

## Appendix B: Cannabis Production Study Discussion Guide

### **CANNABIS PRODUCTION STUDY: DISCUSSION GUIDE**

This document provides additional details of the technical review undertaken to inform the proposed Zoning By-law Amendment to implement the findings of the Cannabis Production Study. The tables below summarize:

1. the conclusions of the review for all policy documents where changes were deemed unnecessary;
2. how various cannabis production activities would be classified to inform the review of planning applications;
3. how each of the community concerns identified during preliminary public engagement is/is not addressed through the; and recommendations and why, as well as supporting context regarding:
  - a) the Health Canada application process for cannabis production licences and
  - b) how Health Canada enforces its licencing requirements.

### **1. CONCLUSIONS OF POLICY REVIEW**

Based on preliminary research conducted during Stage 1 of the Cannabis Production Study, the Stage 2 work plan proposed the development of:

- a) a set of cannabis production guidelines that address odour and light nuisance;
- b) an amendment to the Official Plan to enable the guidelines;
- c) an amendment to the Zoning Bylaw to incorporate updated language for cannabis; and
- d) an amendment to the Site Plan Control Bylaw to address cannabis production facilities.

At the outset of Stage 2, staff undertook further review of the applicable policy framework regulating cannabis production in Canada and Ontario, including the:

- *Cannabis Act, 2018* and Cannabis Regulations
- Good production practices guide for cannabis
- Physical security measures guide for cannabis
- Cannabis licensing application guide
- Health Canada Compliance and Enforcement Policy for the Cannabis Act
- Provincial Policy Statement, 2020
- Growth Plan for the Greater Golden Horseshoe, 2019
- Greenbelt Plan, 2017
- Niagara Escarpment Plan, 2017
- Farming and Food Production Protection Act, 1998
- Ontario Guideline D-6: Compatibility between Industrial Facilities

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Based on this review, staff concluded that the existing federal and provincial policy frameworks, which inform municipal policies, already includes sufficient provisions to regulate cannabis production in a manner that supports land use compatibility. The table below provides a brief explanation for each of the City policy documents included in the Cannabis Production Study, and why changes are not being recommended at this time.

Policy Document	Conclusions of Review
<p><b>Official Plan, 1997</b></p>	<p>The current policies are sufficient to address proposals for cannabis production facilities, both within and outside of settlement area boundaries.</p> <p>Indoor cannabis cultivation will be classified as an industrial use (manufacturing) and addressed by Section III Land Use Policies – Urban Planning Area and Section II – Functional Policies.</p> <p>Greenhouse and outdoor cannabis cultivation will be classified as an agricultural use and addressed by Section IV Land Use Policies -Rural Planning Area and Section II – Functional Policies.</p> <p>Cannabis processing associated with a cannabis cultivation operation that has been classified as a commercial agricultural use <i>may</i> be classified as an accessory use to a commercial farm, depending on the nature of the operation. Cannabis processing that is not associated with a commercial agricultural use will be classified as an industrial use.</p>
<p><b>Official Plan, 2020</b></p>	<p>The current policies are sufficient to address proposals for cannabis production facilities, both within and outside of settlement area boundaries.</p> <p>Indoor cannabis cultivation will be classified as an industrial use (manufacturing) and addressed by Section 8 Land Use Policies – Urban Planning Area and Section 4 –Environment and Sustainability (specifically Section 4.6 - Land Use Compatibility).</p> <p>Greenhouse and outdoor cannabis cultivation will be classified as an agricultural use and addressed by Section 9 Land Use Policies -Rural Planning Area and Section 4 – Environment and Sustainability (specifically Section 4.6 - Land Use Compatibility).</p> <p>Cannabis processing associated with a cannabis cultivation operation that has been classified as a commercial agricultural use <i>may</i> be classified as an agriculture-related use or an on-farm diversified use in accordance with</p>

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<b>Policy Document</b>	<b>Conclusions of Review</b>
	<p>Section 9 of the Burlington Official Plan, depending on the nature of the operation. Cannabis processing that is not associated with an agricultural use will be classified as an industrial use.</p>
<p><b>By-Law 35-2017: Site Plan Control</b></p>	<p>The Regional Official Plan Review (ROPR) is currently underway. The ROPR will analyze new Provincial policies with respect to agricultural uses, agriculture related uses, and on-farm diversified uses, which will impact cannabis production facilities operating as an agricultural use. The nuances between agriculture and urban agriculture, including commercial/industrial agricultural operations in a fully indoor setting, require comprehensive analysis. Until updated Regional/local Official Plan policies have been implemented through updates to the Zoning By-Law for these uses, it would be premature to amend the Site Plan Control By-Law with respect to agricultural uses.</p> <p>Health Canada cannabis production licence applications require the submission of a detailed site plan to ensure compliance with all federal requirements. While the City may wish to enact additional controls beyond federal requirements in future, it would be not be appropriate to apply more restrictive policies to a specific agricultural crop, as this may conflict with provincial policies. Site plan control should be applied more broadly, e.g. large agricultural structures, or agriculture-related and on-farm diversified uses meeting certain trigger criteria. Such amendments would require accompanying guidelines and would have a resourcing impact on the City’s Site Plan Review team.</p> <p>In the interim, the risk is relatively low, as indoor cannabis production facilities within settlement boundaries would generally be considered an industrial use and would be subject to site plan control. Within the Niagara Escarpment Area of Development Control- which covers most of the rural area- cannabis production facilities would not generally be considered exempt as an agricultural use by the Niagara Escarpment Commission (NEC) and would still require an NEC development permit, where a site plan would be required as part of the application.</p>
<p><b>By-Law 19-2003: Nuisance and Noise</b></p>	<p>Burlington’s Nuisance and Noise By-Law does not specifically address odour. Given the potential for conflict with the Farming and Food Production Protection Act within the Agricultural Area, it would not be appropriate to introduce controls for cannabis production alone.</p>

Policy Document	Conclusions of Review
	<p>Rather, the by-law would need to be amended to address odour broadly. This approach is not recommended, given the existing provincial and federal regulatory controls for managing odour in both the rural and urban area. Odour science is imperfect, meaning monitoring and enforcement can be challenging and labor intensive. Introducing odour provisions to the Nuisance and Noise By-law would have a significant resourcing impact on the City's By-law Enforcement division.</p>

## 2. PROPOSED CLASSIFICATION OF CANNABIS PRODUCTION FACILITIES

Given the conclusions above, the following table provides an explanation of how the various types of cannabis production facilities would be classified under the existing City policy framework, to inform the review of planning applications.

Licence Type	Authorized Activities (according to the <i>Cannabis Act, 2018</i> )	Proposed Classification
<b>Standard Cultivation</b>	<ul style="list-style-type: none"> <li>• Possess cannabis</li> <li>• Obtain dried or fresh cannabis, cannabis plants or cannabis plant seeds by propagating, cultivating, harvesting</li> </ul>	<p>Greenhouse/Outdoor: Agricultural Use</p> <p>Indoor: Industrial Use</p>
<b>Micro-Cultivation</b>	<ul style="list-style-type: none"> <li>• For the purpose of testing, alter the chemical or physical properties of the cannabis</li> <li>• Sell and distribute dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds to other licence holders (cultivators, processors, analytical testers, researchers, cannabis drug licence holders), with the exception that dried cannabis or fresh cannabis cannot be sold to the holder of a nursery licence</li> <li>• Sell and distribute cannabis plants or cannabis plant seeds to a licensed nursery</li> <li>• Sell and distribute cannabis products that are cannabis plants or cannabis plant seeds to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act</li> </ul>	<p>Greenhouse/Outdoor: Agricultural Use</p> <p>Indoor: Industrial Use</p>

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Licence Type	Authorized Activities (according to the <i>Cannabis Act, 2018</i> )	Proposed Classification
	<ul style="list-style-type: none"> <li>• Send and deliver cannabis products that are cannabis plants or cannabis plant seeds to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or of a person authorized to sell cannabis under a provincial or territorial Act</li> <li>• Conduct ancillary activities (e.g., drying, trimming, milling, etc.)</li> </ul> <p>Note: Cultivation may be conducted indoors or outdoors</p>	
<b>Nursery</b>	<ul style="list-style-type: none"> <li>• Possess cannabis</li> <li>• Obtain cannabis plants or cannabis plant seeds by propagating, cultivating, harvesting</li> <li>• For the purpose of testing, alter the chemical or physical properties of the cannabis</li> <li>• Sell and distribute cannabis plants or cannabis plant seeds to other licence holders (cultivators, processors, analytical testers, researchers, cannabis drug licence holders)</li> <li>• Sell and distribute cannabis products that are cannabis plants or cannabis plant seeds to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act</li> <li>• Send and deliver cannabis products that are cannabis plants or cannabis plant seeds to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or of a person authorized to sell cannabis under a provincial or territorial Act</li> <li>• Conduct ancillary activities (e.g., drying)</li> </ul> <p>Note: Cultivation may be conducted indoors or outdoors</p>	<p>Greenhouse/Outdoor: Agricultural Use</p> <p>Indoor: Industrial Use</p>

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Licence Type	Authorized Activities (according to the <i>Cannabis Act, 2018</i> )	Proposed Classification
<b>Standard Processing</b>	<ul style="list-style-type: none"> <li>• Possess cannabis</li> <li>• Produce cannabis, other than obtaining it by propagating, cultivating, or harvesting</li> <li>• For micro-processing, the cannabis cannot be obtained by synthesis.</li> <li>• Sell and distribute cannabis to other licence holders (processors, analytical testers, researchers, cannabis drug licence holders)</li> <li>• Sell and distribute to licensed micro-cultivators or standard cultivators:               <ul style="list-style-type: none"> <li>○ dried cannabis, fresh cannabis, cannabis plants, or cannabis plant seeds</li> <li>○ cannabis produced for the purposes of testing that is necessary to determine the chemical characterization of cannabis, such as a reference standard</li> </ul> </li> <li>• Sell and distribute to licensed nursery:               <ul style="list-style-type: none"> <li>○ cannabis plants or cannabis plant seeds</li> <li>○ cannabis produced for the purposes of testing that is necessary to determine the chemical characterization of cannabis, such as a reference standard</li> </ul> </li> <li>• Send and deliver cannabis products to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or of a person authorized to sell cannabis under a provincial or territorial Act</li> </ul> <p>Note: Cannabis must be produced, packaged, labelled, stored, sampled and tested indoors</p>	<p>If associated with a commercial agricultural use: Accessory Farm Commercial</p> <p>If not associated with a commercial agricultural use: Industrial Use</p>
<b>Micro-processing</b>		

### 3. COMMUNITY CONCERNS

On September 14, 2019 staff participated in the City’s Food for Feedback Community Engagement BBQ to collect feedback regarding the City’s Cannabis Production Study. Attendees were consulted on six potential areas of consideration; the following table explains how each concern was considered in the recommendations being brought forward by staff.

Area of Consideration	Approach
<p><b>1) Job Opportunities</b></p> <p><b>2) Economic Development</b></p>	<p>The proposed approach seeks to maintain consistency with the federal and provincial framework for regulating cannabis production facilities and relies on existing policies rather than seeking to establish additional restrictions at the local level. Applications for cannabis production facilities are to be categorized based on their general use (i.e. industrial or agricultural) rather than creating an entirely separate category and corresponding set of policies. This streamlined approach has developed with input from the Burlington Economic Development Corporation and is in keeping with the Red Tape/Red Carpet initiative. The approach simplifies the planning approvals process for applicants and functions as a positive signal to businesses considering location in Burlington.</p>
<p><b>3) Security</b></p>	<p>The Cannabis Regulations contain detailed requirements for physical security measures, which are outlined in the Health Canada <a href="#">“Physical Security Measures Guide for Cannabis”</a>. As per section 63 of the Cannabis Regulations, the site must be designed in a manner that prevents unauthorized access. Examples of the key security requirements contained in the Cannabis Regulations and enforced by Health Canada are as follows:</p> <ul style="list-style-type: none"> <li>-The perimeter of the site must be monitored at all times by visual recording devices to detect any attempted or actual unauthorized access to the site.</li> <li>-The perimeter of the site 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 and any attempted or actual tampering with the system.</li> <li>-The intrusion detection system must be monitored continuously at all times (i.e. 365 days a year, 7 days a week and 24 hours a day) and licence holders should have a procedure in place when an alarm for the intrusion detection system of any operations area or storage area is triggered.</li> <li>-Access to each operations area and storage area must be restricted to individuals whose presence in the area is required by their duties. Each</li> </ul>

	<p>operations area and storage area must be surrounded by a physical barrier that prevents unauthorized access for standard cultivation, standard processing and sale for medical purposes with possession licence classes.</p> <p>-Outdoor grow areas are operations areas and must be surrounded by a physical barrier. A common physical barrier for outdoor grow areas is a chain-linked fence. If used, the fence should be taut and firmly secured to rigid metal posts. In some cases, the perimeter fence for the site may be used as the physical barrier for or may be a part of the physical barrier for an outdoor grow area. For outdoor grow areas, the entire perimeter of the grow area is secured with intrusion detection.</p>
<p><b>4) Odour Nuisance</b></p> <p><b>5) Lighting Nuisance</b></p>	<p>The Cannabis Regulations contain detailed requirements for production practices, which are outlined in the Health Canada “<a href="#">Good Production Practices Guide for Cannabis</a>”. As per section 85 of the Cannabis Regulations, any building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be equipped with a system that must be able to filter air to prevent the escape of cannabis odours associated with cannabis plant material to the outdoors.</p> <p>Licence holders must have a maintenance program in place to ensure that:</p> <ul style="list-style-type: none"> <li>-ventilation and air filtration are maintained in accordance with a schedule;</li> <li>-the presence of odours surrounding the building or part of a building are monitored in accordance to a schedule and responded to if necessary; and</li> <li>-inspection and repair activities occur when required.</li> </ul> <p>Licence holders who choose to grow cannabis outdoors must ensure that all activities associated with cannabis post-harvest (e.g., drying, trimming) are conducted within a building or part of a building and are conducted in compliance with the above.</p> <hr/> <p>To ensure that the rights of all rural Ontario residents are respected, the Ontario government passed Bill 146, the Farming and Food Production Protection Act (FFPPA), in May 1998. There are two main themes in the FFPPA:</p> <ul style="list-style-type: none"> <li>-Farmers are protected from nuisance complaints (including noise, odour, dust, light, vibration, smoke and flies) made by neighbours, provided they are following normal farm practices.</li> <li>-No municipal by-law applies to restrict a normal farm practice carried on as part of an agricultural operation (this is why no minimum setback has</li> </ul>

	<p>been recommended for outdoor cannabis production within the Agricultural Area).</p> <p>What is normal, or not, varies depending on location, type of farm, method of operation, and timing of the farm practice. Normal is site specific for a given set of circumstances and may change over time. The Act defines a normal farm practice as one which: "is conducted in a manner consistent with proper and acceptable customs and standards, as established and followed by similar agricultural operations under similar circumstances, or makes use of innovative technology in a manner consistent with proper advanced farm management practices".</p> <p>The FFPPA established the Normal Farm Practices Protection Board (NFPPB) to hear from parties involved in formal complaints that cannot be resolved through mediation efforts. The NFPPB then conducts a hearing to determine if the disturbance causing the complaint results from a normal farm practice. The FFPPA would apply to cannabis production facilities operating as an agricultural use in agricultural areas and would address nuisance issues relating to both lighting and odour.</p> <hr/> <p>Cannabis production facilities operating as an industrial use would be subject to the City's Site Plan Control By-law and the associated design guidelines, which include <a href="#">Outdoor Lighting Design Guidelines</a>. Further, industrial facilities are subject to the provincial "<a href="#">Guideline D-6 Compatibility between Industrial Facilities</a>" which is applied in the land use planning process to prevent or minimize future land use problems due to the encroachment of sensitive land uses and industrial land uses on one another.</p> <p>The guideline applies to all types of proposed, committed and/or existing industrial land uses which have the potential to produce point source and/or fugitive air emissions such as noise, vibration, odour, dust and others, either through normal operations, procedures, maintenance or storage activities, and/or from associated traffic/transportation.</p>
<p><b>6) Other</b></p>	<p>Other concerns related to energy consumption, morality, and the protection of agricultural lands and greenspace. Energy consumption and morality are not within the scope of this study and the protection of agricultural lands/greenspace is addressed via the updated Provincial policy framework, which requires the identification and protection of an Agricultural System and a Natural Heritage System. The City is in the process of implementing these policies through its new Official Plan.</p>

### 3. A) HEALTH CANADA LICENCE APPLICATION REQUIREMENTS

Health Canada’s [Cannabis Application Licencing Application Guide](#) outlines the detailed requirements for the submission of an application for a cannabis production licence. The three components that are most relevant to local planning processes are:

- Notice to Local Authorities
- Site Details
- Site Ownership Details

#### 1. Notice to Local Authorities

Prior to submitting an application in the federal Cannabis Tracking and Licensing System (CTLS), applicants for licences to cultivate, process and sell for medical purposes (with possession of cannabis) must provide a written notice to local authorities who are located in the area of the proposed site, and submit a copy of this notice as part of their application, along with the following:

- The date each notice was sent or provided, and the name, title and address of the senior official to whom it was addressed.
- A copy of the actual notices provided.

Component	Requirements
Recipients	<p>The notice must be provided to a senior official of the following local authorities:</p> <ul style="list-style-type: none"> <li>• the local government</li> <li>• the local fire authority</li> <li>• the local police force or Royal Canadian Mounted Police detachment (RCMP) that is responsible for providing policing services to that area</li> </ul>
Content	<p>The content of the notice must include:</p> <ul style="list-style-type: none"> <li>• the name of the applicant</li> <li>• the expected date on which the applicant will submit the application to Health Canada</li> <li>• the class and subclass if applicable of licence that is being sought and the cannabis-related activities that are expected to be conducted under that licence</li> <li>• the site address (and address of each building on site, if applicable) at which the applicant is expecting to conduct cannabis-related activities</li> </ul>

#### 2. Site Details

Applicants are required to submit a detailed explanation of the site associated with the proposed operation. Requirements differ depending on the licence class. For Processing,

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Cultivation and Sale for Medical Purposes with Possession Licences, in addition to documents submitted as a part of a CTLS application, applicants are required to submit a site evidence package with visual evidence to demonstrate the completion and functionality of their facility. This means that applicants are unable to obtain a Health Canada licence prior to engaging in any municipal permitting process that may be required for the facility to be considered ready for operation.

Component	Requirements
Complete site address	<p>Include Canadian address as well as latitude and longitude.</p> <p><b>Important:</b> The CTLS allows for entry of a single address in relation to a site. Should the site have multiple addresses (e.g., several buildings in an area used exclusively by the licence holder), all site details as outlined in this section must be uploaded into the CTLS as a separate document titled Additional Site Details. This must be uploaded in the "Site Survey" section of the CTLS.</p>
Site survey	A building location survey, location certificate or similar document, prepared and certified by a person qualified to do so in the jurisdiction where the site is located, such as a qualified land surveyor. The survey must accurately depict the site at the point of submission.
Aerial view	A clear and legible aerial view of the proposed site and surrounding lots to within 500 metres. The aerial view must accurately depict the site at the point of submission.
Production capacity (Not required for sale for medical purposes)	<p>An estimate of the proposed annual production amount (e.g., kg per year, number of plants or seeds per year) for each applicable cannabis class as found in Schedule 4 of the Act.</p> <p>The total combined area (m<sup>2</sup>) of the grow areas and the total combined area (m<sup>2</sup>) of the operations areas excluding grow areas that are being proposed for licensing. For the grow areas, the total combined area should include all surface areas, taking into account if multiple surfaces are being utilized (e.g., vertically arranged).</p>
Areas (buildings and rooms, outdoor areas) and activities	Each outdoor area (if applicable), and indoor area (building or part of building) including rooms must be named and this name must be provided. The names used to identify each area must match all other information submitted (e.g., on the site plan). All activities conducted,

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	<p>and the room in which they are conducted must also be identified (e.g., operations area [either cultivation or non-cultivation], testing area, storage area or sales with possession area or sales without possession area). There is no requirement to identify areas and rooms in the CTLS in which no activities with cannabis will take place (e.g., lavatory) or transitory areas (e.g., hallways). However, these areas and rooms should still be identified on the floor plan(s).</p> <p>More than one activity can occur in each area. Additional information may be requested to assess how the proposed activities meet all regulatory requirements.</p>
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### 3. Site Ownership Details

Applicants are required to confirm either site ownership, or site owner consent, at the time of their licence application. This is another reason that applicants are unable to obtain a Health Canada licence prior to engaging in any municipal permitting process that may be required for the facility to be considered ready for operation.

Component	Requirements
Site owner	<p>If the site is owned by the individual or the corporation applying for the licence, this must be indicated by linking their Account ID in the CTLS.</p> <p>If the site is owned by another individual(s) or corporation, a site owner consent form is required (see section below).</p>
Site owner consent form, if the site or any portion of the site is not owned by the applicant	<p>A declaration, signed and dated by all the site’s owners— or, if the owner is a corporation, by an authorized representative of the owner — consenting to activities with cannabis being conducted at the site.</p> <p>The consent form must contain:</p> <ul style="list-style-type: none"> <li>• the full address of the site or any portion of the site for which the owner is not the applicant</li> <li>• the class and subclass if applicable of the licence being applied for, and the proposed activities to be conducted on-site</li> <li>• a declaration signed by all owners of the site stating that they:               <ol style="list-style-type: none"> <li>a) are the owner(s) of the site, as described</li> </ol> </li> </ul>

	<p>b) are aware of the activities with cannabis that the applicant proposes to conduct at the site</p> <p>c) consent to those activities with cannabis being carried out at that site</p>
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### 3. B) HEALTH CANADA ENFORCEMENT

Generally, the Cannabis Act seeks to prevent youth accessing cannabis, protect public health and public safety, and deter criminal activity. Health Canada receives cannabis-related reports from consumers, health professionals, industry and the general public as it relates to its area of responsibility. For concerns and complaints that might represent a possible violation of the federal cannabis laws or regulations, individuals may contact Health Canada’s Cannabis Legalization and Regulation Branch (CLRB) through the [Cannabis Reporting Form](#). The form is intended for use by the general public, municipalities, and variety of other stakeholders, and includes “Cannabis site-related issue (e.g., odour, security)” among the drop-down options available to indicate the nature of the report.

All reports are reviewed to determine if they are within Health Canada’s responsibilities. If so, they will be assessed and prioritized for action according to public health and safety risk. High-risk reports will receive priority attention. Actions taken will be consistent with Health Canada’s [Compliance and Enforcement Policy](#) for the Cannabis Act with the objective of achieving compliance using the most appropriate level of intervention. Not all reports will lead to a reply from Health Canada. The Compliance and Enforcement Policy for the Cannabis Act details how Health Canada manages risks posed to public health and public safety in connection with cannabis through a variety of compliance and enforcement activities based on:

- *Compliance promotion*
  - Includes educational activities and information sharing on legislative and regulatory matters, such as policies and guidance documents intended to help regulated parties better understand the requirements and their responsibilities.
- *Compliance monitoring*
  - Includes gathering and analyzing information, carrying out compliance verification activities and collaborating with other regulatory agencies. As part of monitoring and verifying compliance, Health Canada has the authority to conduct inspections.
- *Enforcement actions*
  - Includes voluntary compliance measures initiated by the regulated party and measures initiated by Health Canada, such as:
    - Issuing warning letters to non-compliant regulated parties
    - Issuing public advisories or other forms of risk communication

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- Seizure and detention
- Refusing, suspending or revoking an authorization, including a licence or permit
- Issuing administrative monetary penalties up to \$1 million
- Issuing a ministerial order to recall products from the market, conduct tests or studies, produce information or documents, or take other measures

Health Canada may refuse to issue a licence under circumstances set out in the *Cannabis Act* and its Regulations, specifically if:

- issuing a licence is likely to create a risk to public health or public safety including the risk of diversion; or
- there are reasonable grounds to believe that false or misleading information has been submitted.

Health Canada considers many factors to inform its compliance monitoring and enforcement activities, and to determine the most appropriate level of intervention, including:

- Public health and public safety risk
  - The real or potential risk to public health or public safety
  - The risk of diversion of a product to an illicit market
- Behaviour of the regulated party
  - Whether the regulated party acted with indifference, recklessness or premeditation
  - The degree of co-operation and responsiveness offered by the regulated party once non-compliance is identified
- Compliance history
  - Previous compliance issues
  - Actions taken by the regulated party to comply with the law
- Other factors
  - The likelihood that the same problem will recur
  - The expected impact and success of compliance and enforcement actions
  - The need to maintain public confidence in the integrity of the regulatory regime

Under the Act, regulated parties have the right to request a review of decisions relating to certain compliance and enforcement measures undertaken by Health Canada, including administrative monetary penalties and ministerial orders. There are also opportunities to be heard on licensing decisions, including licence amendment, suspension and revocation.