

International *Cannabis* Regulation(s) and Market Opportunities

Legal and Practical Issues in the Evolving
World of Cannabis Regulation



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International treaties on the control of certain medicines



UNODC

United Nations Office on Drugs and Crime

The International Drug Control Conventions

Single Convention on Narcotic Drugs of 1961
as amended by the 1972 Protocol

Convention on Psychotropic Substances of 1971

United Nations Convention against Illicit Traffic in
Narcotic Drugs and Psychotropic Substances of 1988
with final acts and resolutions

➤ 1961 'Single' Convention

*Single Convention on **Narcotic Drugs** of 1961,
as amended by the 1972 Protocol*

Compilation of pre-WWII opium treaties. Controls medications
("drugs") based on similarity with cannabis, coca or opium.

➤ 1971 Convention

*Convention on **Psychotropic Substances** of 1971*

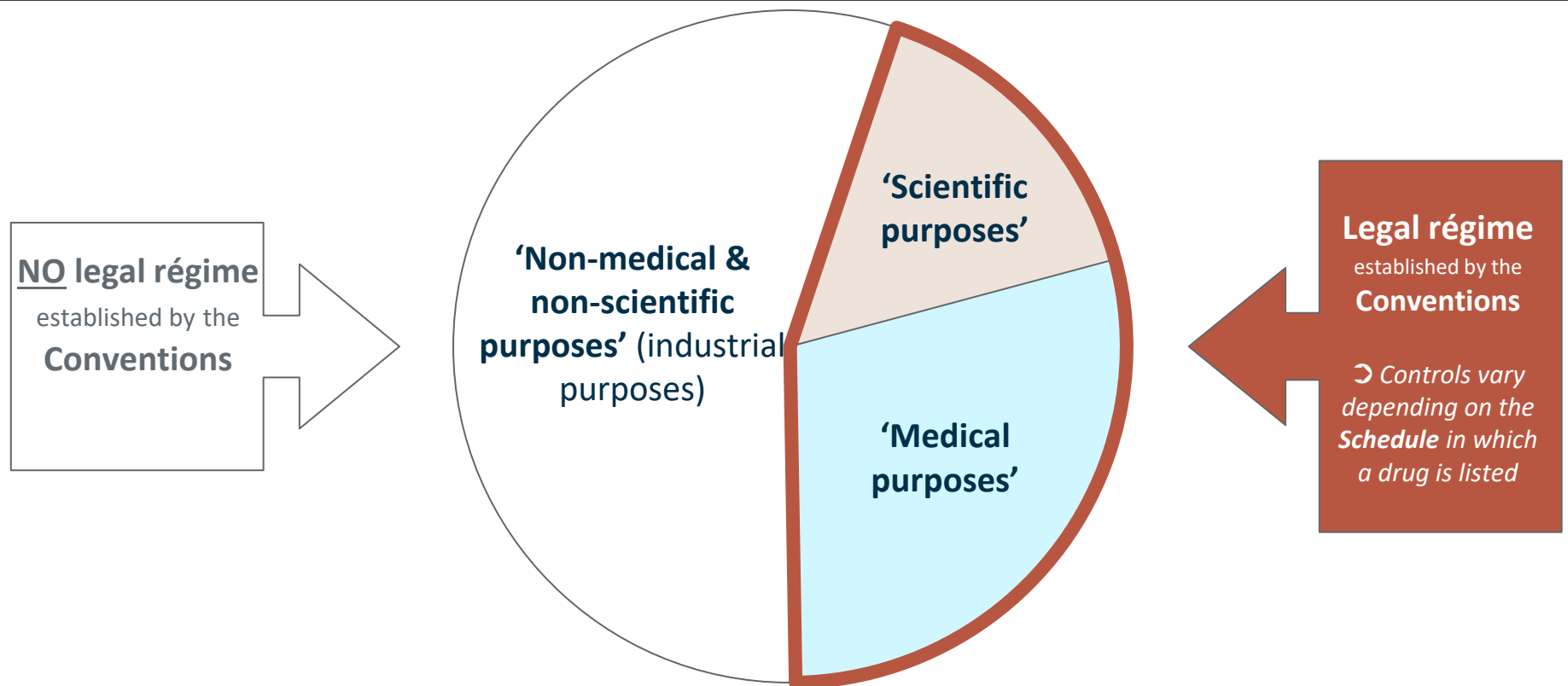
Controls other and novel psychoactive substances
as a complement to the 1961 Convention.

The international drug control Conventions

‘most of the national drug statutes ... share a high degree of conformity with the Single Convention and its supplementary treaties. The Single Convention has been used as the basis for the standardization of national drug-control laws.’

Source: Gallagher, C.T., Atik, S.K., Isse, L., & Mann, S.K. (2020),
“Doctor or drug dealer? International legal provisions for the legitimate handling of drugs of abuse”,
Drug Science, Policy and Law Vol. 6, pp. 1–9, DOI:10.1177/2050324519900070

Medical & scientific uses: framework of
the Conventions and mandate of the ECDD



Schedules

1961 Schedule I + IV

1961 Schedule I

1961 Schedule II

1961 Schedule I + III

1961 Schedule II + III

1971 Schedule I

1971 Schedule II

1971 Schedule III

1971 Schedule IV

Definition of a 'drug' in the 1961 and 1971 Conventions:

drug = listed in the Schedules.

WHO Expert Committee on Drug Dependence: from 1948 to 2020

Scheduled cannabis and cannabinoids

➤ **‘Cannabis’** – ‘the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated’ (1961 Convention, Art. 1[b]). ‘the term ‘cannabis’ [...] covers all tops including those which are not yet dried, as well as those of the male plants’ (Commentary, p.2 §1).

➤ **‘Cannabis resin’** – ‘the separated resin, whether crude or purified, obtained from the cannabis plant’ (1961 Convention, Art. 1[d]). ‘resin, however, becomes “cannabis resin” only when it is “separated” from the plant; without such separation, it remains a part of the cannabis plant, and if in the top part, of “cannabis”’ (Commentary, p.5 §3)

➤ **‘Extracts and tinctures of cannabis’** – No definition is provided.

➤ **‘Dronabinol and its stereoisomers’** – Δ^9 -THC

➤ **‘Isomers of THC’** – $\Delta^{6a(10a)}$ -THC, $\Delta^{6a(7)}$ -THC, Δ^7 -THC, Δ^8 -THC, Δ^{10} -THC, $\Delta^{9(11)}$ -THC

➤ **‘Cannabidiol’**

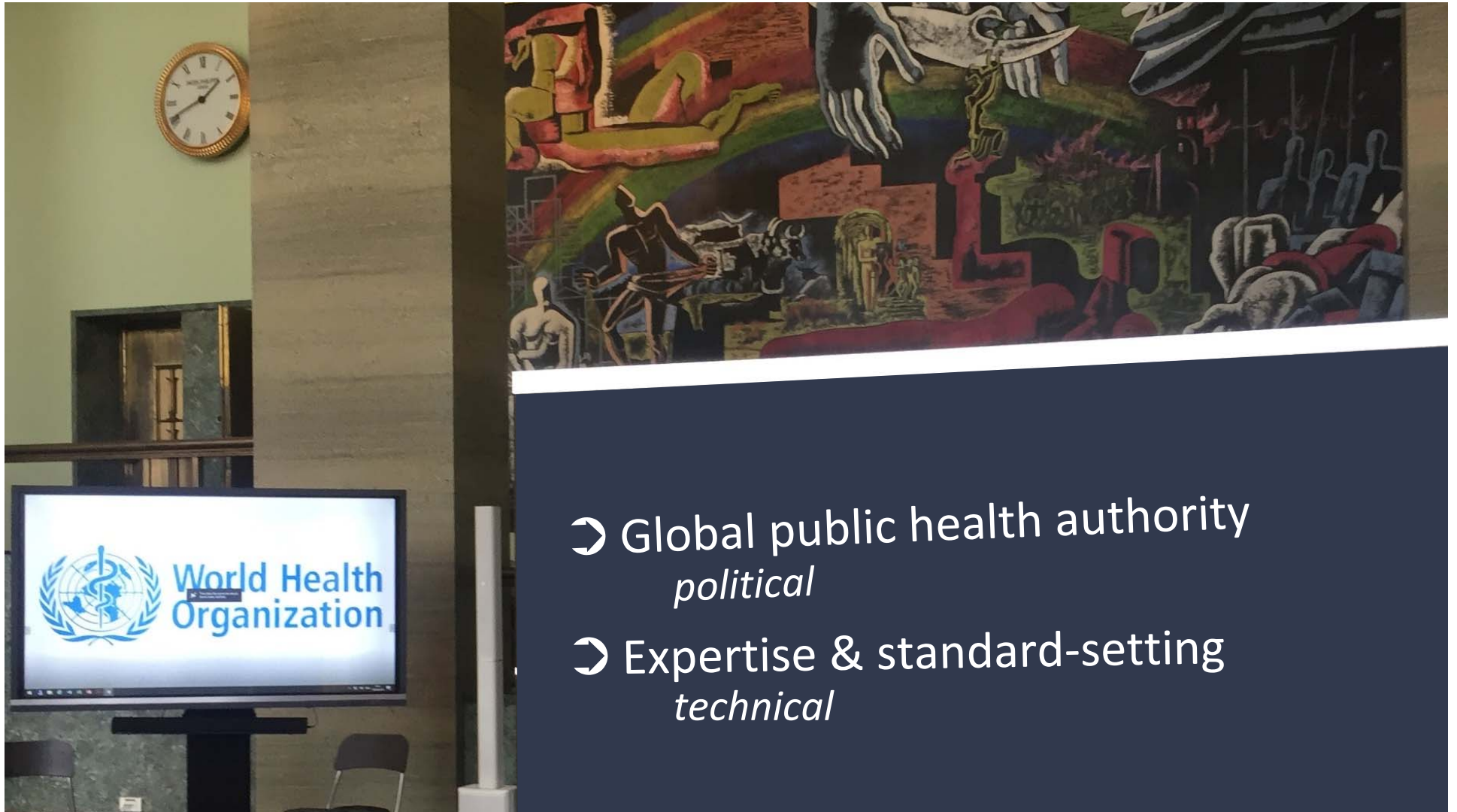
➤ **‘Cannabis plant’** – ‘any plant of the genus Cannabis’ (1961 Convention, Art. 1[c]),

**‘Drugs’ in the
meaning of the
Conventions**

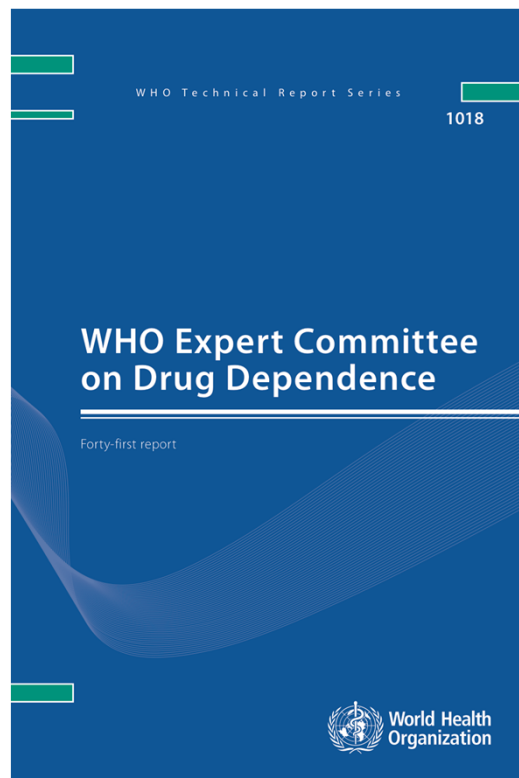
Not ‘drugs’

Scheduling of cannabis and cannabinoids before vote

1961 Schedule I + IV	cannabis cannabis resin	THC isomers	1971 Schedule I
1961 Schedule I	extracts & tinctures	Δ^9 -THC	1971 Schedule II
1961 Schedule II			
1961 Schedule I + III			1971 Schedule III
1961 Schedule II + III			1971 Schedule IV



- Global public health authority
political
- Expertise & standard-setting
technical



1968 – present

Expert Committee on Drug Dependence (ECDD)

1964 – 1968

Expert Committee on Dependence Producing Drugs

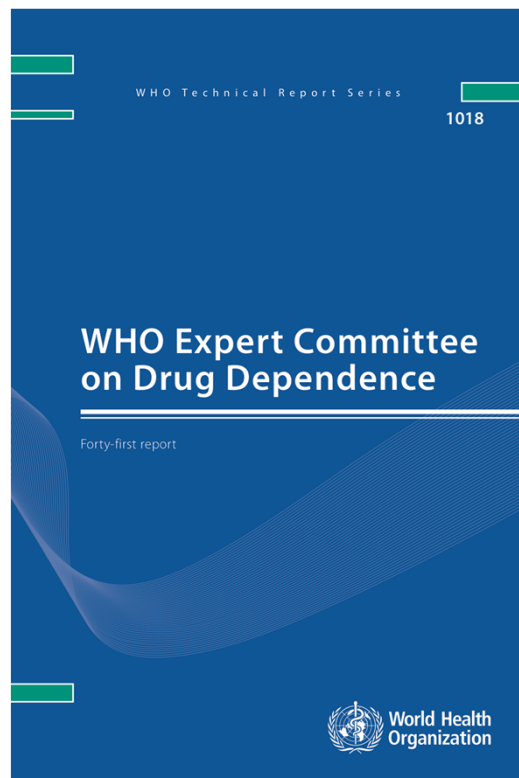
1955 – 1964

Expert Committee on Drugs Liable to Produce Addiction

1948 – 1955

Expert Committee on Habit-Forming Drugs

WHO Expert Committee on Drug Dependence: from 1948 to 2020



WHO's mandate under the 1961 and 1971 Conventions:

- **Scientific assessment of substances**
- **Recommendation on changes in the scope of control of substances to:**
 - add a substance to a Schedule
 - remove a substance from a Schedule
 - move a substance to a different Schedule
- **Criteria:** similarity, convertibility, therapeutic uses, liability to produce dependence or 'ill-effects'

Mandate of the WHO Expert Committee on Drug Dependence under the drug control Conventions

WHO ECDD

Recommendation

*from the 40th meeting in
June 2018*

5.5 The Committee recommended that preparations considered to be **pure CBD should not be scheduled** within the International Drug Control Conventions.

WHO ECDD Recommendation No. 5.1

*from the 41st meeting in
Novembre 2018*

The Committee recommended
that cannabis and cannabis
resin be **deleted from**
Schedule IV of the 1961
Single Convention on
Narcotic Drugs

WHO ECDD Recommendation

No. 5.4

*from the 41st meeting in
Novembre 2018*

The Committee recommended **deleting “extracts and tinctures of cannabis” from Schedule I of the 1961 Single Convention on Narcotic Drugs.**

WHO ECDD Recommendation

No. 5.6

*from the 41st meeting in
Novembre 2018*

The Committee recommended that preparations containing *delta*-9-THC (dronabinol), produced either by chemical synthesis or as a preparation of cannabis, that are compounded as pharmaceutical preparations with one or more other ingredients and in such a way that *delta*-9-THC cannot be recovered by readily available means or in a yield which would constitute a risk to public health, be added to **Schedule III of the 1961 Convention**.

WHO ECDD Recommendations

Nos. 5.2

*from the 41st meeting in
Novembre 2018*

The Committee recommended the **deletion** of dronabinol and its stereoisomers (*delta*-9-THC) **from the 1971 Convention** on Psychotropic Substances, Schedule II, subject to the Commission's adoption of the recommendation to **add dronabinol and its stereoisomers (*delta*-9-THC) to Schedule I of the 1961 Single Convention** on Narcotic Drugs.

WHO ECDD Recommendations

Nos. 5.3

*from the 41st meeting in
Novembre 2018*

The Committee recommended that tetrahydrocannabinol (understood to refer to the **six isomers** currently listed in Schedule I of the 1971 Convention) be **deleted from the 1971 Convention** on Psychotropic Substances, subject to the Commission's adoption of the recommendation to **add tetrahydrocannabinol to Schedule I of the 1961 Single Convention** on Narcotic Drugs.

Recommended changes in the scheduling of THC

tetrahydrocannabinol									
$\Delta^{6a(10a)}$	$\Delta^{6a(7)}$	Δ^7	Δ^8	Δ^9				Δ^{10}	$\Delta^{9(11)}$
				(+)cis	(+)trans	(-)cis	(-)trans		
71-Sch.I				71-Sch.II		61-Sch.IV ^a 61-Sch.I ^a or 71-Sch.II ^b		71-Sch.I	
61-Sch.I 61-Sch.III ^c									

- Current international controls on THC
 - Changes recommended by WHO
- (a) Only when obtained from *Cannabis sativa* (INCB 2019, Form P, V.18-02480(E))
 (b) Only when 'from synthetic origin' (*ibid.*)
 (c) Only for some preparations for medical use, depending on each jurisdiction (ECDD41)

Adapted from: Riboulet-Zemouli K
(2020) 'Cannabis' ontologies I.
Drug Science, Policy and Law DOI:
10.1177/2050324520945797

Scheduling of cannabis and cannabinoids before

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1961 Schedule II			
1961 Schedule I + III			1971 Schedule III
1961 Schedule II + III			1971 Schedule IV

Thank you!

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International Cannabis Regulation and Market Opportunities

Eileen McMahon

Chair of Food and Drug Regulatory/IP Groups Torys LLP

December 9, 2020

Toronto, Ontario, Canada

Overview

- History in Canada
- Current state
- What is encompassed
- Current status of licenses
- Canada's Treaty obligations
- Opportunities for US companies



I would like to thank Sebastian Gorlewski, an articling student at Torys LLP, for his assistance in preparing this presentation

History of Cannabis in Canada

- Cannabis was a scheduled “narcotic” as defined by s. 2(1)(a) of the *Narcotic Control Regulations (NCR)* to the *Controlled Drugs and Substance Act (CDSA)*
- 2000 - Historically, cannabis for medical use has been subject to decisions under the *Canadian Charter of Rights (R v. Parker)*
- 2001 - *Marihuana Medical Access Regulations* to CDSA
 - ‘authorized’ individuals to grow own cannabis subject to physician prescription
- 2013 - *Marihuana for Medical Purposes Regulations* to CDSA
 - ‘authorized’ individuals to grow own cannabis or purchase dried cannabis from licensed producer subject to physician prescription
- 2015 - *Access to Cannabis for Medical Purposes Regulations* to CDSA
 - Expanded rights for licensed producers to produce and sell cannabis oil and fresh cannabis buds and leaves in addition to dried cannabis

1900s- Early 2000s

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2013

Marihuana for Medical Purposes Regulations to CDSA

‘authorized’ individuals to grown own cannabis or purchase dried cannabis from licensed producer subject to physician prescription



October 17, 2018

Legalization

Passing of the *Cannabis Act* and its *Regulations* which allowed for recreational usage

2001

Marihuana Medical Access Regulations to CDSA

‘authorized’ individuals to grow own cannabis subject to physician prescription



2015

Access to Cannabis for Medical Purposes Regulations to CDSA

Expanded rights for licensed producers to produce and sell cannabis oil and fresh cannabis buds and leaves in addition to dried cannabis



Cannabis Act and Regulations

- October 17, 2018
- Overarching framework to regulate cannabis
- Major change: recreational Adult Use Cannabis
 - Permits individuals who are 18 years of age or older to cultivate, propagate, and harvest up to four cannabis plants in their dwelling-house
 - Creates licensing framework for entities that cultivate, produce, distribute cannabis
 - Introduces packaging, labelling and promotion requirements for cannabis and cannabis accessories (will be discussed later)



What Is Encompassed?

- Cannabis includes any part of a cannabis plant (i.e. includes THC and CBD)
- Cannabis includes any substance or mixture of substances that contains or has on it any part of such a plant
- Cannabis includes any substance that is identical to any phytocannabinoid produced by or found in such a plant
- There are some exclusions



What About Hemp?

- Historical: since 1998, Canada has allowed for the planting and processing of industrial hemp
- *Industrial Hemp Regulations*
 - Regulations moved under Canada's Cannabis Act (2018)
 - activities related to the possession, production and sale or distribution of industrial hemp, including importation and exportation, require a license



What About Hemp?

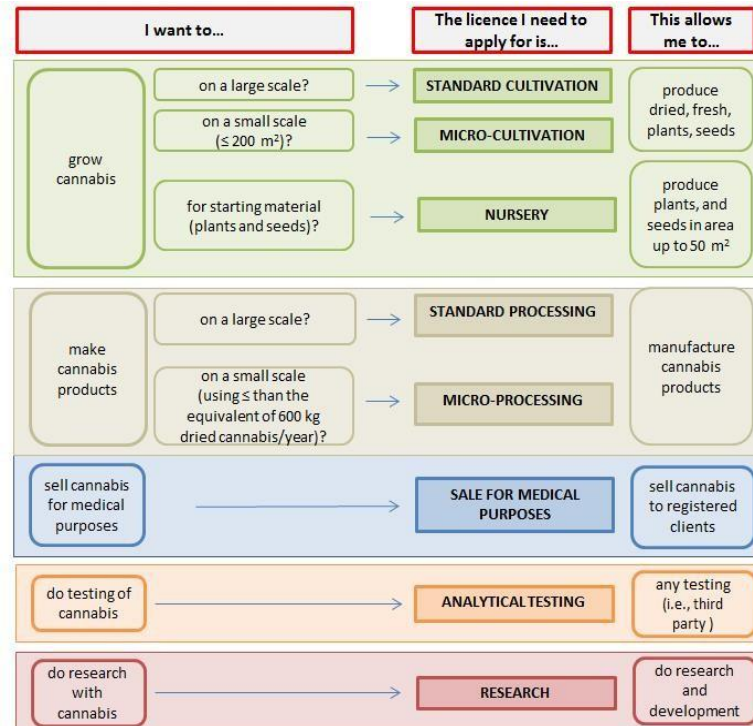
- Industrial hemp defined as cannabis plant, or any part of that plant, in which the concentration of THC is 0.3 % w/w or less in the flowering heads and leads



Federal Regulatory Framework

- The *Cannabis Regulations* establish six types of licenses
 1. Cultivation
 2. Processing
 3. Analytical Testing
 4. Sale
 5. Research
 6. Drug License
- The *Cannabis Regulations* establish seven classes of legal cannabis:
 1. Dried cannabis
 2. Fresh cannabis
 3. Cannabis plants
 4. Cannabis plant seeds
 5. Edible cannabis
 6. Cannabis extract (incl. oils)
 7. Cannabis topicals
- Import and export permits limited to medical or scientific purposes or in respect of industrial hemp

Federal Regulatory Framework



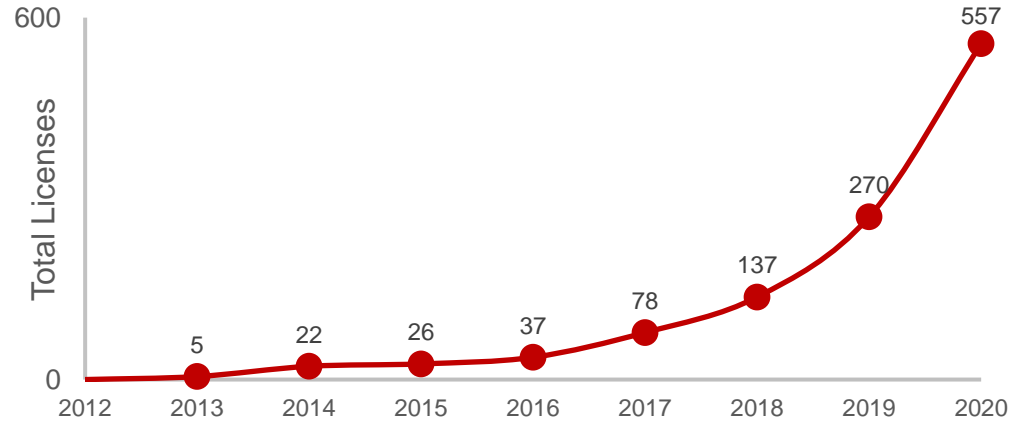
Source: Health Canada (<https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/industry-licensees-applicants/licensing-summary/guide.html#a5.2>)

Federal Licensing Requirements

- Security Clearances
 - Individuals occupying "key positions", directors, officers, majority shareholders, must hold valid security clearances issued by the Minister.
 - Minister may 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.
- Specific Real Estate
 - Land and buildings
- Cannabis Tracking System
 - Licensed entities must report monthly to Minister with specific information about their authorized activities with cannabis (e.g. cannabis inventory quantities)
- Post-licensing requirements
 - Inspections, reporting, recall activities



Federal Licensing Numbers



Data from Health Canada: <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/industry-licensees-applicants/licensed-cultivators-processors-sellers.html>

- As of December 6, 2020
 - 557 total licensed producers
 - 194 licensees permitted to produce edibles

Federal Advertising Restrictions

- Restrictive advertising provisions
 - No advertising of price except at point of sale
 - No promotion that is appealing to young persons
 - No lifestyle branding
 - No testimonials and endorsements
 - No health claims
- Permitted Promotional Activities:
 - Informational Promotion (e.g., characteristics of product)
 - Brand Preference Promotion
 - Only permitted by entities licensed under the *Cannabis Act*



Federal Packaging/Labelling

- Plain Packaging Rules
 - One uniform color
 - Mandatory warnings, including rotating health warning messages on Health Canada's list of standard health warnings
 - Health Canada standardized cannabis symbol
 - Information specifying THC and CBD content
 - Brand name may only be displayed once



SYNR.G
Fantasy Island
Indica Dominant
THC 12.00 - 18.00%
CBD 0 - 1.00%
from \$9.50
Taxes Included



SOLEI
Gather
Sativa Dominant
THC 12.00 - 22.00%
CBD 0 - 1.00%
from \$9.50
Taxes Included



Source: ocs.ca



Federal vs Provincial Oversight

- Legal in all provinces of Canada
 - Provinces can
 - increase legal age limit
 - establish locations for use
 - limit home growth
 - control retail sale and distribution within province
 - Municipal and regional governments
 - Determine distances of retail locations from schools
 - whether to permit retail stores



Cannabis Licenses – Provincial

- Varying models
 - Public – retail stores are operated by provinces who buy supplies from federally licensed producers (Quebec, NB, NS)
 - Private – provincial wholesaler/distributor and private retail locations (Alberta)
 - Hybrid – provincial wholesaler/distributor and mix of private and public retail locations (BC, ON)
- E.g., Ontario Cannabis Store (OCS)
 - Subsidiary of Liquor Control Board of Ontario
 - OCS is sole wholesaler
 - Federally licensed cannabis producers can only operate one retail location and must be at growing facility
 - Many Ontario municipalities “opted-out” of retail store model



ONTARIO CANNABIS STORE



Cannabis Products

- Current Permitted Cannabis Products
 - Fresh or dried leaves
 - Plants
 - Seeds
 - Single-Dose Format Products
 - E.g., pre-rolled, vaporization cartridges
 - Edibles
 - Topicals
 - Concentrates/Extracts (incl. Oils)



Cannabis Edibles

- Similarities to food facility regulation
 - Good Production Practices similar to requirements under the *Safe Food For Canadians Act*
 - Ingredients must be permitted under *Food and Drug Regulations*
- Additional Requirements
 - Cannot contain meat, poultry and fish
 - Cannot be fortified with vitamins and minerals
 - Cannot produce cannabis products in same facility as food products
 - Must be shelf stable (cannot require refrigeration or freezing)



Edibles (Cont.)

- Caffeine/Alcohol Restrictions
 - Cannot contain more than 30mg of naturally occurring caffeine and caffeine cannot otherwise be used as a food additive.
 - Cannabis infused alcohol beverages are prohibited
 - Selling cannabis products in the same location as alcohol beverages is prohibited
 - Using alcoholic-related brands with cannabis products is prohibited
 - Allows for carbonated beverages
- Packaging and Labelling
 - Ingredient lists
 - Allergen warnings
 - Nutrition Facts Table
 - Best Before Date
 - Allows for metallic beverage cans
- Prohibits products that are appealing to children



Cannabis Extracts

- Cannabis Extracts (e.g. extracts for vaping products)
 - Cannot contain prohibited ingredients under the *Tobacco and Vaping Products Act*
 - No sugars and sweetening agents
 - No vitamins, minerals, probiotics
 - Can contain flavouring agents
- Packaging and Labelling
 - Ingredient lists
 - Allergen warnings



Cannabis Topicals

- Cannabis Topicals (e.g. creams, balms, serums)
- Must comply with the ingredient requirements and prohibitions of the Cosmetic Ingredient Hotlist
- Packaging and Labelling
 - Ingredient lists
 - Intended Use (e.g. apply to skin)
 - Best Before Date
 - Ingredient Record Keeping
 - No claims can be made relating to health and cosmetic benefits



Cosmetics, Natural Health Products, Veterinary Health

- Cannabis is listed on the prescription drug list (eg if health claims made for cannabis)
- Cosmetics, NHPs and VHPs may not contain cannabis
 - May contain industrial hemp or hemp derivatives made from hemp grains with less than 10 µg/g of THC
- Once CBD (no psychoactive effects) is concentrated, falls under *Cannabis Act*



Regulatory Enforcement

LICENSE REVOKED

- Agrima Botanicals Corp.
- RavenQuest BioMed Inc.
- Evergreen Medicinal Supply Inc.

LICENSE SUSPENDED

- Ten-10 Ventures Corp.

LICENSE REINSTATED

- CannTrust Holdings Inc.
- Bonify Holdings Corp.

Canada's International Position

- Following Legalization, Canada was violating UN drug treaties
 - Criticized by UN Officials – Minister of Foreign Affairs acknowledges violation but rebukes criticism
- February 2019
 - WHO recommends the Commission on Narcotic Drugs (CND) to reschedule “cannabis and cannabis resin” from Schedule 4 of the Single Convention on Narcotics Drugs (1961)
- March 2020
 - Director General for Health Canada's controlled substances department provides report to UN stating that legalization has decreased illegal market share and has not increased cannabis usage
- December 2020
 - Canada votes to remove “cannabis and cannabis resin” from Schedule IV at CND's 63rd session
 - Vote passes (27-25, with one abstention)
 - i.e., no longer listed on the strictest control schedule, alongside heroin, cocaine, fentanyl but remains in Schedule I of the 1961 Convention.



Opportunities for US Companies

- Opportunities to:
 - Conduct research in Canada
 - Conduct trials in Canada
 - Acquire companies in Canada
 - Enter into partnerships/agreements with companies in Canada

Opportunities for US Companies

- Aphria buys SweetWater brewer
- Canadian pot stocks down, resulting in investment/acquisition opportunities
- MolsonCoors and Hexo launch five new brands (getting people interested in consuming cannabis in drinkable format)

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Questions?

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