



Cannabis and hemp derivatives

APPLICABLE REGULATIONS IN LUXEMBOURG

INFORMATION FOR THE GENERAL PUBLIC



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

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Direction de la santé

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Introduction

Aside from the use of cannabis for medicinal purposes, many products which are reported to contain cannabidiol (CBD) recently appeared on the Luxembourgish market. CBD is one of the major active compounds of cannabis, otherwise known as hemp, together with delta-9-tetrahydrocannabinol (THC). Hemp (*Cannabis sativa*) features on the list of narcotics⁽¹⁾. Its usage is therefore strictly regulated.

In addition to the regulations on these products derived from cannabis (hemp), it's also important to take into account the different parts of the plant and their uses, because they are not subject to the same laws.

(1) Grand-Ducal Regulation of 4 March 1974 on certain toxic substances.

What is cannabis?

The cannabis plant, its components and substances

The term **cannabis** refers to the *Cannabis sativa* plant, the Latin name for **hemp**.

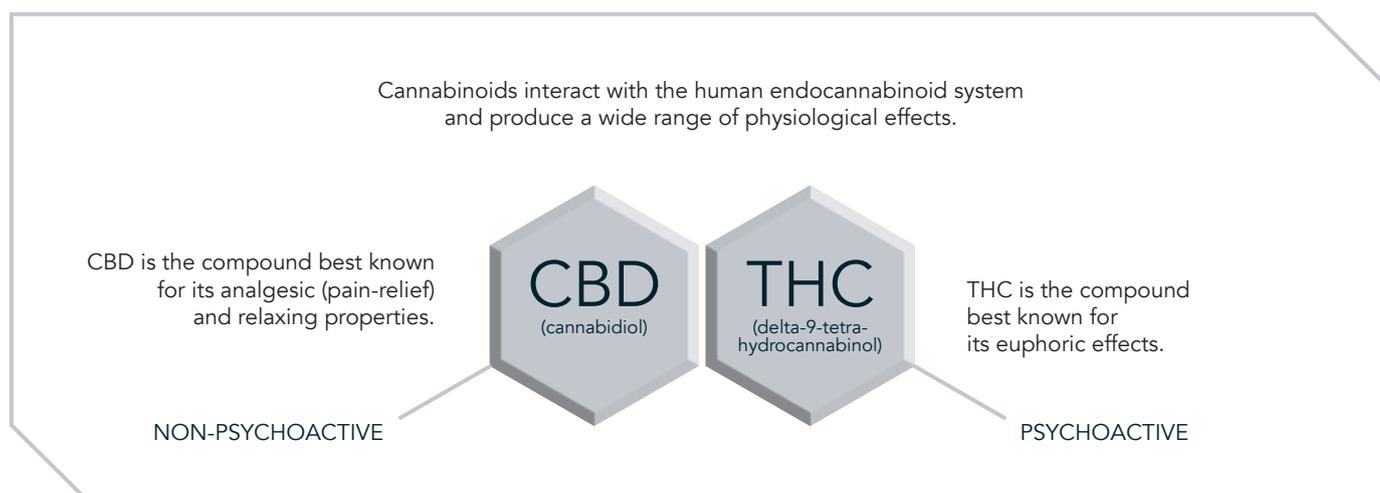
Industrial hemp is often confused with **cannabis**. There are in fact many different applications for these two plants, which share the same roots. Industrial hemp and cannabis differ in terms of their **morphology** and their **use** due to their **composition**.

The factor which divides this plant into two different categories is the quantity of THC that it produces. Whereas **industrial hemp varieties** contain very low quantities of THC, other varieties of cannabis may contain much greater and more variable quantities of both THC and CBD.

The difference between THC and CBD

Cannabis is made up of hundreds of different substances, including the following two best-known active ingredients:

- **THC** (delta-9-tetrahydrocannabinol)
- **CBD** (cannabidiol).

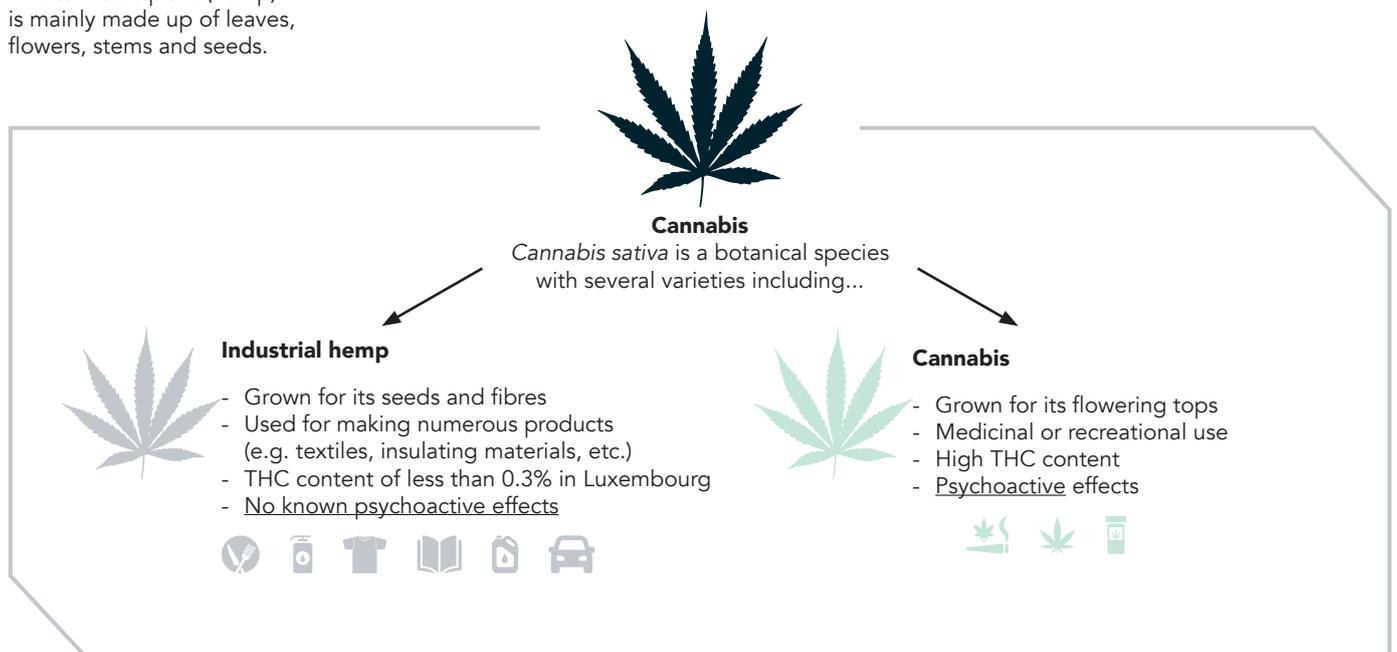


THC is the compound which is mainly responsible for the psychoactive effects of cannabis, whereas CBD has therapeutic potential and no recognised psychoactive effects. The effects of cannabis are due to the actions of its cannabinoids on biological “targets”, i.e. a system of specific molecules and receptors found in the entire human body, called the endocannabinoid system^(2, 3).

THC and CBD are regulated under the legislation on the products derived from hemp and cannabis⁽⁴⁾.

The various forms and uses of cannabis

The cannabis plant (hemp) is mainly made up of leaves, flowers, stems and seeds.



(2) Santé Canada, Information for health care professionals, Cannabis (marihuana, marijuana) and the cannabinoids, October 2018.

(3) For more information about the endocannabinoid system, read the “Medicinal cannabis authorised in Luxembourg” booklet.

(4) Note on cannabis and hemp derivatives - Sante.lu, Dec. 2021.

A summary of the regulations

Three types of products containing cannabinoids are currently regulated or in the process of being regulated:

- **Cannabis for medicinal purposes, known as "medicinal cannabis"**⁽⁵⁾ is already legal and made available to patients under certain conditions and on prescription by a certified doctor.
- **Cannabis (industrial hemp) derivatives** are subject to restrictions depending on their use (cf. p. 8).
- **Cannabis for non-medicinal purposes, known as "recreational cannabis"**: recreational use of cannabis is currently illegal (cf. p.14).

Hemp plants (*Cannabis sativa*) and the seeds, extracts, dyes and resins derived from this plant **are not considered as narcotics** provided they are:

- hemp varieties which are eligible for a support scheme under the common agricultural policy, and as long as their THC content is less than 0.3%*;
- varieties intended for commercial use and non-intoxicating purposes for which no potential abuse has been proven based on current knowledge on drug abuse^(6,7).

Products containing cannabis and compounds derived from cannabis must meet the regulations on their respective use (e.g. therapeutic, food, cosmetic or recreational use) so that they do not put consumers' health and safety at risk.

* The 0.3% THC content is not the threshold for the presence of THC in the end product but in the plant itself.

(5) Law of 20 July 2018 amending the amended Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse.

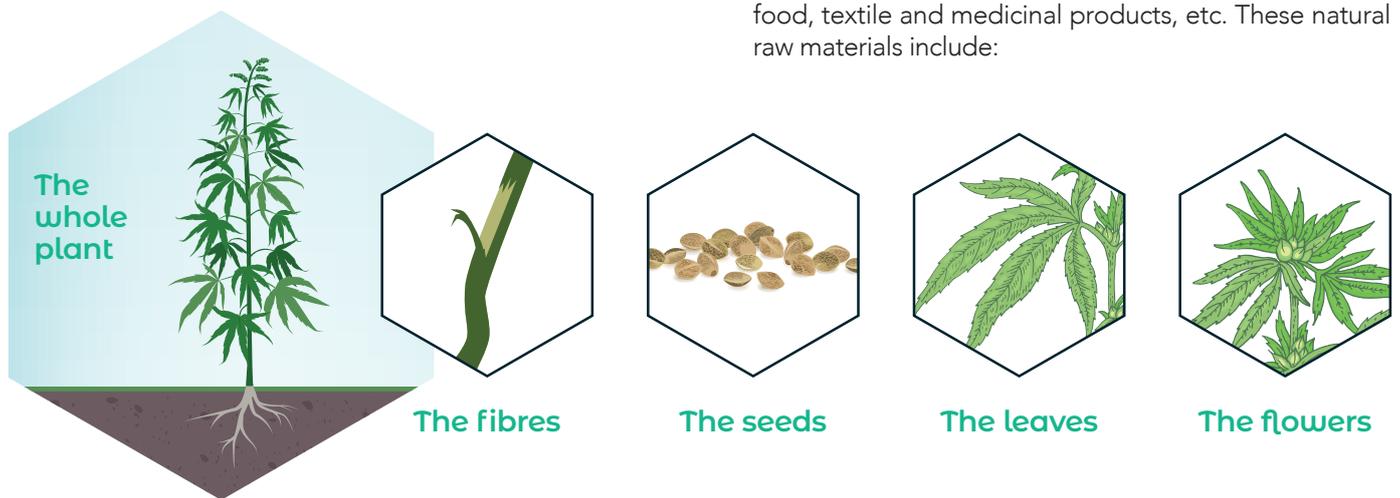
(6) Article 7 of the Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse.

(7) Article 1 of the Grand-Ducal Regulation of 26 March 1974 establishing the list of narcotics.

Raw materials

Natural raw materials

The natural raw materials of the cannabis plant come from different parts of the plant and are used to make various food, textile and medicinal products, etc. These natural raw materials include:



Chemical raw materials

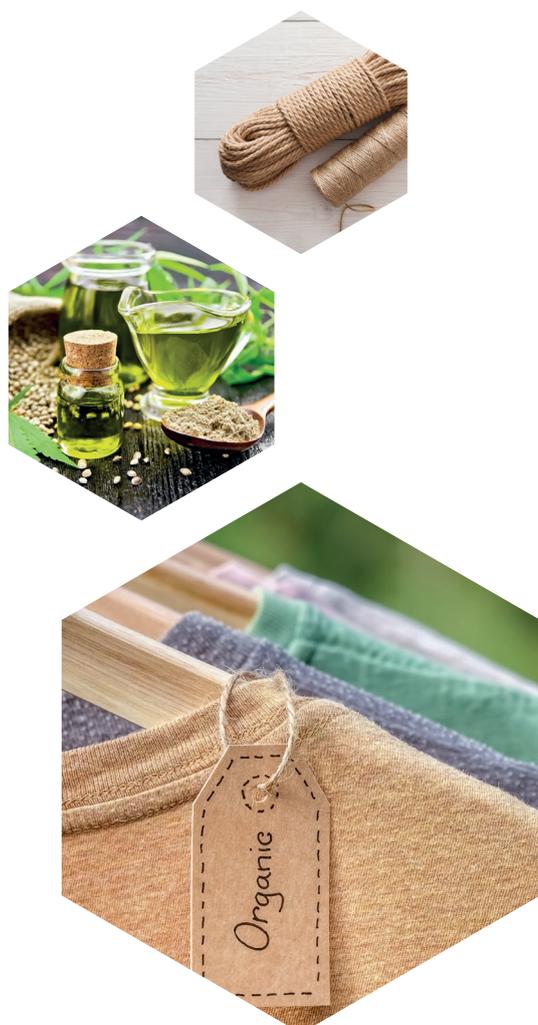
THC and CBD crystals/powder

Powders and crystals are a very pure and isolated form of the plant extract. These substances remain subject to the legislation on "chemical substances for therapeutic activity" and "narcotics", among others.

Cannabis (hemp) and its uses

Industrial use

When talking about cannabis or hemp, we can see that there is a wide range of uses depending on the area of activity. However, the regulations applicable to each use or area of activity must be respected by taking into account the substances (THC/CBD) and the respective contents authorised by the regulations in Luxembourg.



Industrial cannabis (industrial hemp) comprises a certain number of varieties of *Cannabis sativa L.* intended for agricultural and industrial use. **These varieties are grown for their:**

- seeds,
- flowers,
- fibres,
- leaves.

Industrial hemp is characterised by its low THC content (< 0.3%).

The derivative products considered as industrial hemp include hemp seed oil and hemp flour.

The fibres of the stem can be used for making paper, fabric, rope, string and building materials. The seeds can be used for making food, beauty products, plastics and fuels⁽⁸⁾. Industrial hemp flowers can be used for making herbal teas.

What does the law say?

In Luxembourg, the industrial hemp plant may be used under certain conditions. According to the law, the whole plant must not contain more than 0.3% THC, no matter what it is used for.

(8) Source : <https://www.canada.ca/fr/sante-canada/services/drogues-medicaments/cannabis/production-vente-chanvre/au-sujet-chanvre-industrie/foire-questions.html#a23>

Medicinal use

With the entry into force of the Law of 20 July 2018, the use of cannabis for medicinal purposes is authorised in an extremely restrictive framework associated with very specific conditions.

By “medicinal cannabis” Luxembourgish legislation refers to the dried flowering tops of the plant with defined THC and CBD contents, as well as all of the components and compounds derived from a plant of the cannabis genus, of a standardised and certified quality, other than industrial hemp, approved by the Health Directorate for medicinal use.



The products authorised in Luxembourg are:

Medicinal cannabis

Flowering tops

(Dried flowering tops of the plant with defined THC and CBD contents).



Oil extracts

With defined THC and CBD contents.



Medicines containing THC or CBD

Medicines with an MA⁽⁹⁾

At present, Sativex[®]* and Epidyolex[®]* are the only cannabinoid-based medicines which are authorised in Luxembourg. Sativex[®]* is a medicine with a marketing authorisation (MA). It is a complete plant extract marketed in the form of an oral spray. Epidyolex[®] is a CBD-based oral solution that can be used to treat certain forms of epilepsy.

* Sativex[®] is a treatment to improve the symptoms of adult patients suffering from moderate to severe spasticity due to multiple sclerosis (MS), who have not responded sufficiently to other antispasmodic treatments and who have shown a clinically substantial improvement in their spasticity symptoms during an initial trial of the treatment.

(9) MA: Marketing authorisation.

The conditions for obtaining medicinal cannabis

Luxembourgish legislation provides for the prescription of cannabis for medicinal use (containing THC and CBD):



Authorised products

- Dried flowering tops (with defined THC and CBD contents).
- Standardised oil extracts, with defined THC and CBD contents.
- Medicines with an MA*.



For which conditions?

- Serious chronic diseases classified as long-term illnesses (affections de long durée – ALD) referred to in Article 19bis, paragraph 1 of the Luxembourg Social Security Code, at an advanced or terminal stage, causing chronic and debilitating pain which has not responded to the available therapies, or without conventional treatments available..
- Cancerous diseases, other than those referred to in the first indent, which are treated by chemotherapy, leading to nausea or vomiting.
- Multiple sclerosis with symptomatic muscle spasticity.



For whom?

Patients must meet one of the following criteria:

- Live in Luxembourg.
- Be a beneficiary of the Luxembourg health insurance system.
- Have Luxembourgish nationality.



How to obtain it?

Patients must meet one of the following criteria:

- Live in Luxembourg.
- Be a beneficiary of the Luxembourg health insurance system.
- Have Luxembourgish nationality.



Where to obtain it?

- Medicinal cannabis can be obtained from hospital pharmacies in Luxembourg.
- Medicinal cannabis is dispensed to patients free of charge upon presentation of a special prescription.



More information

For more information about MEDICINAL CANNABIS, contact us at infocannabis@ms.etat.lu or visit the www.sante.lu website.

* MA: Marketing authorisation.

** If necessary, GPs can contact the Health Directorate to request a list of the practitioners who have completed this training course and are located nearby.

Food use

As regards the industrial hemp plant (*Cannabis sativa* L. derived from an authorised variety of hemp and with a THC content of less than 0.3%), the difference between the various parts of the plant used is very important.

Industrial hemp **seeds** and other derivative products such as **hemp seed oil** are used as foodstuffs.

Hemp **leaves** are commonly **used as a herbal tea**. However, the consumption history for **flowers used in herbal teas** in the European Union prior to 15 May 1997 has not yet been confirmed, and 'novel food' status is currently being discussed for these flowers (flowering tops) at the European Commission.

Hemp **extracts** that are concentrated in **cannabinoids** are considered as foodstuffs with no consumption history in the European Union prior to 15 May 1997. These cannabinoid extracts (also referred to as CBD extracts, CBD oil, CBG extracts, etc.) are classified as "Novel Foods".

"Novel foods" are governed at European level by Regulation (EU) 2015/2283. They require an authorisation to be marketed as a foodstuff.

Since January 2019, many requests for novel food authorisations have been submitted to the Commission. However, due to a lack of comprehensive and conclusive scientific studies, the European Food Safety Authority (EFSA), which is responsible for assessing the risk, has not yet published a scientific opinion on CBD. Consequently, the marketing of any foodstuffs or food supplements containing CBD without a marketing authorisation pursuant to the aforementioned Regulation (EU) 2015/2283 is prohibited both in Luxembourg and in Europe.

Furthermore, as regards foodstuffs in general, including hemp-based foodstuffs, a risk assessment regarding delta-9-tetrahydrocannabinol (THC) pursuant to Regulation (EC) No 178/2002 remains possible to determine the safety of the product⁽¹⁰⁾.



CBD extract/
CBD oil is
considered as
an unauthorised
Novel Food.



To remain informed:



(10) Food Safety Division.

Usage du tabac

The use of cannabis in tobacco products, even for plants with a **THC content of less than 0.3%**, gives rise to a **“characteristic” scent**. **Cannabis is therefore not authorised for use in tobacco products.**

Art. 7.3.a of the amended Law of 11 August 2006 on the fight against tobacco prohibits the use of **tobacco products** with a specific characteristic scent⁽¹¹⁾.

The cannabis plant may be used in plant-based smoking products provided that:

- the product contains no tobacco, even in trace amounts,
- the cannabis plant contains less than 0.3% THC.

The list of product ingredients and a certificate attesting to the THC content must be submitted to the Health Directorate before the product is placed on the market.

Neither cannabis nor any other form of plant may be used in **e-liquids**. Only high-purity ingredients may be used in these products. The ingredients contained in e-liquids must also comply with Article 7 of the amended Law of 11 August 2006 on the fight against tobacco.



(11) Food Safety: <https://securite-alimentaire.public.lu/fr/actualites/communiqués/2019/01/cannabis.html>

Cosmetic use

Products marketed as cosmetics

A "cosmetic product" is defined as "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours"⁽¹²⁾.

Whereas the presence of THC is strictly prohibited in cosmetics, cannabidiol (CBD), a non-narcotic substance, can be found in many marketed products. As is the case for all cosmetics, those containing CBD must comply with European legislation (provisions of European Regulation (EC) No 1223/2009).

Only hemp seed oils derived from an industrial plant with <0.3% THC are permitted.



(12) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Art. 2.1.

Recreational use

Luxembourgish legislation on drugs is based on the amended Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse. This text governs the production, consumption, possession, supply, trading in and trafficking of controlled drugs. An amendment to this Law in 2001 introduced for the first time a distinction between penalties depending on the type of substances involved, particularly for cannabis and its derivatives. Since then, the simple consumption or possession of cannabis for personal use is not punished by a prison sentence but by fines and administrative penalties.

Furthermore, the United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 protocol and of which Luxembourg is a signatory, stipulates the following:

The production, manufacture, export, import, distribution of, trade in, use and possession of drugs, including cannabis, must be exclusively limited to medical and scientific purposes.

Cannabis is currently changing from an illegal substance to an increasingly popular drug. Today, it is the most consumed illicit psychoactive product in Luxembourg, the European Union and the world.

Moreover, the image of cannabis and the general public's perception of it have changed considerably due to the intensification of research on the composition and properties of cannabis, and particularly by the growing recognition of the use of medicinal cannabis. Given the widespread and persistent use of illicit-origin cannabis of unknown quality among the general public, who are unreceptive to repressive measures, it seems legitimate, or even necessary, for the Government to address this topic in order to find more satisfactory, long-term solutions in terms of public health and safety.

In accordance with the 2018-2023 coalition agreement which provides for the setting up of a system to grant legal access to cannabis, together with the corresponding legislation, a working group made up of experts in the field was set up at inter-ministerial level to develop an initial concept regarding this topic.

The associated work is still under way, although progress has been delayed by the COVID-19 pandemic, among other things. Despite this, we need to move forward to resolve the current situation and begin the initial stage of legislative work.

During an initial phase, legislation will be drawn up to create a regulatory framework regarding the cultivation of cannabis at home and reclassification limited to three grams of cannabis.

- Four cannabis plants per domestic community, to be grown at home from seeds.
- Cultivation location restricted to usual residence.
- Maintenance of the ban to consume cannabis in public.

This regulatory framework will also include a second part on reclassification limited to three grams of cannabis:

- Lighter criminal proceedings for the offences of consuming, possessing and transporting cannabis in public and for purchasing cannabis, provided the quantity does not exceed three grams.
- Reduction of the amount of the criminal fine (*currently: 251 to 2,500 euros / suggestion: 25 to 500 euros*).
- Possibility of issuing a warning for a fee of 145 euros.

However, until this legislation comes into force, the sale, import, cultivation and consumption of cannabis together with aggravating circumstances are punishable by prison sentences and very hefty fines.



References

Sante.lu, Cannabis and hemp derivatives, December 2021

<http://sante.public.lu/fr/espace-professionnel/recommandations/direction-sante/medicaments/index.html>

- (1) Grand-Ducal Regulation of 4 March 1974 on certain toxic substances.
- (2) Santé Canada, Information for healthcare professionals, Cannabis (marijuana, marijuana) and the cannabinoids, October 2018.
- (3) For more information about the endocannabinoid system, read the "Medicinal cannabis authorised in Luxembourg" booklet.
- (4) Note on cannabis and hemp derivatives - Sante.lu, December 2021.
- (5) Law of 20 July 2018 amending the amended Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse.
- (6) Article 7 of the Law of 19 February 1973 on the sale of medicinal substances and the fight against drug abuse.
- (7) Article 1 of the Grand-Ducal Regulation of 26 March 1974 establishing the list of narcotics.
- (8) Source: <https://www.canada.ca/fr/sante-canada/services/drogues-medicaments/cannabis/production-vente-chanvre/au-sujet-chanvre-industrie/foire-questions.html#a23>
- (9) (MA) Marketing authorisation.
- (10) Health Ministry, food safety, legal situation of cannabis products, 2019.
- (11) Food safety: <https://securite-alimentaire.public.lu/fr/actualites/communiqués/2019/01/cannabis.html>
- (12) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Art. 2.1.



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