

# Hemp regulations

**Market  
Research**

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**NEW ZEALAND  
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Te Taurapa Tūhono**

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# Introduction

## Purpose

Provide an overview of hemp regulations for a shortlist of countries. Classifying the regulations for Cannabidiol Products (CBD), Hemp Seeds (Industrial Hemp) and Tetrahydrocannabinol Products (THC).

## Methodology

Secondary market research methodology has been applied using information from government websites containing information on regulations for each country. These sources have been linked and quoted throughout the document.

## Warnings

The legal status of CBD (and THC) products is complex and constantly changing as more countries accept its safety and efficacy. For instance, Canada is set to legalise cannabis in 2018, which will also result in CBD supplements becoming legal.

There are a few countries that have a “loop holes” with regards to the importation of CBDs even though the products itself is not regulated. This is based on the fact that is allowed to import hemp products that contain <0.2/0.3% THC. In most cases the products are marketed as Hemp oil instead of CBDs. However, it is very important to note that investigating loopholes is going against a governments policy and therefore is high risk and unsustainable. It is recommended to avoid using loop holes while servicing international markets.

## Limitations

China has been removed from the overview, as the regulation within the country are strict around CBD and THC products and do not provide any significant opportunity.

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# Opportunities

The majority of governments have put in place stringent security and control measure for the consumption and import of hemp products. Countries are very hesitant in making it easy to import products into their countries that can be considered a narcotic substance. For this reason there are usually quite a lot of barriers that customers and companies have to go through to import hemp products into a country. Usually a cultivator license, the establishment of a local entity, and-or a local representation is a necessity.

However there are few opportunities within the shortlisted countries that offer slightly less barriers and-or better return on investment. The following opportunities have been identified<sup>1</sup>.

## Canada

### CBD & THC Opportunity

New regulations will come in place from the end of October. Allowing the use of recreational cannabis use.

### Reasoning

A market that is going through deregulations that is establishing legal domestic supply. Assumption is that the market is facing a cannabis shortage.

## Australia

### Hemp seed - Opportunity

Market that allows the importation of hemp seeds (incl. derivatives) and food products containing hemp seeds (incl. derivatives)

### Reasoning

Market that close by and provides easy market access for the importation of hemp seeds and hemp seed derived food products.

## Japan

### CBD - Opportunity

Limited amount of producers active within the Japanese market and a Japanese importers that is looking to import more product.

### Reasoning

Only two CBD producers have currently product on the Japanese market and an advertising ban on CBDs has been lifted most recently allowing.

## European Union

### CBD & THC - Opportunity

Partnering with EU companies that have a license to import medicinal cannabis product.

### Reasoning

The EU market for Medicinal cannabis has exploded and it is really hard to keep up with demand. There are a limited amount of suppliers within the EU that can supply product. Therefore more medical cannabis importers are looking into importing product from countries abroad like Canada, United States and Israel.



# Market Entry

Methods of market entry for companies selling CBD and-or THC products into international markets.

1. Work together with a local entity that has a license to import CBD and-or THC products<sup>1</sup>.
2. Acquire an existing import company that has a license to import CBD and-or THC products<sup>1</sup>.
3. Setup a local entity and acquire a license from the local government to import product<sup>1</sup>.

## 1. Partnering with local company

Phivida signs distribution agreements with Japanese Asayake Inc.

The inaugural import shipment was sent in advance of a national market roll-out. Asayake Inc. CEO, Mr. Kazuhiko, states, "We are excited to distribute Phivida's CBD-Hemp Oil products in Japan. Federal government approval of cannabidiol [CBD] products is very uncommon and is a testament to Phivida's quality standards."

Phivida now plans to prepare a formal application to Japan's Consumer Affairs Agency (CAA) to register Phivida's CBD infused functional food and beverage products for approval under the Food with Functional Claims (FFC) regime. The FFC allows companies to market health benefits (aka "functionality").

[Read full article](#)

## 2. Acquire existing company

Scythian Biosciences Corp. acquires Argentina-based ABP S.A.

Scythian Biosciences Corp is pleased to announce that Argentina-based ABP S.A., a pharmaceutical import and distribution company that Scythian is in the process of acquiring, has received its license to import CBD oil into Argentina ABP had previously entered into an exclusive international supply agreement for Argentina Aphria Inc. a prominent Canadian producer of medical cannabis, in anticipation of receiving the License.

[Read full article](#)

## 3. Set-up local entity

Medical Marijuana, Inc sets up local Brazilian entity HempMedsTM Brazil

HempMedsTM Brazil, LLC currently has three cannabis products approved for importation into Brazil as a prescription medication for multiple. The Brazilian health care system is HempMedsTM Brazil's single largest client. The company had the first-ever cannabis product allowed for import into Brazil and its products are currently subsidized by the Brazilian government, under their health care system, for the medical indications listed above. It is believed to also be the world's first prescription cannabis product for Epilepsy, Parkinson's, and pain. HempMedsTM Brazil is working on additional approvals for multiple indications.

# Country Summary<sup>1</sup>

	Rank	CBD	Hemp Seeds	THC
<b>EU (incl. GMP)</b>	4	Yes	Legal (listed)	Per country
<b>Australia</b>	3	Legal	Legal	Medical
<b>USA</b>	2	Technically Illegal	Legal (sterilised)	Medical & Recreational
<b>Singapore</b>		Legal	TBD	Prohibited
<b>Canada</b>	1	Legal	Legal (sterilised)	Medical & Recreational
<b>China</b>		Illegal	Exporter	Prohibited
<b>Korea</b>		Legal	TBD	Medical
<b>Japan</b>	5	Legal	Legal (sterilised)	Prohibited
<b>Argentina</b>		Legal	TBD	Medical (some areas)
<b>Germany</b>	4	Legal	Legal (listed)	Medical
<b>Italy</b>	4	Legal	Legal (listed)	Medical
<b>Switzerland</b>	4	Legal	Legal (listed)	Medical
<b>UK</b>	4	Legal	Legal (listed)	Medical

# Country Regulations

# Australia

## CBD Products

### Status: Legal (license)

The importation of CBDs is illegal unless the importer holds a licence and permit to import from the Office of Drug Control (ODC).

There have been some issues around companies located in the United States that have been illegally exporting cannabidiol (CBD) and hemp products to persons in Australia without import permission.

The only product registered containing cannabidiol within [the Register of Therapeutic Goods](#) is “GD Cann-C cannabidiol 100mg/mL Oral Liquid bottle”

## Hemp Seed

### Status: Legal

With the recent changes to the Food Standard certain hemp seed products are now permitted for human consumption. It is important to be aware that only the seeds of the hemp plant can be used for human consumption - extracts from the remainder of the plant are considered a drug.

The following substances are allowed to be imported without import permission under the [PI Regulations](#):

- Hulled hemp seeds
- Hemp seed meal
- Hemp fibre
- Hemp seed oil if:
  - the total cannabidiol content of the hemp seed oil is 75mg/kg or less, and
  - the total tetrahydrocannabinol content of the oil is 50mg/kg or less

More details are available via the [ODC website](#).

## THC Products

### Status: Medicinal (only licensed products)

Medicinal cannabis products are currently only available through importation while the Australian domestic cultivation scheme is being developed.

Medicinal cannabis products will only be available for specific patient groups under medical supervision. Cannabis grown for medicinal purposes, as well as the resulting product, is subject to stringent security and quality control measures.

Full details on the importation of medicinal cannabis products can be found via the [following website](#).

# United Kingdom

## CBD Products

### Status: Legal (non-medicinal)

A license is required to distribute Cannabidiols (CBDs) as medicine. However, it is allowed to be marketed without a license as natural supplement. This might be subject to change in the future, as the government is working to classify all CBDs as medicine.

CBD products from hemp are legal in the UK only if they're sold as a food supplement and do not make medicinal claims. MHRA (Medicines and Healthcare products Regulatory Agency) have made statements on products containing CBDs. If a product makes a medical claims, then it requires a marketing authorisation license before it is legal to sell CBD.

More information on [UK government website](#).

## Hemp Seed<sup>1</sup>

### Status: Legal (see seed list)

The EU database of registered plant varieties offers a search tool for all the agricultural and vegetable plant varieties whose seed can be marketed throughout the European Union.

Imported varieties also fall under the [EU Regulation 1308/2013](#) to ensure that all imported hemp is not above the 0.20% THC threshold. EU Regulation is arbitrary in all member states, but this is only the case with growing cannabis for hemp products, not for sale as a recreational drug. In some instances, countries in the EU have had to change the law permitting the sale and production of hemp to comply with EU Regulations.

## THC Products

### Status: Medicinal (only licensed products)

Regulations have just changed recently. The Department for Health and Social Care (DHSC) and the Medicines and Health products Regulatory Agency (MHRA) will now develop a clear definition of what constitutes a cannabis-derived medicinal product so they can be rescheduled and prescribed. Only products meeting this definition will be rescheduled. Other forms of cannabis will be kept under strict controls and will not be available on prescription.

It is worth noting that UK is the world's largest exporter and producer of cannabis-based medicines; a British company, GW Pharmaceuticals, is the global leader in developing them.

It developed and markets Sativex, a drug for treating multiple sclerosis which has limited availability in the UK. The firm has recently launched an epilepsy drug, Epidiolex, which recently became the first cannabis-derived medicine to gain US government approval.



# Switzerland

## CBD Products

### Status: Legal (license)

A license is required, which is dependent on the product use (medicinal, food, raw, cosmetics, tobacco substitutes)

Products containing cannabidiol (CBD) are gaining popularity in Switzerland, as elsewhere.

Increasing numbers of suppliers are seeking to satisfy customer demand by offering a wide range of CBD-containing products. Unlike THC (tetrahydrocannabinol), CBD is not subject to the Narcotics Act because it does not produce a comparable psychoactive effect. However, this does not mean that CBD can simply be added to random preparations at will or advertised arbitrarily.

Full document containing all information on the licensing of CBDs can be found [here](#).

## Hemp Seed<sup>1</sup>

### Status: Legal (see seed list)

Switzerland adheres to the same regulations as the EU on the importation of Hemp seeds.

The EU database of registered plant varieties offers a search tool for all the agricultural and vegetable plant varieties whose seed can be marketed throughout the European Union.

Imported varieties also fall under the [EU Regulation 1308/2013](#) to ensure that all imported hemp is not above the 0.20% THC threshold. EU Regulation is arbitrary in all member states, but this is only the case with growing cannabis for hemp products, not for sale as a recreational drug. In some instances, countries in the EU have had to change the law permitting the sale and production of hemp to comply with EU Regulations.

## THC Products

### Status: Medicinal (only licensed products)

Cannabis has pain- and cramp-relieving properties. Medicines containing the active substances in cannabis require authorisation. Currently only one product is licensed for sale in Switzerland (Sativex – figure 1).

The Federal Office of Public Health (FOPH) can grant special authorisation for the medical use of prohibited narcotics. Only the doctor responsible for the case can apply for authorisation. The patient must consent to the treatment.

Figure 1.



# Italy

## CBD Products

### Status: Tolerated

CBD sale/use appears to be tolerated by government.

However EU law does not explicitly prohibit the importation and use of CBDs.

## Hemp Seed<sup>1</sup>

### Status: Legal (see seed list)

The EU database of registered plant varieties offers a search tool for all the agricultural and vegetable plant varieties whose seed can be marketed throughout the European Union.

Imported varieties also fall under the [EU Regulation 1308/2013](#) to ensure that all imported hemp is not above the 0.20% THC threshold. EU Regulation is arbitrary in all member states, but this is only the case with growing cannabis for hemp products, not for sale as a recreational drug. In some instances, countries in the EU have had to change the law permitting the sale and production of hemp to comply with EU Regulations.

## THC Products

### Status: Medicinal (only supplied by government)

Originally, medical marijuana was imported from other EU countries. However On September 18, 2014, Italy passed legislation to regulate the legal cultivation of medical marijuana within Italy. Florence's military pharmaceutical lab (Stabilimento Chimico Farmaceutico Militare di Firenze) is currently the only authorized cannabis producer within Italy.

Locally produced marijuana, called FM-2, is now being distributed to Italian pharmacies in Florence with the intent on expanding out into the rest of the country. Italian cannabis products produced by SCFM range in THC and CBD levels: between 1.8% to 5% THC and 7.5% to 12% CBD. Products are sold at €6.88 a gram, IVA tax included. The SCFM hybrid growing and testing lab currently contains around 100 cannabis varieties that can yield approximately 8 kg (18 lbs.). The military researchers intend to continue growing their operation with the goal of producing over 90kg (200 lbs.) by the end of the year.

# Germany

## CBD Products

### Status: Legal (non-medicinal)

According to the German Narcotics Law, it does not explicitly list CBD (Cannabidiol) as a substance under strict control and regulation. In 2004, an update was issued and exceptions specify an amendment allowing the use of hemp (cannabis) only if the THC content does not exceed 0.2 percent.

It is worth adding that The European Union law and Germany Narcotic Laws harmonize and agree that CBD oil is legal in Germany. Not explicitly prohibiting the use of CBDs.

## Hemp Seed<sup>1</sup>

### Status: Legal (see seed list)

The EU database of registered plant varieties offers a search tool for all the agricultural and vegetable plant varieties whose seed can be marketed throughout the European Union.

Imported varieties also fall under the [EU Regulation 1308/2013](#) to ensure that all imported hemp is not above the 0.20% THC threshold. EU Regulation is arbitrary in all member states, but this is only the case with growing cannabis for hemp products, not for sale as a recreational drug. In some instances, countries in the EU have had to change the law permitting the sale and production of hemp to comply with EU Regulations.

## THC Products

### Status: Medicinal

Doctors may only prescribe medicinal cannabis to severely ill patients if they can demonstrate that other therapies are not promising. THC, the active ingredient in cannabis, can be prescribed as dried cannabis buds. The pharmacy charges €125 (\$150) for five grams of dried cannabis buds.

Process for registration as an medicinal cannabis importer cumbersome. Since the introduction of the new law in 2016, only four companies that have received permission by [Germany's Federal Opium Agency](#) to import medicinal cannabis and supply it throughout the country.

One of the companies with a license to import is [Cannamedical Pharma](#).

# Japan

## CBD Products

### Status: Legal

There are strict rules for importing CBDs, with oils only being legalised in 2016. Two producers selling products on the Japanese market are the Canadian company Phivida Holdings Inc and Australian company Elixinol (figure 2).

Both companies are supplying their product via a single importer and distributor ASAYAKE INC. It is worth mentioning that [ASAYAKE is looking for importer looking for suppliers](#)

Figure 2



## Hemp Seed

### Status: Legal (sterilised)

Unsterilised cannabis seeds are legal to possess in Japan but in practice only sterilised seeds may be imported. "Cannabis Fruit" is also an import prohibited item as "marijuana", and submitting "Documents that prove that it has been subjected to germination impossible treatment by heat treatment etc.", "However, what the government imports and It is permitted to be imported as a person who is deemed to be able to import according to the provisions of other laws and ordinances according to the other laws and regulations ".

## THC Products

### Status: Prohibited

# United States

## CBD Products

### Status: Technically illegal – by state<sup>1</sup>

Federal law prohibits human consumption and possession of schedule I controlled substances. Products containing tetrahydrocannabinols (THC), the hallucinogenic substance in marijuana are illegal to import.

In June 2018, the FDA approved oral use of CBD as an anti-seizure drug in treating rare types of childhood epilepsy. This is a contradiction as Schedule I substances by definition have no accepted medical use.

### The Hemp Loophole

One explanation for why the FDA does not seem to be cracking down on CBD supplement companies – despite their stance that CBD is a drug – is what we like to call the hemp loophole. Simply put, hemp products are legal to consume and import into the United States, even though hemp naturally contains CBD. This explains why many CBD companies market their products as “hemp oil” and do not state how much CBD it contains.

## Hemp Seed

### Status: Legal (sterilised)

Hemp seeds are allowed to be imported into the United States (U.S.) if sterilized. Non-sterilised hemp seeds remain a schedule I controlled substance and therefore may only be imported into the U.S. with a Drug Enforcement Agency (DEA), Application for Permit to Import Controlled Substances/Domestic and/or Scientific Purposes form. Application can be made using the [following form](#).

The following hemp products such as clothing, hats, shirts, shoes, cosmetics, lotion, paper, rope, twine, yarn, shampoo, and soap, (containing sterilized cannabis seeds or oils extracted from the seeds), etc. may be imported into the U.S.

## THC Products

### Status: Legal (by State<sup>1</sup>)

Federal law prohibits human consumption and possession of schedule I controlled substances. Products containing tetrahydrocannabinols (THC), the hallucinogenic substance in marijuana are illegal to import.



# Argentina

## CBD Products

### Status: Legal

The use of CBDs has been legalised since the 29<sup>th</sup> of March 2017. Under the new law, patients who seek cannabidiol (CBD) must register with a planned national programme that will be administrated by the Ministry of Health.

[The National Administration of Drugs, Foods and Medical Technology \(ANMAT\)](#) is the body responsible for the importation of cannabis oil and other ingredients included in the program that fulfil the requirements. Anybody not enrolled in the program with a normal prescription will be required to pay the costs of the treatment.

A license from ANMAT is required to import products into a country. This has to be a local entity and it is common place to either acquire an entity that has a license, set-up a local entity or collaborate with an importer.

Example of importer is [Flos Innovation](#)

## Hemp Seed

### Status: Legal (sterilised)

Hemp seeds are allowed to be imported into the United States (U.S.) if sterilized. Non-sterilised hemp seeds remain a schedule I controlled substance and therefore may only be imported into the U.S. with a Drug Enforcement Agency (DEA), Application for Permit to Import Controlled Substances/Domestic and/or Scientific Purposes form. Application can be made using the [following form](#).

The following hemp products such as clothing, hats, shirts, shoes, cosmetics, lotion, paper, rope, twine, yarn, shampoo, and soap, (containing sterilized cannabis seeds or oils extracted from the seeds), etc. may be imported into the U.S.

## THC Products

### Status: Decriminalised

# Canada

## CBD Products

### Status: Legal

Legal – will be part of the law change in October 2018

Import only by license – fitting requirements under Health Canada which are similar to industrial hemp.

## Hemp Seed<sup>1</sup>

### Status: Legal

Anyone wishing to cultivate industrial hemp is required to obtain a licence from Health Canada. Providers/sellers, processors, importers and exporters of hemp seed or viable grain (not fibre) also require a licence from Health Canada.

Seed importers are required to be a Registered Seed Establishment with the permit to import industrial hemp issued by Health Canada. Additionally, each imported shipment of seed requires a phytosanitary certificate, and if the import is from outside the continental United States, a CFIA import permit issued under the Plant Protection Act. Seed exporters are required to meet importing country's requirements.

In short: All importers of Cannabis sativa plants and seeds for propagation must first obtain a license to grow and a permit to import from Health Canada's Office of Controlled Substances. [Full regulations](#)

## THC Products

### Status: Recreational

Legal – will be part of the law change in October 2018

Surprisingly the federal Cannabis Act bans importing recreational marijuana. But nothing, in principle, would stop licenced producers from supplying the medical market with imported cannabis and devoting their entire domestic production to recreational users (quote for news).

[Link to legislation explaining the rules on importation.](#)



# Annex I

## Exception relating to *Cannabis sativa* seeds and seed products

- (1) *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale if:
  - (a) the seeds:
    - (i) are seeds of low THC *Cannabis sativa*; and
    - (ii) contain not more than 5 mg/kg of total THC; and
    - (iii) if the food is for retail sale – are non-viable and hulled; and
  - (b) the only cannabinoids in or on the seeds are naturally present.
- (2) Subject to subsection (3), all or any of the following seed products may be a food for sale or used as an ingredient in a food for sale:
  - (a) oil extracted from seeds of low THC *Cannabis sativa* if the oil contains not more than 10 mg/kg of total THC;
  - (b) a beverage derived from seeds of low THC *Cannabis sativa* if the beverage contains not more than 0.2 mg/kg of total THC;
  - (c) any other product that is extracted or derived from seeds of low THC *Cannabis sativa* and contains not more than 5 mg/kg of total THC.
- (3) The only cannabinoids in the product must be those that were naturally present in or on the seeds from which the product was extracted or derived.
- (4) In subsection (2):

**seeds of low THC Cannabis sativa** includes viable and unhulled seeds.

- (5) In this section:

**hulled seeds** means seeds from which the outer coat or hull of seeds has been removed.

**low THC Cannabis sativa** has the meaning given by subsection (6).

**non-viable seeds** means seeds that are not able to germinate.

**seeds** includes a part of a seed.

**total THC** means the total amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid.

- (6) *Cannabis sativa* is low THC *Cannabis sativa* if the leaves and flowering heads of the *Cannabis sativa* do not contain more than 1% delta 9-tetrahydrocannabinol.

# Annex II

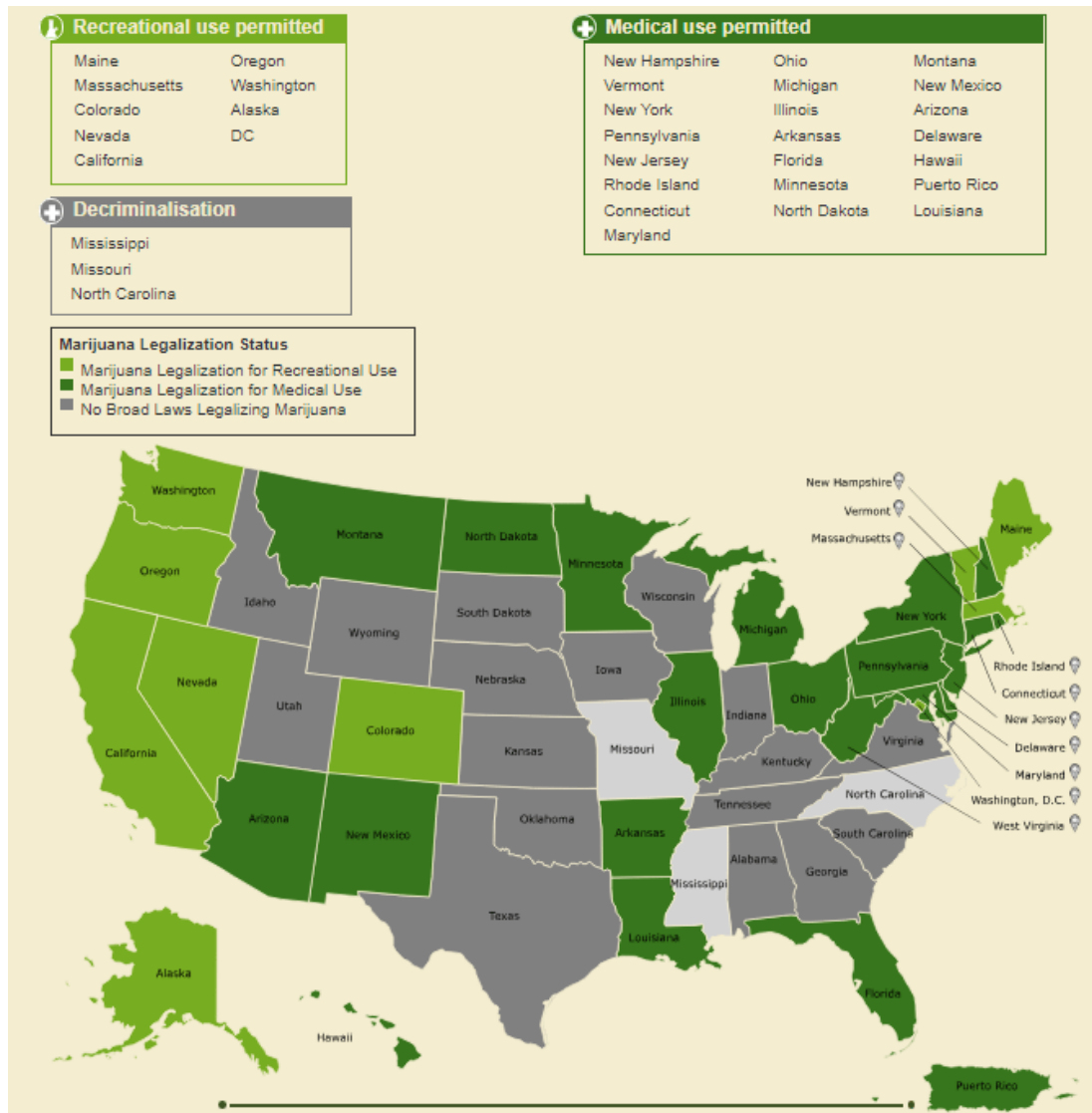
**Hemp seeds (industrial hemp)** - In the Industrial Hemp Regulations, industrial hemp includes Cannabis plants and plant parts, of any variety, that contains 0.3% tetrahydrocannabinol (THC) or less in the leaves and flowering heads.

## EU CANNABIS SATIVA L. – HEMP list – [EU Website](#)

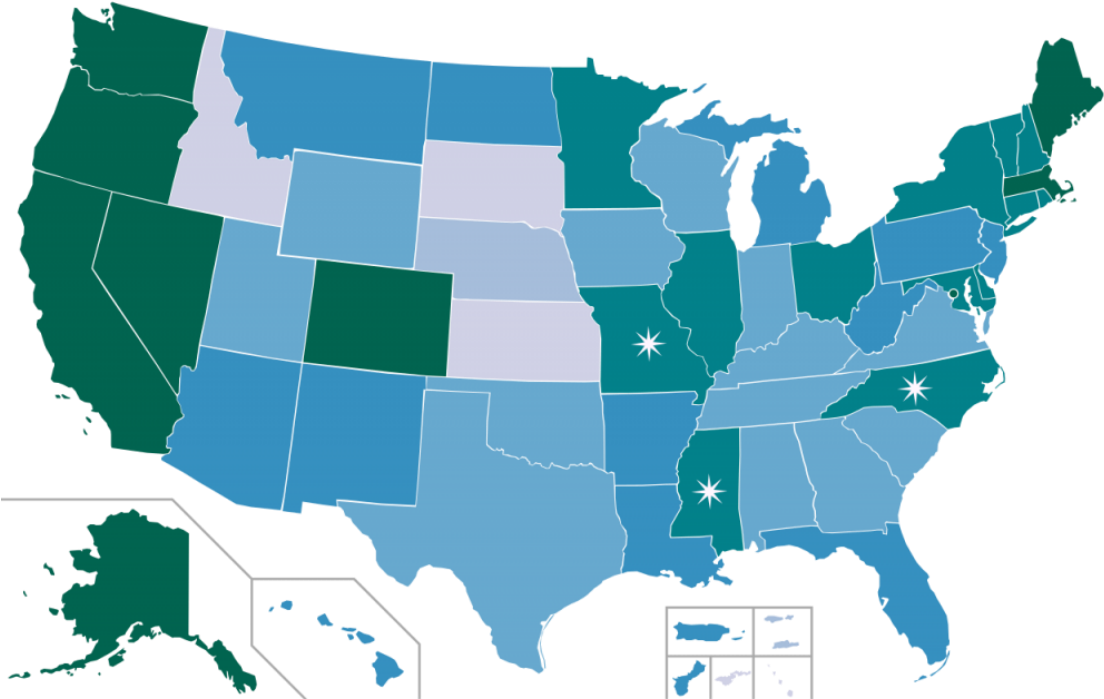
Adzelvieši	*LV 188	Delta-Ilosa	*ES 275	Gliana	*IT 1324	Ratza	*RO 1018
Antal	*CZ 1465	Denise	*RO 1018	Glyana	*PL x	Santhica 23	*FR 8194
Armanca	*RO 1002	Diana	*RO 1018	Henola	*PL 893	Santhica 27	*FR 8194
Asso	*IT 15	Dioica 88	*FR 8194	Ivory	*NL 722	Santhica 70	*FR 8194
Austa SK	*LT 208, *LV 186	Eletta Campana	*IT 15	KC Bonusz	*HU 149424	Secuieni Jubileu	*RO 1018
Beniko	*NL x, *PL 1109	Epsilon 68	*FR 8194	KC Dora	*HU 149424	Silvana	*RO 1002
Bialobrzeskie	*CZ 1067						
- Bialobrzeskie	*PL 893	Fedora 17	*FR 8194	KC Virtus	*HU 149424	Succesiv	*RO 1018
Bialobrzeskie		Felina 32	*FR 8194	KC Zuzana	*HU 149424	Szarvasi	
		Férimon	*FR 8194				
Cannakomp	*HU 149424	- Ferimon		KCA Borana	*HU 149424	Tiborszallasi	*HU 149424
Carma	*IT 1532	Ferimon		Kompolti hibrid TC	*HU 149424	Tisza	*HU 149424
Carmagnola	*IT 15	Fibranova	*IT 15	Kompolti	*HU 151322, *NL x	Tygra	*PL 893
Carmaleonte	*IT 15	Fibrante	*IT 15	Lipko	*HU 151322	Uniko B	*HU 151322
Chamaeleon	*NL 391	Fibrol	*HU 149424	Lovrin 110	*RO 1002	Uso-31	*NL x
Codimono	*IT 15	Fibror 79	*FR S8194	Marcello	*NL 722	Villanova	*IT 1495
CS	*IT 15	Finola	*FI 6157	Markant	*NL 722	Wielkopolskie	*PL 589
					*CZ 1272, *HU		
Dacia Secuieni	*RO 1018	Futura 75	*FR 8194	Monoica	149424	Wojko	*PL 893
Delta-405	*ES 275	Glecia	*IT 1324	Rajan	*PL 893	Zenit	*RO 1018



# Annex III



# Annex IV



- Dark Green: Jurisdiction with legalized cannabis.
- Teal: Jurisdiction with both medical and decriminalization laws.\*
- Blue: Jurisdiction with legal psychoactive medical cannabis.
- Light Blue: Jurisdiction with legal non-psychoactive medical cannabis.
- Light Purple: Jurisdiction with decriminalized cannabis possession laws.
- White: Jurisdiction with total cannabis prohibition.
- Star: Marked states have only legal non-psychoactive medical cannabis.



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