Products containing cannabidiol (CBD)

Overview and implementation guide
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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 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).

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. TPA, FoodA) are covered by the Federal Act on Product Safety (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 tetrahydrocannabinol (THC). This is the substance responsible for the psychotropic effect of cannabis. Another important cannabinoid that occurs in large quantities in the plant is cannabidiol (CBD). Unlike THC, it does not possess any psychoactive action. It interacts with various receptors and evidently also reduces the psychotropic effect of THC.

Possible therapeutic effects include antioxidant, anti-inflammatory, anticonvulsant, antiepileptic, anxiolytic, hypnotic or antipsychotic effects.

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.

It is not possible to classify CBD-containing raw materials without a knowledge of the dosage or the end product and intended purpose. The situation is comparable with that for caffeine or nicotine, substances that are also used in different product categories despite possessing a pharmacological action. Certain raw materials can also be used legally, for example to produce scented oils.

The typical CBD-containing raw materials on sale include
- cannabis buds with a high CBD content (they are exempt from narcotics legislation if the total THC content [THC and THC-A] < 1 %)
- CBD-pastes and extracts with a high CBD content
- pure CBD.

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.
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Products sold as medicinal products
Under Art. 4 para. 1 let. a of the Therapeutic Products Act (TPA; CC 812.21), 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.

The use of CBD in magistral formulations or formula-based medicinal products in accordance with Art. 9 para. 2 let. a-c TPA, is currently not permitted in Switzerland. No monopreparations containing pure CBD are authorised either in Switzerland or in any other country with comparable medicinal product control. In Switzerland, CBD is currently available in just one authorised preparation (Sativex®). However, the relevant active substance in this herbal medicine is not pure CBD, but a thick extract of cannabis leaves and cannabis buds obtained using liquid carbon dioxide as an extracting agent, and containing 60-71 % CBD.

According to Art. 19d of the Therapeutic Products Ordinance (TPO; CC 812.212.21), CBD is therefore not regarded as a permitted active substance for the preparation of magistral formulations or formula-based medicinal products. Moreover, the fact that a monograph for CBD has now been added to the DAC/NRF (German Drug Codex/New German Formulary) does not change the situation at all; DAC/NRF is not mentioned in the list of recognised pharmacopoeias in the Annex to the Ordinance of the Swiss Agency for Therapeutic Products on the drafting of pharmacopoeia texts and the recognition of pharmacopoeias (SHI-PhaV; CC 812.214.11).

Unlike in Switzerland, the use of CBD in pharmacy-compounded preparations is permitted in Germany, even though no authorised CBD-containing monopreparation is currently available in Germany. In order to ensure the quality of such medicinal products, Supplement 2015/2 of DAC/NRF includes a CBD monograph as well as a monograph for the preparation of an oily solution of CBD 50 mg/ml. As of 1 October 2016, CBD has been included in the German Ordinance on the Prescribing of Medicinal Products, i.e. it may only be dispensed on presentation of a medical prescription.

The monographs also specifically state that since CBD is not authorised, it is not possible to issue any dosage recommendation for it, and that daily doses ranging from the lower double-digit to the medium three-digit milligram range appear to be used.

Contact
Swissmedic, Swiss Agency for Therapeutic Products
www.swissmedic.ch
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Products sold as foodstuffs
New foodstuffs legislation comes into force in Switzerland on 1 May 2017. 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.

It is a basic precondition that foodstuffs must be safe. This means that they may be neither harmful to health nor unsuitable for consumption by humans. 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 authorized by the Federal Food Safety and Veterinary Office or authorized by the European Commission. CBD-enriched foodstuffs (e.g. CBD-enriched cannabis extracts, hemp seed oil with added CBD, food supplements with CBD) are classed as novel foods and require authorization.

As part of the authorization procedure for novel foods, the FSVO checks whether the product is safe and not deceptive. A basic precondition for authorization is that the product is not classified as a foodstuff and is not subject to therapeutic products legislation.

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

Products sold as cosmetics
Cannabidiol is governed by Article 54 para. 1 of the Ordinance on Foodstuffs and Commodities (FCO; CC 817.02), which refers to the annex of prohibited substances (Annex II) of European Regulation no. 1223/2009 on cosmetic products¹, under entry no. 306: "All substances listed in Tables I and II of the Single Convention on Narcotic Drugs signed in New York on 30 March 1961".

Cannabis is listed in Table I of the Single Convention on Narcotic Drugs and, according to the definition, refers to 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. Since CBD is a cannabis derivative, it may not therefore be used in cosmetic products. However, seeds and leaves that are not accompanied by the tops are excluded from this prohibition.

Furthermore, like any other cosmetic product, the safety of each ingredient present in the product must be demonstrated in a product safety report, and the product must satisfy the definition of a cosmetic in accordance with Art. 53, (1) FCO.

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 Foodstuffs Act (FoodA; CC 817.0), these are defined as articles that come into contact with mucous membranes. According to Art. 61 of the FCO, 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. 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.

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.
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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% total THC content). According to the FoodA, the person or entity placing the product on the market must observe self-supervision (Art. 23 FoodA) and register the products with the FOPH before placing them on the market.

According to Art. 3 of the Tobacco Products Ordinance, 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 Foreign Substances and Components Ordinance [XCO, CC 817.021.23]).

As regards narcotic effect, the legislation states that tobacco substitutes must not contain any raw materials or products that are listed in lists a to e of the Narcotics Lists Ordinance (NarcLO-FDHA, CC 812.121.11). This ordinance lists cannabis products with a total THC content of 1 % or more as banned controlled substances (List d).

Cannabis with a total THC content of less than 1 % is therefore not regarded as psychotropic and can also be sold as a tobacco substitute. Cannabidiol (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. 2 FoodA in conjunction with 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.

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) (0)58 462 65 00 / e-mail: 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 <1 % 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 %), 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 %), 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.tobacco.foph.admin.ch [German, French, Italian]
Under what conditions may hemp seed products be placed on the market or procured?

Generally speaking, when it comes to seeds and plants, the Federal Office for Agriculture (FOA) is responsible for the provisions governing the production and placing on the market of plant propagation material intended for professional use. Plant seed legislation specifies that only an approved plant variety listed in the catalogue of varieties may be placed on the market for use in agriculture and horticulture.

As regards cannabis, the principal requirement for its approval is a THC level of less than 0.3% and a THC/CBD ratio of less than 1 according to Annex 2, section D, Table 4 of the EAER ordinance on seeds and plants (CC 916.151.1). A variety may only be listed in the ordinance on varieties (CC 916.151.6) if these conditions are fulfilled.

At present, no cannabis variety is listed in Annex 4 of the catalogue of plant varieties used for agricultural purposes. However, according to Article 5 of Annex 6 (Seed industry) of the Agreement between the Swiss Confederation and the European Community on Trade in Agricultural Products (CC 0.916.026.81), Switzerland accepts the marketing on its territory of seeds of varieties accepted in the European Community (Art. 20 let. a and Art. 27 para. 1 let. c of the EAER ordinance on seeds and plants). The European catalogue currently (January 2017) comprises more than fifty authorised varieties, which can also be propagated and placed on the market in Switzerland.

The placing on the market of certified plant material obtained from varieties officially listed in the Swiss or European catalogue does not require subsequent authorisation by the Federal Office of Agriculture.

Contact
Federal Office for Agriculture FOAG
www.foag.admin.ch