context or conditions.

The City has concerns surrounding edible products containing cannabis. The dosage level would be difficult to control and edibles may appeal to many people, particularly youth. In addition, edibles by appearance are indistinguishable from normal food products.

In protecting youth access to cannabis, the federal government, in the upcoming regulations, should strictly regulate edible products to ensure dosage is set at a minimum and strictly regulate how edibles are packaged, labeled, marketed and stored at home. Public education on cannabis edibles must be made a top priority to ensure the Act's objective to restrict youth access to cannabis is achieved.

Question 8:

What do you think about the proposed THC limits based on 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?

For additional information, refer to the discussion paper Subsection 5.3 "Product Forms."

City Response:

The City acknowledges the proposal set out in Section 5.3 Product Form in the discussion paper, to standardize product labels on cannabis products by percentage of weight for dried cannabis and milligrams for edibles and oils.

The City will continuously work with the local health authority, Vancouver Coastal Heath, to review dosage levels to ensure the concentration levels in cannabis products do not become a public health issue. The City recommends that the dosage levels be reviewed after receiving input from health agencies across the country.

Question 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?

For additional information, refer to the discussion paper Section 6 "Packaging and Labelling."

City Response:

The City acknowledges the information that would be on the label of cannabis products as outlined in Section 6.3, particularly the prohibition on promotion and packaging that would appeal to youth. The packaging of cannabis should be tamper-evident, child-resistant and prevent contamination. The presentation of the cannabis packaging should be plain with standard font and size to include public safety and health warnings similar to that of tobacco products, inclusive of photos as necessary.

The City continuously works with the Richmond RCMP to ensure that the amount of cannabis in a single package level will not impact police resources in carrying out their duties. The City recommends that the maximum amount of cannabis in a single package be set to a minimum after receiving input from health and/or law enforcement agencies across the country.

Question 10:

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

For additional information, refer to the discussion paper Section 7 "Cannabis for Medical Purposes."

City Response:

The City has existing zoning regulations and policies contained in the Official Community Plan to enable the City to manage and regulate medical cannabis production and all related activities. It is critically important for local governments to maintain authority over regulation of land use, zoning and business operations as it pertains to cannabis-related activities intended for medical purposes, including any changes to regulations on the access to cannabis for medical purposes.

Question 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?

For additional information, refer to the discussion paper Section 8 "Health Products and Cosmetics with Cannabis."

City Response:

The City does not support health related products containing cannabis as set out in Section 8 of the discussion paper, unless such health products are medical devices and authorized through prescription.

The City believes regulating health products to ensure consumer safety is challenging. There are risks in youth obtaining over the counter, non-prescription, cannabis products that are contrary to the objectives of the Cannabis Act. The City does not support cannabis products sold outside of the regulated framework.

Question 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?

City Response:

It is important to the City of Richmond to protect the quality of life of its residents and to enact measures to afford such protection. The City has provided the following feedback to the Province of British Columbia in the fall of 2017 regarding the legalization of cannabis:

- The City of Richmond strongly opposes the legalization of non-medical use of cannabis.
- That local governments continue to maintain authority over regulation of land use and zoning as it pertains to cannabis-related activities.
- That the minimum age to buy, grow, and possess cannabis be 19 for all of Canada, and that personal possession under age 19 should be 0 grams.
- Local governments should be given no less than \$0.50 per gram of the federal and provincial revenues from the proposed excise duty to offset extra costs for policing, bylaw enforcement, training, community education and outreach.
- Provincial regulations should be a minimum and municipalities should be able to impose stricter regulations.
- Regulations for farm land use for cannabis activity be provided.
- There should be firmer controls on public consumption of cannabis that match public tobacco and alcohol consumption regulations.
- There should be a low tolerance for drug impaired driving for fully licenced (non "new") drivers and zero tolerance for new drivers.
- The maximum number of cannabis plants allowable for personal cultivation should be set by building premises, not by household.
- The legal rights of the landlord (including strata council or owner) to forbid tenants to cultivate, consume, and buy/sell marijuana should be protected.
- Enable the strata council or the building owner to prohibit smoking or cultivation of cannabis in any buildings (such as apartments) with central air ventilation systems.
- Require any products containing cannabis to be labeled and carry health warnings similar to cigarettes.
- The cultivation, smoking, and use of cannabis and cannabis related products should be prohibited in any place, including residences, where children may reside or be around.

Financial Impact

None.

Conclusion

The City has an existing regulatory existing regulatory framework for medical cannabis. The commentary provided in Part 2 above is the proposed response to Health Canada's stakeholder consultation on behalf of the Council for non-medical use of cannabis. Staff will submit this report as the City of Richmond's written submission along with completing the online consultation questionnaire. In addition, staff are in the process of creating an internal working group, and working with external agencies such as Vancouver Coastal Health, in preparation of any forthcoming federal and provincial legislation and policy directions on the legalization of cannabis.

Douglas Liu

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Program Coordinator. Development Development Applications Dept.

DL/BK:dl/bk

- Att. 1: Proposed Approach to the Regulation of Cannabis
 - 2: City Response to Health Canada's Consultation Questionnaire
 - 3: Council Resolution from October 23, 2017
 - 4: Council Resolution from November 27, 2017
 - 5: Existing OCP Policies Regarding Medical Marihuana
 - 6: Existing Zoning Regulations Regarding Medical Marihuana

For Consultation

PROPOSED
APPROACH TO
THE REGULATION
OF CANNABIS







Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Également disponible en français sous le titre : Approche proposée en matière de la réglementation du cannabis

To obtain additional information, please contact:

Health Canada Address Locator 0900C2 Ottawa, ON K1A 0K9 Tel.: 613-957-2991

Toll free: 1-866-225-0709 Fax: 613-941-5366

TTY: 1-800-465-7735

E-mail: publications@hc-sc.gc.ca

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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 Act¹

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 Health² 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.qc.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:

- 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.
- Establish an appropriate regulatory framework for industrial hemp that is riskbased 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 microcultivation 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 microprocessing 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 microprocessor. 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).

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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 safequards 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 nonmedical 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

		CULTI	VATION		PROCE	SSING	SA	LE
ACTIVITIES	Standard	Micro	Nursery	Hemp	Standard	Micro	Medical	Non- medical
CORE ACTIVITIES	(4.124.6.9)	ALAN AT		TESTER.	ALTERNA	Manage.	17-18-EV	544 A Sp. 1
Cultivation		4						
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	•	•	•	•	1			
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			FIELD				CYME	
Transportation	1	•	•	•	•	•	•	
Storage	•	•	•	•	•	•	•	- agini kili sanggara nagara dipaka (nama agi
Destruction		•	•	•				
Research and Development (within authorized core activities)	2 P	•	•	•		·	•	•

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, microcultivation, 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-precursorchemicals/directive-physical-security-requirements-controlled-substances-licenseddealers-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 securitycleared 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

		CULTIN	CULTIVATION		PROCESSING	SSING	SA (medic non-medici	SALE (medical and non-medical purposes)
REQUIREMENTS	Standard	Micro	Nursery	Hemp	Standard	Micro	Cannabis on-site	No cannabis on-site (for example, a call centre)
LOCATION	The state of the s	September 1	The State of	STATE STATE	No. of Concession, Name of Street, or other Persons and Street, or other P			STATE AND ADDRESS OF THE PARTY
Indoor			•	•	•	•	•	•
Outdoor		•	•	•				
PHYSICAL SECURITY						Calebrat	THE PARTY OF THE P	大学と
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	present, exclud	ing growing an	eas					
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	e cannabis produ	ict (for exampl	e cannabis product (for example, dried, oil) is stored	tored				
Identity of every person entering or exiting must be recorded	•				•			

		CULTIN	CULTIVATION		PROCESSING	SSING	SA (medic non-medic	SALE (medical and non-medical purposes)
REQUIREMENTS	Standard	Micro	Nursery	Hemp	Standard	Micro	Cannabis on-site	No cannabis on-site (for example, a call centre)
PERSONNEL SECURITY CLEARANCE		SATURDAY OF						
Specified employees must hold a valid security clearance issued by the Minister	•		•		•		•	
GOOD PRODUCTION PRACTICES						THE REAL PROPERTY.		· · · · · · · · · · · · · · · · · · ·
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								3
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.		•	•					
Report information with respect to tracking cannabls, 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.

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.

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.

Appearance of Packaging 6.6

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:
 - 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. Tamperevident 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

		PROVIS	IONS OF THE PRO	PROVISIONS OF THE PROPOSED CANNABIS ACT*	S ACT*	
PRODUCT LINES	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**	×	×	C	,	<i>*</i>	>
Non-Prescription Drugs	×	×	U	`	>	>
Non-Prescription Veterinary Drugs	×	×	ن ن	>	>	>
Prescription Drugs	×	×	×	,	>	>
Prescription Veterinary Drugs	×	×	×	`	>	>
Medical Devices for consuming cannabis for medical purposes	N/A	N/A	ပ	`	>	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.

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

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.

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.

Amendments to the New Classes 9.3 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?



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Consultation on the Proposed Approach to the Regulation of Cannabis

From Health Canada

Current status: OPEN

The Government of Canada has committed to legalizing, strictly regulating, and restricting access to cannabis. In April 2017, the government introduced Bill C-45, the proposed Cannabis Act. Subject to the approval of Parliament, the Government of Canada intends to bring the proposed Cannabis Act into force no later than July 2018.

We are now seeking feedback on Health Canada's proposed approach to the regulation of cannabis.

Why

Health Canada is seeking your feedback on the <u>Consultation Paper: Proposed Approach to the Regulation of Cannabis</u>. This approach builds on the extensive consultations already conducted by the Task Force on Cannabis Legalization and Regulation and Canada's existing system of regulated production of cannabis for medical purposes and industrial hemp.

The proposed Cannabis Act would create a strict national framework for controlling the production, distribution, sale and possession of cannabis in Canada. As part of this framework, Health Canada would be responsible for regulating production and setting standards for health and safety. The provinces and territories would oversee the distribution and sale of cannabis, subject to minimum federal conditions.

This consultation relates to Health Canada's proposed approach to the regulation of cannabis.

Who

- Canadians
- Provincial, territorial governments
- Indigenous governments and representative organizations

- Municipalities
- Patients
- Public health community
- Law enforcement
- · Cannabis industry, present and future
- Hemp industry

What

The Consultation Paper outlines regulatory proposals for:

- · Licences, permits, and authorizations
- Security clearances
- Cannabis tracking system
- Product standards
- Packaging and labelling
- Cannabis for medical purposes
- · Health products and cosmetics containing cannabis

How to participate

After reviewing the Consultation Paper you can provide your feedback in the following ways:

- 1. Complete the online questionnaire
- 2. Send a written submission by email to <u>cannabis@canada.ca</u>. If you wish, you may attach an electronic file in one of the following formats:
 - Microsoft Word
 - Adobe Acrobat
- 3. Send a written submission in hard-copy format by mail to:

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

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

Health Canada is actively seeking the input of all interested and affected parties to inform the development of the regulations. In addition to the online consultation, Health Canada will continue to meet with provincial and territorial governments and work with Indigenous partners, as well as hold dedicated discussions with stakeholders to promote understanding of the proposal and seek input.

As previously indicated, the Government of Canada intends to bring the proposed Cannabis Act into force no later than July 2018, subject to Parliamentary approval. 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 during the 60-day consultation period as draft regulations will not be pre-published. Instead, at the end of this 60-day consultation period, Health Canada intends to publish a summary of the 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.

Related information

- Canada.ca/cannabis
- Supply Chain for the Commercial Production and Sale of Cannabis Proposed Federal Licences
- Proposed Requirements for Cultivation, Processing, and Federal Sale Licences

Contact us

Cannabis Legalization and Regulation Secretariat Address locator 0602E
Health Canada
Ottawa, Ontario K1A 0K9
Email: cannabis@canada.ca

Date modified:

2017-11-22

English ▼

Progress

11%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

Introduction

Health Canada is seeking your feedback on the <u>Proposed Approach to the Regulation of Cannabis</u>. This consultation builds on the extensive consultations conducted by the Task Force on Cannabis Legalization and Regulation. The consultation is guided by the <u>Consultation Paper</u>. You are invited to read the paper and complete this guestionnaire.

The Government of Canada intends to bring the proposed Cannabis Act into force no later than July 2018, subject to Parliamentary approval. 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 the 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.

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 you provide input during this 60-day consultation period 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 requirement.

You can also send a written submission to canada.ca in electronic files such as Microsoft Word or Adobe Acrobat.

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

Instructions for Completing the Questionnaire

The questionnaire consists of 12 questions on specific elements of the proposed regulatory framework. Your responses will help inform the development of the regulations. Each question appears on a separate page. You will be limited to 10,000 characters, including spaces, for each answer. You do <u>not</u> have to answer each question – you can skip a question and move on to the next one. Question 12 has been reserved at the end of the questionnaire to provide any additional feedback on areas not covered by the questions.

Please note, for your feedback to be considered, you must press SUBMIT on the last page.

Before you begin, we kindly ask that you provide us with some additional demographic information which will help inform the results of the feedback.

Privacy Notice

The personal information you provide is protected in accordance with the Privacy Act and is collected under the authority of Section 4 of the *Department of Health Act*. Your personal views and opinions are being collected in order to seek your feedback on the proposed approach to the regulation of cannabis. We require your demographic information in order to ensure we are representing the views of Canadians for meaningful analysis of this consultation. Health Canada will be collecting your information via the Voxco tool and, as such, is subject to Voxco's privacy policy available at http://www.voxco.com/privacy-statement/. Further information about this platform is available at http://www.voxco.com/survey-software/online-survey-tools/. Health Canada intends to publish a summary of comments received following the end of the consultation period. Comments featured in the summary will not be attributed to any specific individual or organization. To further 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. For more information please refer to the personal information bank Public Communications PSU 9

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You have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly. For more information, please contact the Privacy Management Division at 613-948-1219 or privacy-vie.privee@hc-sc.gc.ca.



English ▼

Progress

14%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

Please indicate whether you are providing input:

- O As an individual
- M As a representative of a group or organization





English V

Progress

51%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

Please choose which type of type of group/organization that best describes who you represent.
X Provincial/Territorial/Municipal government
() Indigenous government or group
() Healthcare association or organization
() Academic or research organization
Non-Governmental Organization or non-profit
Organization which currently, or plans to in the future, derive income from the production, distribution, or sale of cannabis products
() Business or Industry
Advocacy organization/lobby group
() Other (please specify type of organization and area of activity)
(i) Profession to any
() Prefer not to say
Name of group/organization: City of Richmond
City of Richmond
In which province/territory is your organization based?
() Alberta
₩ British Columbia
() Manitoba
() New Brunswick
() Newfoundland and Labrador
() Northwest Territories
() Nova Scotia
() Nunavut
() Ontario
() Prince Edward Island
() Quebec
() Saskatchewan
() Yukon
() National
() Outside of Canada
() Prefer not to say

- () Yes
- X No
- () Prefer not to say

Do you anticipate that you would apply for one or more of the proposed licences described in the consultation paper?

- X No
- () Yes, within the next 1-5 years
- () Yes, within the next 6-10 years
- () Prefer not to say





English ▼

Progress

55%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?

For additional information, refer to the discussion paper Section 2.2 "Licences, Permits and Authorizations."



English ▼

Progress

59%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?

For additional information, refer to the discussion paper Subsection 2.2.2 "Micro-cultivation."



English ▼

Progress

62%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?

For additional information, refer to the discussion paper Subsection 2.2.6 "Micro-processing."





English V

Progress

66%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?

For additional information, refer to the discussion paper Section 2.3 "Licence Requirements."



English ▼

Progress

70%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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 identifies positions of greatest risk?

For additional information, refer to the discussion paper Subsection 3.8 "Application for Security Clearance."





English ▼

Progress

74%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?





English *

Progress

77%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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 the government should prohibit?

For additional information, refer to the discussion paper Subsection 5.3 "Product Forms."





English 7

Progress

81%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

8. What do you think about the proposed THC limits based on 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?

For additional information, refer to the discussion paper Subsection 5.3 "Product Forms."



English ▼

Progress

85%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?

For additional information, refer to the discussion paper Section 6 "Packaging and Labelling."





English v

Progress

88%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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

For additional information, refer to the discussion paper Section 7 "Cannabis for Medical Purposes."





English >

Progress

92%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?

For additional information, refer to the discussion paper Section 8 "Health Products and Cosmetics with Cannabis."





English ▼

Progress

96%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

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?





Santé Canada et l'Agence de la santé publique du Canada

English ▼

Progress

100%

Online Questionnaire on the Proposed Approach to the Regulation of Cannabis

Thank You

If there are any changes you would like to make to your responses, please do so now before you click the "Submit" button below.







Minutes

Regular Council Monday, October 23, 2017

13. TRAFFIC RECORDING CAPABILITIES AT INTERSECTIONS IN RICHMOND

(File Ref. No. 10-6450-08-01) (REDMS No.)

That Traffic Recording Capabilities at Intersections be submitted in the 2018 budget process for Council consideration.

ADOPTED ON CONSENT

CONSIDERATION OF MATTERS REMOVED FROM THE CONSENT AGENDA

NON-CONSENT AGENDA ITEMS

GENERAL PURPOSES COMMITTEE

Mayor Malcolm D. Brodie, Chair

14. CITY OF RICHMOND SUBMISSION REGARDING CANNABIS LEGALIZATION AND REGULATION IN BC

(File Ref. No. 09-5000-03-02; 12-8000-01) (REDMS No. 5567746; 5567869; 5594044 v. 7)

R17/18-5

It was moved and seconded

WHEREAS it is important to the City of Richmond to protect the quality of life of its residents and to enact measures to afford such protection, therefore be it RESOLVED:

- (1) That the comments summarized in the staff report titled, "City of Richmond Submission Regarding Cannabis Legislation and Regulation in BC" and detailed in Table 1, be approved for submission to the Province of British Columbia with the following additions:
 - (a) that the minimum age to buy, grow, and possess cannabis be 19;



Regular Council Monday, October 23, 2017

- (b) that a copy of the staff report titled, "City of Richmond Submission Regarding Cannabis Legalisation and Regulation in BC" be submitted to the Province along with a letter detailing the following points of clarification:
 - (i) the City of Richmond strongly opposes the legalization of non-medical use of cannabis;
 - (ii) that municipalities continue to maintain authority over regulation of land use and zoning as it pertains to cannabis-related land uses;
 - (iii) the limit for youth personal possession (under age 19) should be 0 grams;
 - (iv) Provincial regulations should be a minimum and municipalities should be able to impose stricter regulations;
 - (v) regulations for farm land should be provided;
 - (vi) municipalities should be given a share of the federal and provincial revenues to offset extra costs;
 - (vii) there has been insufficient time given to respond to the Province's request for feedback;
 - (viii) there should be firmer controls on public consumption of cannabis that match public tobacco and alcohol consumption regulations;
 - (ix) there should be a low tolerance for drug impaired driving for fully licenced (non "new") drivers and zero tolerance for new drivers;
 - (x) the cultivation, smoking, and use of cannabis and cannabis related products should be prohibited in any place, including residences, where children may reside or be around;
 - (xi) the maximum number of cannabis plants allowable for personal cultivation should be set by building premises, not by household;



Regular Council Monday, October 23, 2017

- (xii) the legal rights of the landlord (including strata council or owner) to forbid tenants to cultivate, consume, and buy/sell marijuana should be protected;
- (xiii) enable the strata council or the building owner to prohibit smoking or cultivation of cannabis in any buildings (such as apartments) with central air ventilation systems; and
- (xiv) require any products containing cannabis to be labeled and carry health warnings similar to cigarettes.
- (2) That a letter be sent to the Prime Minister, with copies to the Minister of Justice and Attorney General of Canada, Richmond Members of Parliament, and the federal leader of the official opposition, expressing concern over the inadequate time given to Provincial and Municipal governments to prepare prior to cannabis legalization.

The question on Resolution No. R17/18-5 was not called as discussion took place in regards to (i) the survey answers addressed in Table 1 of the staff report, (ii) limiting retail to locations accustomed to selling controlled substances such as pharmacies or liquor stores, (iii) the minimum age to buy, grow, and possess cannabis, (iv) protection of strata council and owners' rights to their property, and (v) the growth of cannabis on agricultural land.

Discussion further ensued and Council expressed concern regarding (i) protection of children from cannabis use, (ii) youth consumption and impaired driving, (iii) the increased potency of marijuana and its affects, (iv) issues associated with enforcement of the proposed legislation and (v) the short time period in which non-medical cannabis will be legalized.

It was agreed that Part (1)(a) of Resolution No. R17/18-5 would be voted separately and the question on Part (1)(a) was called and it was CARRIED with Cllrs. Au, Day, and Dang opposed.

The question on the balance of Resolution No. R17/18-5 was then called and it was CARRIED.



Minutes

Regular Council Monday, November 27, 2017

- 2018 AGE-FRIENDLY COMMUNITIES GRANT SUBMISSION (File Ref. No. 03-1087-32-01; 07-3400-01) (REDMS No. 5621510 v. 3-535499)
 - (1) That the application to the Union of British Columbia Municipalities (UBCM) 2018 Age-friendly Communities Grant Program for \$25,000 in the Age-friendly Assessments, Action Plans and Planning Category be endorsed; and
 - (2) That should the funding application be successful, the Chief Administrative Officer and a General Manager be authorized to enter into agreement with the UBCM for the above mentioned project and the 5-Year Financial Plan (2018-2022) be updated accordingly.

ADOPTED ON CONSENT

10. PROPOSED TAXATION FRAMEWORK FOR CANNABIS PRODUCTS

(File Ref. No. 03-1240-03-05) (REDMS No. 5657159 v. 2; 5660256)

That the comments summarized in the staff report titled, "Proposed Taxation Framework for Cannabis Products", dated November 16, 2017, including that the municipal share of revenue be no less than 50 cents per gram, be approved for submission to the federal government.

ADOPTED ON CONSENT

11. ELECTION RESERVE AND ADVANCE PLANNING FOR THE 2018 ELECTION

(File Ref. No. 12-8125-80-01) (REDMS No. 5490268 v.2; 5656539; 5656709)

- (1) That a divisional-voting approach to the 2018 election, which is consistent with the current Civic Election Administration and Procedure Bylaw, and as generally described in the staff report dated November 3, 2017 from the Director, City Clerk's Office, be approved; and
- (2) That the following additional level requests be considered as part of the 2018 budget process:
 - (a) a one-time additional level request in the amount of \$130,000 for the 2018 election, and



3.6.4 Potential City Centre Building Height Increase

OVERVIEW

The City wishes to explore increasing building height in a portion of the City Centre. Transport Canada regulates building heights around the airport. YVR and the City have identified a possible area to study for increasing building height (around City Hall see OCP ANSD Map).

OBJECTION 1:

Maximize City Centre viability safely by exploring with YVR possible increases in building height around City Hall to improve sustainability, social, economic and environmental benefit.

POLICIES:

- a) continue to explore with YVR the possibility of increasing building height around City Hall;
- b) if such building height increases are allowed by the Federal Government, study the implications and benefits (e.g., how high to build, what uses would occur, what the community benefits may be).

Bylaw 9110 * 2014/03/24

3.6.5 Health Canada Licensed Medical Marihuana Production, and Research and Development Facilities

OVERVIEW

In June 2013, Health Canada enacted the *Marihuana for Medical Purposes Regulations (MMPR)* to better manage the research, production and distribution of medical marihuana.

In December 2013, Council amended the Zoning Bylaw to not permit medical marihuana production facilities and medical marihuana research and development facilities in any zoning district City-wide, as they were a new land use, their potential impacts were unknown and it is desirable to prevent the unnecessary proliferation of facilities. Over time, if Council receives requests to approve medical marihuana production facilities and medical marihuana research and development facilities, to protect the City's interests, Council may consider such proposed facilities, on a case-by-case review basis, subject to meeting rigorous social, community safety, land use, transportation, infrastructure, environmental and financial planning, zoning and other City policies and requirements. This section establishes the policies and requirements, by which such proposed facilities may be considered and, if deemed appropriate, approved.

TERMS

In this section, the following terms apply:

"Medical Marihuana Production Facility"—means a facility for the
growing and production of medical marihuana in a fully enclosed
building as licensed and lawfully sanctioned under Health Canada's
Marihuana for Medical Purposes Regulations (as amended from time
to time), including the necessary supporting accessory uses related to
processing, testing, research and development, packaging, storage,
distribution and office functions that are directly related to and in
support of growing and cultivation activities;



Bylaw 9110 2014/03/24

"Medical Marihuana Research and Development Facility"—means a
facility for the research and development of medical marihuana only in
a fully enclosed building as lawfully sanctioned by Health Canada under
the Controlled Drugs and Substances Act (as amended from time to
time).

OBJECTION 1:

Protect the City's social, economic, land use and environmental interests when considering proposed medical marihuana production facilities and medical marihuana research and development facilities by preventing their unnecessary proliferation, avoiding long-term negative effects, and ensuring minimal City costs.

POLICIES:

- a) limit medical marihuana production facilities and medical marihuana research and development facilities, through the rezoning process, to one facility in an OCP designated Mixed Employment or Industrial area. Any future proposals for a medical marihuana production facility or a medical marihuana research and development facility may be considered on a case-by-case basis and may require additional OCP amendments;
- b) a medical marihuana production facility must:
 - i) be located in a stand-alone building, which does not contain any other businesses;
 - ii) have frontage on an existing, opened and constructed City road, to address infrastructure servicing and emergency response requirements:
 - iii) avoid negatively affecting sensitive land uses (e.g., residential, school, park, community institutional);
 - iv) not emit any offensive odors, emissions and lighting to minimize negative health and nuisance impacts on surrounding areas;
- c) medical marihuana production facility applicants shall engage qualified professional consultants to prepare required studies and plans through the City's regulatory processes (e.g., rezoning, development permit, building permit, other);
- d) medical marihuana production facility applicants shall ensure that proposals address the following matters, through the City's regulatory processes (e.g., rezoning, development permit, building permit, other):
 - i) compliance with City social, community safety, land use, building, security (e.g., police, fire, emergency response), transportation, infrastructure (e.g., water, sanitary, drainage), solid waste management, environmental (e.g., Environmentally Sensitive Areas, Riparian Management Areas, Ecological Network), nuisance (e.g., noise, odour and emissions) financial and other policies and requirements;
 - ii) compliance with all federal, provincial and regional (e.g., Metro Vancouver) policies and requirements;



Bylaw 9110 1 2014/03/24

- iii) compliance with the City Building Regulation Bylaw, Fire Protection and Life Safety Bylaw, Noise Regulation Bylaw, Business License Bylaw, Business Regulation Bylaw and other related, applicable City Bylaws;
- iv) compliance with the current BC Building Code, BC Fire Code, BC Fire Services Act, BC Electrical Code, and other related codes and standards;
- e) the applicant/owner of a Health Canada licensed and City approved medical marihuana production facility shall be responsible for full remediation of the facility should it cease operations or upon closure of the facility;
- f) consultation with stakeholders on a proposed medical marihuana production facility shall be undertaken as deemed necessary based on the context specific to each proposal.

Farm-based winery

means a British Columbia licensed winery or cidery, and includes directly associated processing and storage, if: [Bylaw 9699, Jun 19/17]

- at least 50% of the farm product used to make the wine or cider produced each year is grown on the farm on which the winery or cidery is located, or [Bylaw 9699, Jun 19/17]
- b) the farm on which the winery or cidery is located is more than 2 ha in area and at least 50% of the farm product used to make the wine or cider produced each year is grown:

 [Bylaw 9699, Jun 19/17]
 - i) on the farm, or [Bylaw 9699, Jun 19/17]
 - ii) both on the farm and on another farm located in British Columbia that provides that farm product to the winery or cidery under a contract having a term of at least three (3) years; and [Bylaw 9699, Jun 19/17]
- c) other **ancillary uses** as set out in the *Agricultural Land*Reserve Use, Subdivision and Procedure Regulation. [Bylaw 9699, Jun 19/17]

Farm business

means a **business** in which one or more of the following farm activities are conducted, and includes a farm education or farm research institution to the extent that the institution conducts one or more of the following farm activities: [Bylaw 9071, Dec 16/13]

- growing, producing, raising or keeping animals or plants, including mushrooms, or the primary products of those plants or animals; [Bylaw 9071, Dec 16/13]
- b) clearing, draining, irrigating or cultivating land; [Bylaw 9071, Dec 16/13]
- c) using farm machinery, equipment, devices, materials and structures; [Bylaw 9071, Dec 16/13]
- d) applying fertilizers, manure, pesticides and biological control agents, including by ground and aerial spraying; [Bylaw 9071, Dec 16/13]
- e) conducting any other agricultural activity on, in or over agricultural land; [Bylaw 9071, Dec 16/13]
- f) intensively cultivating in plantations, any [Bylaw 9071, Dec 16/13]
 - i) specialty wood crops, or [Bylaw 9071, Dec 16/13]
 - ii) specialty fibre crops prescribed by a Minister of the Province of BC; [Bylaw 9071, Dec 16/13]

Farm business con't

- conducting turf production in an Agricultural Land Reserve with the approval under Agricultural Land Commission Act of the Provincial Agricultural Land Commission; [Bylaw 9071, Dec 16/13]
- h) aquaculture as defined in the *Fisheries Act* when carried on by a person licensed, under Part 3 of that Act, to carry on the **business** of aquaculture; [Bylaw 9071, Dec 16/13]
- raising or keeping game, within the meaning of the *Game Farm Act*, by a person licensed to do so under that Act; [Bylaw 9071, Dec 16/13]
- j) raising or keeping fur bearing animals, within the meaning of the Fur Farm Act, by a person licensed to do so under that Act; [Bylaw 9071, Dec 16/13]
- k) processing or direct marketing by a farmer of one or both of [Bylaw 9071, Dec 16/13]
 - i) the products of a farm owned or operated by the farmer, and [Bylaw 9071, Dec 16/13]
 - ii) within limits prescribed by a Minister of the Province of BC, of products not of that farm, to the extent that the processing or marketing of those products is conducted on the farmer's farm, but [Bylaw 9071, Dec 16/13]

farm business does not include: [Bylaw 9071, Dec 16/13]

- a) an activity, other than grazing or hay cutting, if the activity constitutes a forest practice as defined in the *Forest and Range Practices Act*; [Bylaw 9071, Dec 16/13]
- b) breeding pets or operating a kennel; [Bylaw 9071, Dec 16/13]
- c) growing, producing, raising or keeping exotic animals, except types of exotic animals prescribed by a Minister of the Province of BC; [Bylaw 9071, Dec 16/13]
- d) a medical marihuana production facility; and [Bylaw 9071, Dec 16/13]
- e) a medical marihuana research and development facility.
 [Bylaw 9071, Dec 16/13]

Farm home plate

means the portion of a **lot** including or located between a **principal dwelling unit**, additional **dwelling unit(s)**, and any **accessory buildings** or **accessory structures**, including driveways to **dwelling unit(s)**, decorative landscaping, artificial ponds not serving farm drainage, irrigation needs or aquaculture use, and sewerage septic tanks, in one contiguous area. [Bylaw 9707, May 17/17]

Farm home plate setback

means the distance that the rear of a **farm home plate** may be set back from a **lot** line or any other features specified by this Bylaw. [Bylaw 9707, May 17/17]

M

Manufacturing, custom indoor

means the small scale on-site indoor manufacture of goods by hand primarily involving the **use** of hand tools and goods or services which are specialized, which includes but is not limited to jewellery, toy and musical instrument manufacturing, and pottery and sculpture studios, but does not include **businesses** which primarily sell mass-produced goods at retail.

Marina

means docking or mooring facilities where boats, other water vessels and their accessories are berthed, stored, serviced, repaired, constructed or kept for sale or for rent, and includes accessory facilities such as sani-dump and marine fuel sales, and an **office** used exclusively for the **marina**.

Marine sales & rentals

means a facility that sell or rent boats, boating supplies and equipment.

Marine sales and repair

means the servicing and mechanical repair of boats and marine equipment, including the **ancillary** sale, installation or servicing of related marine accessories and parts.

Maritime

means **uses** which are part of the **maritime** economy, with an emphasis on **uses** which support primarily the commercial fishing fleet and other services related to the **maritime** industry.

Maritime mixed use

means the service and repair of boats and marine equipment, fish auction and off-loading.

Medical Marihuana Production Facility means a facility for the growing and production of medical marihuana in a fully enclosed **building** as licensed and lawfully sanctioned under Health Canada's *Marihuana for Medical Purposes Regulations* (as amended from time to time), including the necessary supporting accessory **uses** related to processing, testing, research and development, packaging, storage, distribution and **office** functions that are directly related to and in support of growing and cultivation activities. [Bylaw 9071, Dec 16/13]

Medical Marihuana
Research and
Development Facility

means a facility for the research and development of medical marihuana only in a fully enclosed **building** as lawfully sanctioned by Health Canada under the *Controlled Drugs and Substances Act* (as amended from time to time). [Bylaw 9071, Dec 16/13]

Microbrewery, Winery and Distillery

means a **premises**, licensed under the *Liquor Control and Licensing Act*, on which there is manufacturing of beer, ale, cider, wine or spirits for sale to business customers and shall include **ancillary** retail sale of these liquor products and related non-liquor products to the public within the manufacturer's store and lounge provided that their combined **floor area** and any outdoor lounge patio area do not exceed the manufacturing **floor area**. [Bylaw 9295, Nov 9/15]

Motel

means a **building** divided into self-contained accommodation units rented on a short term basis, each with a separate exterior entrance and convenient **access** to on-site parking, and which may include food services and **personal service** establishments primarily for the convenience of **quests**.

N

n/a

means not applicable, that there is no particular regulation in that **zone** for that category, but that the other regulations in this bylaw still apply.

Neighbourhood public house

means a **premises**, licensed under the *Liquor Control and Licensing Act*, where liquor is served for consumption on **site**, with a maximum occupant load of 125 persons.

Non-porous surfaces

means any constructed surface on, above or below ground that does not allow precipitation or surface water to penetrate directly into the underlying soil. Surfacing materials considered as non-porous are concrete, asphalt, and grouted brick or stone. [Bylaw 9737, Jul 24/17]

Nuisance

means anything that is obnoxious, offensive or interferes with the **use** or enjoyment of property, endangers personal health or safety, or is offensive to the senses, and which may include anything which creates or is liable to create a **nuisance**: through emission of noise, smoke, dust, odour, heat, light, fumes, fire or explosive hazard; results in the unsightly or unsafe storage of goods, salvage, junk, waste or other materials; poses a hazard to health and safety; or adversely affects the amenities of the neighbourhood or interferes with the rights of neighbours to the normal enjoyment of any land or **building**.

0

Office

means a facility that provides professional, management, administrative, consulting or monetary services in an **office** setting, including research and development, which includes **offices** of lawyers, accountants, travel agents, real estate and insurance firms, planners, clerical and secretarial agencies, but excludes the servicing and repair of goods, the sale of goods to the <u>customer on</u> the **site**, the <u>manufacture or handling of product and a **medical** marihuana research and development facility. [B, Vlake QO71, Dec. 16/13]</u>

Official Community
Plan

means the **City** of Richmond's **Official Community Plan** bylaw and related Area Plans and Sub-Area Plans.

Open space

means a portion of a **lot** not occupied by parking or **vehicle** areas or **buildings**, and accessible to and suitable for gardens, **landscaping** and recreational **use** by **building** tenants or residents.

Yard, side

means the area between $\mbox{\bf side}$ lot lines and the nearest wall of a

building extending from the front yard to the rear yard.

Z

Zone

means an area of the City as defined in Sections 8 to 26.

Zone, agricultural &

golf

means any AG or GC zones included in Section 14.

Zone, commercial

means any C zone included in Section 9 and 10.

Zone, industrial

means any I zone included in Section 12.

Zone, marina

means any MA zone included in Section 11.

Zone, institutional

means any AIR, SI, ASY or HC zone in Section 13.

Zone, residential

means any R zone included in Section 8.

Zone, site specific

means any zone included in Sections 15 to 26 of this bylaw.

3.5 Non-Permitted Uses and Definitions

- 3.5.1 The following **uses** are not permitted in any **zone**:
 - a) Abbatoir
 - b) Cemetery
 - c) Manufactured home park
 - d) Manufactured home sales/rentals
 - e) Marihuana dispensary [Bylaw 9671, Feb 20/17]
- 3.5.2 The non-permitted uses are defined as follows:

Abattoir means a facility for the penning and slaughtering of animals where

more than 50% of the livestock being slaughtered is from other sites than the abattoir, and the meat is cut, cured, smoked, aged,

wrapped or frozen for distribution and consumption.

Cemetery means land, buildings and structures for the burial of human or

animal remains. This does not include an interment facility or

memorial park.

Manufactured home park

means a **development** used for **manufactured housing** and not having a registered plan of **subdivision** of individual **lots**. Spaces, or spaces with individual **manufactured housing** already sited on them, may be rented. Ownership and responsibility for the maintenance of internal **roads**, underground services, communal areas and **buildings**, snow clearance and garbage collection, together with general park management, rests with the management. This does not include the situation where an additional agricultural **dwelling unit** is located on a **lot** where the **principal dwelling unit** is **manufactured housing**.

Manufactured home sales/rentals

means a **development** used for the sale or rental of new or used mobile homes and **manufactured housing** together with incidental maintenance services and the sale of parts and accessories.

Marihuana Dispensary

means a business or other operation involving the sale, barter, storage, distribution or dispensing of cannabis, marihuana or any products containing or derived from cannabis or marihuana. [Bylaw 9671, Feb 20/17]

- 3.5.3 The storage of **commercial vehicles** and shipping containers is not permitted in **residential zones** and **site specific zones** which permit residential **uses**.
- 3.5.4 The parking, storage or servicing of **commercial vehicles** and equipment on lands is not permitted within the **Agricultural Land Reserve** unless: [Bylaw 9490, Mar 21/16]
 - the commercial vehicles and equipment are owned and/ or operated by the owner or occupant of the lands; [Bylaw 9490, Mar 21/16]
 - b) the **commercial vehicles** and equipment are not parked within the required **building** setbacks; and [Bylaw 9490, Mar 21/16]
 - c) the **commercial vehicles** and equipment are utilized as part of a **farm operation**. [Bylaw 9490, Mar 21/16]

- 5.13.2 **Urban services** and utility service infrastructure such as poles, wires, traffic controls, telephone booths, bus benches and shelters, underground utility systems, electrical transformer stations and municipal utility operations, are permitted in all **zones**.
- 5.13.3 Residential sales centres shall be permitted in all zones except in the agricultural & golf zones and in any site specific zones that permit farm business. The following conditions apply:
 - a residential sales centre may operate on a site while the owner constructs or supervises construction of buildings within the development, and must be removed when occupancy has been granted for the development;
 - residential sales centres may only be used to market an existing or proposed development that is actively being sold;
 - on-site parking shall be provided in accordance with the office general parking requirements of Section 7.0 whether the residential sales centre is located in the City Centre or elsewhere;
 - d) the **residential sales centre** shall comply with the **setback**, **yard**, **floor area ratio** and other regulations of the **zone** in which it is located.
- Agriculture is permitted as a secondary use in all zones (i.e., it occurs in conjunction with a principal use, for example single detached housing) in order to encourage and accommodate community gardens, green roofs, vertical farming and other forms of urban agriculture. The following conditions apply in certain instances with respect to agriculture being permitted as a secondary use in all zones:
 - a) There may be covenants or caveats registered on the title of the land which could restrict the type of agriculture permitted (e.g., prohibition on the raising of chickens, rabbits or other domesticated animals). Property owners and tenants are advised to check their current certificate of title for any covenants or caveats which may be registered and affect the use of the site.
 - b) Only properties which are assessed as a "farm" under the Assessment Act are permitted to raise livestock.
 - c) A medical marihuana production facility and medical marihuana research and development facility is not permitted. [Bylaw 9071, Dec 16/13]
- 5.13.5 **Parks** owned by the **City** shall be permitted in all **zones**.
- 5.13.6 Amenity space and community amenity space are permitted in all zones where these are permitted as an additional floor area ratio in the permitted density and are not listed as a permitted use in these zones.
- 5.13.7 Wind turbines shall be allowed in all **zones** subject to: [Bylaw 8904, Jun18/12]
 - a) the maximum **height** for **accessory structures** in that **zone**; [Bylaw 8904, Jun18/12]
 - b) the accessory structure and/or principal building yards and setbacks in that zone; [Bylaw 8904, Jun18/12]
 - c) landscaping or other specific provisions in the zone; and [Bylaw 8904, Jun18/12]
 - d) appropriate safety and noise attenuation measures. [Bylaw 8904, Jun18/12]
- 5.13.8 **Telecommunications antennas** shall be allowed in all **zones** subject to: [Bylaw 8904, Jun18/12]