



CANNABIS
COMPLIANCE
INC.

AGENDA

- Presentation of Cannabis Regulations Coming into Force October 17, 2019
 - Licensing overview
 - New product classes and restrictions
 - New requirements and challenges



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Director – Quality and
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WHO IS CCI?

CCI is a global consulting firm with subject matter expertise in the regulated consumer products industry

- A legacy of success based on knowledge of safety and compliance best practice
- Fifteen years of licencing and regulatory expertise
- Successful completion of +66,000 applications
- The original consulting company in Canada to offer a breadth of cannabis services
- A proud Canadian company with a global presence in more than 25 countries around the world



Cannabis Licensing

THE FUTURE

Now

(Post-October 17th, 2018)

- Recreational and medicinal
- Craft cannabis

October 2019

- Edible cannabis
- Cannabis extracts
- Cannabis topicals

Post-October 2019

- Cannabis Health Products
- Veterinary Health Products
- Cosmetics and Household Use Products



TYPES OF CANNABIS LICENCES

The Cannabis Act and Regulations, introduced new facility licensing classes to cultivate, manufacture, research, test and sell cannabis and cannabis products.

- Cultivation – Standard
- Cultivation – Micro
- Cultivation – Nursery
- **Processor – Standard**
- **Processor – Micro**
- **R&D**
- **Sale for Medical Purposes**
- **Cannabis Drug**
- Analytical Testing
- Industrial Hemp



PROCESSING LICENCES: STANDARD & MICRO

Standard Processing Licence permits:

- Processing unlimited quantities of cannabis.
- Formulation development, manufacturing, packaging and labelling.
- Sale of cannabis to licence holders: Cultivation, Processor, R&D, Analytical Testing and Cannabis Drug Licence.
- Sale of cannabis products:
 - Recreational distribution via licensed provincial retail
 - Medical distribution via Federal Medical Sales Licence holders

Micro Processing Licence permits:

- Limited processing of a total of 600 kg of dried cannabis (or equivalent) annually.
- All other permissions as a Standard Processor Licence



SALE, R&D, DRUG & ANALYTICAL LICENCES

Federal Medical Sales Licence:

- Patient registration and prescription processing.
- Direct or indirect sale to patients

R&D Licence:

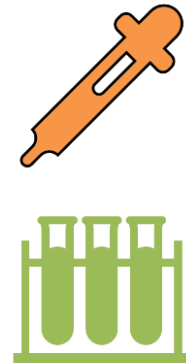
- Limited cultivation, processing and clinical testing based on protocol.
- Development, manufacturing, packaging and labelling.

Cannabis Drug Licence:

- Cannabis drug development, manufacturing, distribution and sale.
- Traditional pharmacy sale via prescription

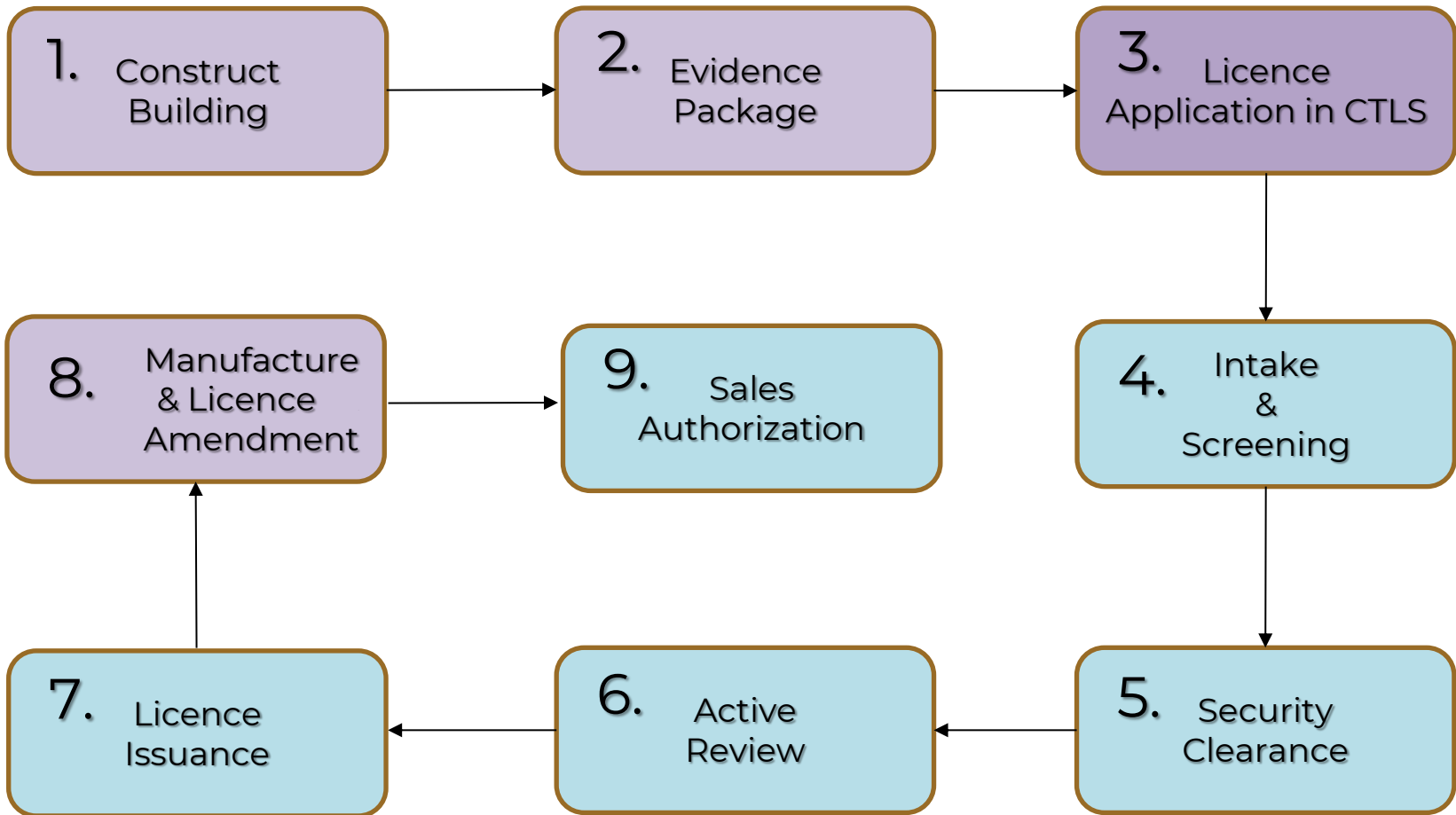
Analytical Testing Licence:

- Mandatory third-party analysis
- Product stability trials



LICENCE – STANDARD & MICRO

Health Canada's Graduated Licensing Approach:



WHAT'S NEW

Micro
Cultivators

Standard
Cultivators

Micro
Processors

Standard
Processors

CONCENTRATES

Edibles

- Solid (consumed as food)
- Beverage



Extracts

- Ingested – not as food
- Inhaled – vaped



Topicals

- External body use



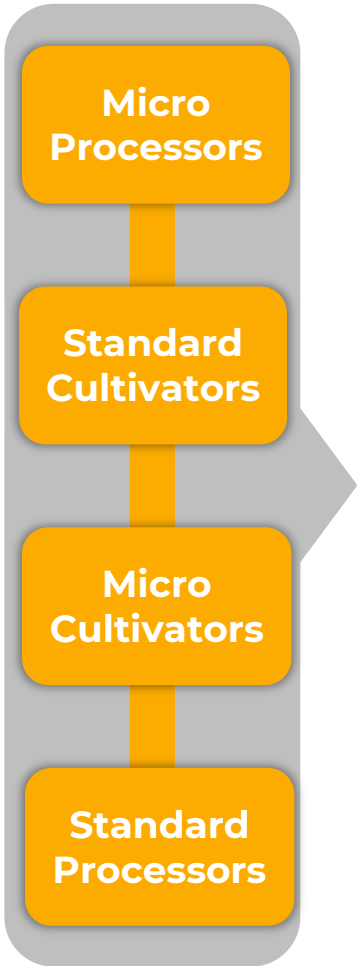
A note on packaging....



Plain packaging requirements currently in place for cannabis products are proposed to remain in effect for edible cannabis products (more on this later...)

THE PLAYERS

NEW ACTS & REGS



The Cannabis Regulations

Safe Food for Canadians Regulations

Tobacco and Vaping Act

THE CHALLENGES

NEW PROCESSES



HC Guidance Documents

Health Canada is committed to ensure public health and safety are paramount.

For licence holders, compliance is key.

- Recent HC publications:

- CTLS User Guide
- Licensing Application Guides
- Physical Security Requirements
- Licence Management Guide
- Excise Tax Licence and Fees Management
- Good Production Practices
- Packaging and Labelling
- Product Notices
- Promotional Prohibitions
- Regulatory Reporting
- Mandatory Testing Requirements
- Voluntary Recall Guide
- Mandatory Testing Requirements
- ...



HACCP & PCP

HACCP (Hazard Analysis and Critical Control Point): A systematic approach to identifying, evaluating and controlling food safety hazards with the goal of producing safe foods

- HACCP was developed in partnership between Pillsbury and NASA to develop food for use in space
- Goal: 100% assurance that food is free from bacterial/viral pathogens, heavy metals, toxins, chemicals and physical hazards

PCP (Preventative Control Plan): Based on HACCP principles and encompasses additional quality and regulatory requirements



Cannabis Products

Authorized Classes of Cannabis

SCHEDULE 4

(Section 33 and subsection 151(3))

Classes of Cannabis That an Authorized Person May Sell

Item	Class of Cannabis
1	dried cannabis
2	cannabis oil
3	fresh cannabis
4	cannabis plants
5	cannabis plant seeds

Amendments to Schedule 4

Classes of Cannabis That an Authorized Person may sell

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- 6. ~~edibles containing cannabis~~ → edible cannabis
- 7. ~~cannabis concentrates~~ → cannabis extracts
- 8. cannabis topicals



ABOUT EDIBLE CANNABIS

Substance or mixture of substances (i.e. products) containing cannabis that are intended to be consumed in the same manner as food

- Major concerns are food safety; preventing foodborne illnesses, accidental and overconsumption; and protection of our export markets:
 - Edible cannabis products must be produced in a separate building from conventional food products
 - All licensed processors of cannabis edibles and extracts must have a Preventative Control Plan (PCP)
 - Recognize delayed onset effects of ingested cannabis compared to inhaled cannabis



SPECIFICATIONS

Cannabis products must be shelf stable at room temperature.

- Must not contain poisonous or harmful substances
- No fortification with vitamins or mineral nutrients
- Must not contain caffeine as a food additive, but naturally occurring caffeine is permitted – for example:
 - Caffeine from chocolate, coffee, and tea to a maximum level of 30 mg per package
- May contain up to 0.5% w/w ethyl alcohol



THC AND PACKAGE SIZE LIMITS

Depending on the type of product, there are very specific requirements that must be adhered to

- 10mg THC per package of edible cannabis
- 1000mg THC per package for cannabis extracts and topical cannabis products
- 10mg THC per unit or dispensed amount for ingested cannabis extracts
- No proposed THC limit per dispensed amount for cannabis extracts intended for inhalation
- Cannabis extracts (liquid) maximum volume 90 mL
- 7.5 g for cannabis extracts containing ethanol that are intended for ingestion
- 7.5 g for all “cannabis concentrates” (products with THC potency > 3% w/w)



PACKAGING & LABELLING

On the label, you must include: ingredient list, product name, allergens, durable life/best before date (if <90 days), and a cannabis-specific nutrition facts table.

- Cannabis-specific requirements (e.g. plain packaging, THC symbol, warning statements, THC/CBD content) also apply
- Food-grade, child-resistant packaging
- Exterior container cannot contain more than one immediate container
- Cannot provide additional information about vitamin/mineral content outside the NFT
- Cannot represent product(s) as suitable for use in addressing specific dietary needs – for example:
 - High in protein
 - Suitable for low-calorie diet



EXPANDED INGREDIENTS

Unlike dried and fresh cannabis; edible cannabis, cannabis topicals, and cannabis extracts may contain “other” ingredients

- Previous regulation limited ingredients in cannabis products to cannabis, oil, and preservatives, no “other” ingredients
- Cannabis products will be permitted to contain “other” ingredients
 - Food and pharmaceutical ingredients and additives (flavours, emulsifiers, sweeteners etc.)
 - Introduces concerns of allergen cross-contamination and quality requirements now extend to all ingredients



CHALLENGES & RESTRICTIONS

QAP will need to have knowledge and experience of the cannabis class being produced, otherwise licence holder must retain another individual with those qualifications

- Requirements in accordance with the Safe Food for Canadians Act and Regulations
- Addition of hand cleaning stations
- Annual recall simulations now a requirement
- Can't manufacture edible cannabis products in the same facility (building) as conventional food products



CHALLENGES & RESTRICTIONS

The use of certain claims, terminology, logos, and manufacturing processes are prohibited

- No health or cosmetic benefit claims – these are recreational products only
- Must not represent edible cannabis as being a suitable means of meeting dietary requirements
- Prohibition on all representations that associate cannabis products with alcohol:
 - No use of the terms “beer” or “wine”
 - No use of company name or logo that manufactures alcoholic beverages
- Must not appeal to youth





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Thank you.