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# **Products containing cannabidiol (CBD)**

## Overview and implementation guide

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## **Table of contents**

<b>Introduction.....</b>	<b>3</b>
<b>Legal basis according to classification.....</b>	<b>4</b>
<b>What is cannabidiol (CBD)? .....</b>	<b>4</b>
<b>In what form are CBD-containing products supplied?.....</b>	<b>5</b>
<b>As a raw material .....</b>	<b>5</b>
<b>As ready-to-use products.....</b>	<b>5</b>
· Products sold as medicinal products .....	6
· Products sold as foodstuffs .....	7
· Products sold as cosmetics .....	9
· Products sold as utility articles (CBD-containing liquids for e-cigarettes).....	10
· Products offered as chemicals .....	11
· Products sold as tobacco substitutes, demarcation from the Narcotics Act .....	12
<i>General requirements</i> .....	12
<i>Reporting obligation</i> .....	13
<i>Road traffic</i> .....	13
<i>Summarising comments</i> .....	13
<b>Under what conditions may hemp seed be placed on the market? .....</b>	<b>14</b>
<b>Procedure for cannabis and cannabis preparations with a high CBD content and a total THC content of less than 1.0% in Switzerland.....</b>	<b>15</b>
<b>Import and export of cannabis and cannabis preparations with a high CBD content and a total THC content of less than 1.0% .....</b>	<b>15</b>

## Introduction

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. This range falls into a variety of product categories, which are primarily offered for sale via the Internet. Items are frequently sold by shops that already supply other cannabis products and have then decided to extend their range.

Unlike THC (tetrahydrocannabinol), CBD is not subject to the Narcotics Act (NarcA, CC 812.121) 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.

Products can only be marketed legally if they comply with the legislation of the country where it is placed on the market. Depending on the classification, the corresponding Swiss legislation is applied.

This Information sheet provides an overview of the various CBD-containing raw materials and products offered by suppliers and their classification and marketability according to the current legal situation. It is intended primarily as an implementation guide for identifying the competent authorities and promoting consistent implementation. At the same time, it aims to raise awareness of the legal requirements among possible suppliers.

The implementation guide has been drawn up by the technical platform for delimitation issues of the Federal Office of Public Health (FOPH), the Federal Food Safety and Veterinary Office (FSVO) and Swissmedic, the Swiss Agency for Therapeutic Products. Its content will be modified accordingly as legislation is revised or relevant new scientific findings come to light (various clinical trials with CBD are currently in progress).

## Products containing cannabidiol (CBD)

Overview and implementation guide

### Legal basis according to classification

The range of CBD-containing products is extensive: It includes raw materials such as cannabis buds or powder with a high CBD-content, extracts in the form of oils or pastes and ready-to-use products such as capsules, food supplements, liquids for e-cigarettes, tobacco substitutes, scented oils, chewing gums and ointments, some of which are offered as personal care products.

Once a product has been assigned to a particular product category, the corresponding Swiss legislation is applied. If the legal requirements in relation to a specific intended purpose are not satisfied, a product may not be distributed in Switzerland and therefore may not be placed on the market.

The end products are classified on a case-by-case basis taking account of all the relevant factors, including composition, intended use, dosage, etc. Differing enforcement authorities are responsible for control, depending on the products' classification. In cases of doubt, the enforcement authority assigns product to particular legislation and takes the necessary measures.

There is no clear assignment, particularly for offerings involving pure raw materials. Products for which there is no specific applicable law (e.g. Therapeutic Products Act [FTPA, CC 812.21], Foodstuffs Act [FSA, CC 817.0]) are covered by the Federal Act on Product Safety [CC 930.11] (catch-all legislation).

### What is cannabidiol (CBD)?

The cannabis plant (*Cannabis sativa* or *Cannabis indica*) contains over 80 so-called cannabinoids. These have the chemical structure of terpene phenols and occur only in the cannabis plant. Cannabinoids occur in the plant predominantly as carboxylic acids.

The most important and most investigated cannabinoid is THC. This is the substance responsible for the psychotropic effect of cannabis. Another important cannabinoid that occurs in large quantities in the plant is CBD. Unlike THC, it does not possess any psychoactive action. It interacts with various receptors and evidently also reduces the psychotropic effect of THC.

The therapeutic potential of CBD in most of the numerous applications circulating on the Internet has as yet either not been scientifically demonstrated or at best inadequately demonstrated.

## **In what form are CBD-containing products supplied?**

### **As a raw material**

It is common to encounter CBD-containing raw materials that are sold without an intended use. These materials cannot be qualified unambiguously since they can be used to manufacture different products with different intended purposes which, in turn, are subject to differing laws.

If no intended use is stated, CBD-containing raw materials should be placed on the market in accordance with the legislation governing chemicals (see section entitled “Products offered as chemicals”).

### **As ready-to-use products**

CBD-containing products are also supplied in ready-to-use form, whether as medicinal products, foodstuffs, cosmetics, utility articles (excl. cosmetics), tobacco substitutes or as chemicals.

The marketability of such products must be checked for conformity with the respective legislation on a case-by-case basis.

Certain suppliers state on their websites that the products may not be used for medical purposes for legal reasons. Other websites, in turn, include links to sites describing medical uses of cannabis.

The legal requirements for the various product categories and their marketability are described below. Information is also provided on quality requirements relating to CBD-containing pharmacy-compounded preparations in Germany since these frequently raise queries.

## Products containing cannabidiol (CBD)

### Overview and implementation guide

#### Products sold as medicinal products

Under Art. 4 para. 1 let. a of the TPA, ready-to-use CBD-containing products with a medical intended use are regarded as medicinal products and, under Art. 9 para. 1 TPA, may not be placed on the market without authorisation.

Until mid-2018 it was impossible to use CBD in Switzerland in magistral formulations or formula-based medicinal products in accordance with Art. 9 para. 2 let. a-c TPA, since neither Switzerland nor any other country with comparable medicinal product control had authorised a monopreparation containing pure CBD. Consequently, CBD did not meet the requirements for permissible active substances for the preparation of formula-based medicinal products under the terms of Art. 19d of the Therapeutic Products Ordinance (TPO, CC 812.212.21).

However, this situation changed when the FDA approved the CBD monopreparation Epidiolex® on 28 June 2018, which is why CBD can now be prescribed for magistral formulations provided certain conditions are met. The following must be borne in mind:

- CBD has a different activity profile from THC and is therefore not suitable as a substitute for THC;
- the FDA has only approved Epidiolex for the adjuvant treatment of two rare forms of epilepsy (further information on dosage, adverse reactions, etc. can be found in the prescribing information for Epidiolex, on the FDA's website).

Pharmacies can now prepare and dispense medicinal products containing CBD using a magistral formula. In addition to the general requirements applicable to the preparation, validation and filling of prescriptions, the following should be observed:

1. A doctor's prescription must be presented.
2. The prescription should be issued by a specialist in Lennox-Gastaut syndrome and Dravet syndrome or other treatment-resistant forms of epilepsy.
3. If, in exceptional, justified cases, a doctor issues a prescription for a different indication, the prescription should only be filled (prepared and dispensed) after the doctor in question has been consulted and appropriate documentation has been presented.
4. The medicinal product must be prepared with CBD that has been produced in compliance with GMP to a quality standard that satisfies the requirements of monograph C-052 Cannabidiol of the current German Drug Codex DAC/NRF as a minimum.
5. Preparation at pharmacy level must comply with the GMP requirements of the current Pharmacopoea Helvetica (Ph. Helv.).

#### Contact

Swissmedic, Swiss Agency for Therapeutic Products

[www.swissmedic.ch](http://www.swissmedic.ch)

## Products containing cannabidiol (CBD)

### Overview and implementation guide

#### Products sold as foodstuffs

In accordance with Art. 4 para. 1 of the FSA foodstuffs are considered to be any substances or products that are intended for consumption by, or that can reasonably be expected to be consumed by, humans in processed, partially processed or unprocessed form. Medicinal products, narcotics and psychotropic substances are not regarded as foodstuffs (Art. 4 para. 3 FSA).

It is a basic precondition that foodstuffs must be safe (Art. 7 FSA). This means that they may be neither harmful to health nor unsuitable for consumption by humans (Art. 8 of the Ordinance on Foodstuffs and Utility Articles [FUAO; CC 817.02]).

However, foodstuffs that have not been used for human consumption to a significant degree prior to 15 May 1997, either in Switzerland or in a member state of the EU, must be authorised by the FSVO or authorised by the European Commission. This applies to extracts of *Cannabis sativa* L., cannabinoids such as cannabidiol (CBD) and foodstuffs enriched with extracts of *Cannabis sativa* L. or CBD (e.g. hemp seed oil with added CBD, food supplements with CBD) which are classed as novel foods (Art. 15 FUAO) and require authorisation (Art. 16 FUAO).

Products derived from *Cannabis sativa* L. or from parts of plants the use of which is safe and was documented as a foodstuff prior to 15 May 1997 and used for human consumption to a significant degree in the EU are not considered to be novel foodstuffs in Switzerland provided they originate from an authorised *Cannabis sativa* L. plant. This applies in particular to hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds. Moreover, in Switzerland hemp infusion based on the leaves of *Cannabis sativa* L. is no longer considered to be a novel foodstuff.

As part of the authorisation procedure for novel foods, the FSVO checks whether the product is safe and not deceptive (Art. 3 para. 1 FUAO). A basic precondition for authorisation is that the product is not classified as a foodstuff and is not subject to therapeutic products legislation (Art. 2 para. 4 let. d FSA).

The Ordinance on the Maximum Levels of Contaminants (Ordonnance on contaminants; CC 817.022.15) is also relevant to cannabis-containing foodstuffs, since it regulates the maximum permitted levels of delta 9-tetrahydrocannabinol in food products.

The presence of CBD is indicated on the labelling of a product derived from *Cannabis sativa* by means of the word “contains...”. Depending on the specific case, this word and others with the same meaning can be considered as nutritional claims, health claims or indications of the presence of an ingredient in a product.

If this indication is considered to be a nutritional claim, it must fulfil the conditions for using the claim “contains...” described in Annex 13 of the FDHA Ordinance on Information on Foodstuffs (FoodIO; RS 817.022.16).

In order to use this claim for the CBD contained in the ingredient *Cannabis sativa*, it must be

## **Products containing cannabidiol (CBD)**

### Overview and implementation guide

possible to demonstrate that a quantity of CBD sufficient to produce the nutritional effect established by generally accepted scientific evidence is present in the product (Art. 29 para. 2 let. b no. 2 FoodIO).

This indication could equally be considered as a non-specific health claim, for example, if it is present in combination with certain graphic elements. In accordance with Art.34 para. 2 FoodIO, claims of this type are not authorised unless they are accompanied by an authorised health claim in keeping with Art. 31 para. 3 FoodIO, or by a health claim as described in Annex 14 FoodIO. No health claims are currently authorised for CBD. It is currently not permitted to indicate the presence of CBD if this is considered to be a health claim.

If it is not considered to be either a nutritional claim or a health claim, it may be considered as an indication of the presence of an ingredient in a product. CBD is not currently authorised as an ingredient (novel foodstuff) in foodstuffs. It is therefore not currently possible to indicate the presence of CBD in this way.

### **Contact**

Federal Food Safety and Veterinary Office FSVO

[www.blv.admin.ch](http://www.blv.admin.ch)



## Products containing cannabidiol (CBD)

### Overview and implementation guide

#### Products sold as cosmetics

CBD may be used in cosmetics. It may be obtained from various parts of cannabis plants (natural CBD) or be synthesised.

- Synthetic CBD is not specifically regulated. However, the general legal requirements for cosmetics are applicable: The product must meet the definition of a cosmetic in accordance with Art. 53 para. 1 FUAO (CC 817.02) and must be safe (Art. 15 FSA).  
As for every other cosmetic product, the safety of the individual ingredients must be documented in a safety report. Moreover, medical or therapeutic indications are prohibited (Art. 47 para. 3 FUAO).
- Natural CBD is lawful in cosmetics only when obtained from cannabis, cannabis resin, cannabis extracts and cannabis tinctures originating from the seeds and leaves that are not accompanied with the fruiting tops of the cannabis plant; this in reference to the plant parts excluded by the signed Single Convention on Narcotic Drugs.
- Cannabis is regulated in accordance with Art. 54 para. 1 FUAO, which refers to the list of prohibited substances in the Annex II of European Regulation no. 1223/2009<sup>1</sup> on cosmetic products under entry no. 306: "Narcotic drugs, natural and synthetic: all substances listed in Tables I and II of the Single Convention on Narcotic Drugs signed in New York on 30 March 1961". Cannabis, cannabis resin, cannabis extracts and cannabis tinctures are listed in Table I of the Single Convention on Narcotic Drugs and are therefore prohibited in cosmetics. According to the definition, cannabis means 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.

The justification for this regulation is that flowering or fruiting tops of the cannabis plant contain higher concentrations of THC and therefore this may also be the case for their CBD extracts or tinctures.

For natural CBD obtained from the seeds and leaves when not accompanied by the tops of cannabis plants, and for THC with a total content below 1.0%, the same legal requirements apply as for synthetic CBD (see above).

In all cases it is recommended to request information relating to the extraction of CBD (the parts of the cannabis plant used, in the case of natural CBD) and relating to the safety of the product (THC content). A product with a total THC content above 1.0% falls under the Narcotics Law.

#### Contact

Federal Food Safety and Veterinary Office FSVO

[www.blv.admin.ch](http://www.blv.admin.ch)

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<sup>1</sup> Regulation (EU) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L342 of 22.12.2009, p. 59; last amended by Regulation (EU) 2018/978 OJ L 176 of 12.07.2017, p 3.

## **Products containing cannabidiol (CBD)**

Overview and implementation guide

### **Products sold as utility articles (CBD-containing liquids for e-cigarettes)**

Some shops offer CBD-containing liquids for e-cigarettes. These are classified as utility articles. According to Art. 5 of the FSA, these are defined as articles that come into contact with mucous membranes. According to Art. 61 FUAO, articles that come into contact with the oral mucosa when used correctly or in the normally expected manner may only release substances in quantities that pose no risk to health.

Substances that give products pharmacological effects may not be added (Art. 61 para. 2 FUAO). Accordingly, it is not permitted to add CBD to liquids for e-cigarettes in pharmacologically effective doses. This also applies to information which suggests that the product is a therapeutic product.

### **Contact**

Federal Food Safety and Veterinary Office FSVO

[www.blv.admin.ch](http://www.blv.admin.ch)

## **Products containing cannabidiol (CBD)**

Overview and implementation guide

### **Products offered as chemicals**

The Chemicals Act applies primarily to the packaging and labelling of chemical products. Placing chemicals on the market is done in a self-regulation system which requires manufacturers to assess whether substances or preparations may endanger human life or health or the environment. To this end, manufacturers must classify, package and label the product in accordance with the provisions of the Chemicals Ordinance (ChemO, CC 813.11) and compile a safety data sheet.

CBD-containing products may be marketed legally as scented oils under the provisions of the Chemicals Act. However, if their presentation indicates, or suggests, also other uses that would be covered by other legal provisions, their marketability must be assessed according to these provisions.

Example: CBD-containing "scented oil" is sold in a cartridge for e-cigarettes: in this case the foodstuffs/utility articles legislation, not chemicals legislation, forms the basis for the assessment of marketability (see preceding section). For the purposes of practical marketing, such marketable cartridges must be labelled and notified in accordance with chemicals legislation.

### **Contact**

Common notification authority for chemicals

[www.anmeldestelle.admin.ch/chem/en/home.html](http://www.anmeldestelle.admin.ch/chem/en/home.html)

## Products containing cannabidiol (CBD)

### Overview and implementation guide

## Products sold as tobacco substitutes, demarcation from the Narcotics Act

### *General requirements*

Under foodstuffs legislation, smoked tobacco substitutes are subject to the Tobacco Ordinance (TobO; CC 817.06). It is possible to market tobacco substitutes with CBD if they have a low THC content (<1.0% total THC content). According to the FSA, the person or entity placing the product on the market must observe self-supervision (Art. 23 FSA) and register the products with the FOPH before placing them on the market. The person or entity placing the product on the market must practise self-supervision (Art. 73 FSA in conjunction with Art. 23 of the old Foodstuffs Act of 9 October 1992) and notify the products to the FOPH before placing them on the market.

According to Art. 3, para. 1 of the TobO, tobacco substitutes must first satisfy the requirements applicable to the smoked tobacco products that they replace. Thus, for example, herbal cigarettes, like tobacco cigarettes, should have photographic warnings.

Secondly, when used normally, the substitutes must not pose a direct or unexpected threat to health. This means that they must not be toxic in the short term and must not contain components or foreign substances that the consumer does not expect.

The third requirement is that tobacco substitutes must not exhibit psychotropic effects in order to prevent smoking products containing tobacco substitutes from being used in the same way as narcotics. Plants used as tobacco substitutes, for example in herbal mixtures for smoking, are not subject to limits for THC or CBD. THC limits exist for narcotics and foodstuffs (see Ordonnance on contaminants; CC 817.022.15).

As regards narcotic effect, the legislation states that tobacco substitutes must not contain any raw materials or products that are listed in lists a - e of the Narcotics Lists Ordinance (NarcLO-FDHA, CC 812.121.11). This ordinance lists cannabis products with a total THC content of 1.0% or more as banned controlled substances (List d).

Cannabis with a total THC content of less than 1.0% is therefore not regarded as psychotropic and can also be sold as a tobacco substitute. CBD is not a narcotic according to the Narcotics Act. The substance is not mentioned either in NarcLO-FDHA or in the international Convention on Psychotropic Substances (CC 0.812.121.02). The term "psychotropic effect" should be interpreted narrowly, because otherwise it would apply to a large number of substances (e.g. including caffeine, etc.)

Accordingly, tobacco substitutes may also contain CBD. On the other hand, therapeutic properties – for example a calming or sedative effect – may not be claimed for tobacco substitutes (Art. 17 TobO). Ultimately it is up to the competent enforcement authority in the cantons to decide whether the claims made for a product are acceptable or not.

## **Products containing cannabidiol (CBD)**

### Overview and implementation guide

Furthermore, products that can be consumed or used in the same way as tobacco products are considered to be tobacco substitutes and, according to Art. 4 of the Federal Act on Tobacco Taxation (TabTA; CC 641.31; > [Factsheet](#) ), are subject to tobacco tax. For further information on tobacco tax, please contact the Swiss Customs Office, Tobacco and Beer Tax Section (Tel. +41 58 462 65 00 / e-mail: [tabak@ezv.admin.ch](mailto:tabak@ezv.admin.ch)).

#### *Reporting obligation*

Reporting to the FOPH is mandatory since products may contain plant material which, in contrast with tobacco products, poses an unexpected health risk (e.g. acute intoxication; for details of the reporting obligation see Federal Office of Public Health FOPH > [Applications for tobacco products](#) [German, French or Italian]).

Accordingly, the company concerned must submit the evidence and documentation required by Art. 3 para. 2 TobO for placing a tobacco substitute on the market to the FOPH. This also includes evidence showing that the product does not pose a direct or unexpected threat to health and does not have any psychotropic effects. To protect consumers against deception, the content of < THC should be declared on the packaging. Since formal approval by the FOPH is not legally required, a degree of supervision and intervention (via the cantons) is provided for.

#### *Road traffic*

Under road traffic legislation, there is a legal assumption that the presence of certain substances (e.g. THC) renders a person incapable of driving. Since CBD tobacco substitutes contain very small quantities of THC (less than 1.0%), they may put consumers above the permitted blood levels for THC in road traffic (1.5 microgram THC per litre of blood), in which case the consumers would be considered incapable of driving.

Anyone who drives a vehicle under the influence of drugs and exceeds this limit (zero tolerance) is considered to be incapable of driving and may not drive a vehicle. Whether, and from when, the limit is exceeded during the consumption of tobacco substitutes cannot be defined in the abstract. Therefore, people should be discouraged from consuming these products and then driving a vehicle.

#### *Summarising comments*

Cannabis products may be marketed as tobacco substitutes if they possess a low total THC content (<1.0%), satisfy the requirements applicable to the tobacco products they replace and have been reported to the FOPH. Drivers should refrain from consuming such products.

## **Contact**

Federal Office of Public Health FOPH

[www.bag.admin.ch](http://www.bag.admin.ch)

[tabakprodukte@bag.admin.ch](mailto:tabakprodukte@bag.admin.ch)

## Products containing cannabidiol (CBD)

### Overview and implementation guide

#### **Under what conditions may hemp seed be placed on the market?**

The Federal Office for Agriculture (FOAG) is responsible for controlling the production and placing on the market of materials for plant propagation intended for professional use in agriculture and commercial horticulture, and thus also for seed. Under current legal provisions, only approved varieties of hemp grown for oil and fibre that are listed in the FOAG's varieties ordinance (CC 916.151.6) or the European Union's Common Catalogue of Varieties can be placed on the market for commercial use in agriculture.

According to Annex 2, Chapter D, Table 4 of the EAER's ordinance on seeds and seedlings (CC 916.151.1), the key criteria for authorising hemp varieties are their yield and quality properties for oil and fibre production, their susceptibility to disease, a THC content of less than 0.3% and a THC to CBD ratio of less than 1. Only varieties that satisfy these criteria are listed in the varieties ordinance. No hemp varieties currently appear in Annex 4 of the varieties ordinance. The European Union's Common Catalogue of Varieties currently lists over fifty authorised varieties, all of which may be placed on the Swiss market.

Only officially recognised (certified) seeds bearing an official label may be placed on the market for commercial use in agriculture (samples of the official labels used in Europe can be seen at <http://www.escaa.org/index/action/page/id/23>).

Propagation, processing, sealing and labelling are carried out by authorised producers under official supervision. Officially recognised seeds may be placed on the market without the need for subsequent authorisation by the FOAG.

#### **Contact**

Federal Office for Agriculture FOAG

[www.foag.admin.ch](http://www.foag.admin.ch)

## **Procedure for cannabis and cannabis preparations with a high CBD content and a total THC content of less than 1.0% in Switzerland**

According to list d of the NarcLO-FDHA, cannabis with a total THC content of less than 1.0% is not regarded as a narcotic, which is why exemptions under Art. 8 para. 5 of the NarcA do not apply.

Authorisation from the FOPH is therefore not required to handle cannabis with a total THC content of less than 1.0%. The exception to this is cannabis resin (hash), which is banned under Ordinance on narcotics lists regardless of its THC content, and therefore cannot be handled without an exemption from the FOPH.

According to Art. 8 para. 5 NarcA, the FOPH can issue exemptions for the cultivation, import, preparation and placing on the market of banned narcotics if there is no international agreement to prevent it from doing so and the narcotics in question are intended for scientific research, medicinal product development or limited medical use. Further information can be found here: [Exemption authorisations for banned narcotics](#).

The decision on whether a specific cannabis product is actually deemed to be a narcotic and subject to Narcotics Act rests with the cantonal enforcement agencies.

## **Import and export of cannabis and cannabis preparations with a high CBD content and a total THC content of less than 1.0%**

Swissmedic cannot issue a no-objection certificate for the import or export of cannabis or cannabis preparations with a total THC content of less than 1.0% since these substances or products are subject to the international Single Convention on Narcotic Drugs.

To comply with narcotics legislation, importers are required to prove that the products they intend to import have a total THC content of less than 1.0%. Corresponding proof in the form of a batch-specific analytical certificate for the delivery in question issued by a laboratory accredited to ISO/IEC 17025 or by a GMP laboratory must be provided.

### **Contact**

Swissmedic, Swiss Agency for Therapeutic Products

[www.swissmedic.ch](http://www.swissmedic.ch)

Federal Office of Public Health FOPH

[www.bag.admin.ch](http://www.bag.admin.ch)