Expert Panel for Delimitation Questions

Swissmedic, Swiss Agency for Therapeutic Products
Federal Office of Public Health FOPH
Federal Food Safety and Veterinary Office FSVO
Association of Cantonal Pharmacists KAV
Association of Swiss Cantonal Chemists VKCS

Products containing cannabidiol (CBD) and other cannabinoids that are not subject to narcotics legislation

Overview and implementation guide

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Contents

1 Introduction

There is a proliferation of cannabinoid-containing products on the Swiss market in terms of claims, offers and compliance with the legal requirements for the actual intended use of the products concerned. Thus, for example, products are frequently placed on the market under chemicals legislation, but are intended for oral administration. Such products only satisfy the safety requirements for toilet cleaners, etc., but not those for oral administration, for which they would have to satisfy the legal requirements of food or therapeutic products legislation; this is the only way of ensuring the safe use of these products.

After several years of the CBD boom, products that are specifically supplemented with other cannabinoids are increasingly appearing on the market. They are often marketed as smoking products (e.g. flowers, e-cigarettes), or offered as foods or products for oral administration. The advertising focuses on health or general well-being.

This information sheet provides an overview of the available raw materials and products containing CBD and other cannabinoids 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 inform possible suppliers about the legal requirements that must be followed. The reader is referred to the report “Criteria for distinguishing therapeutic products from foodstuffs with reference to orally administered products” and to the guide “Criteria for the demarcation of cosmetic products from therapeutic products and biocidal products”[1] for further information about demarcation.

The implementation guide has been drawn up by the cross-agency Expert Panel for Delimitation Questions[2] (formerly "Technical Platform for Delimitation Issues") with representatives from the Federal Office of Public Health (FOPH), the Federal Food Safety and Veterinary Office (FSVO), Swissmedic, the Swiss Agency for Therapeutic Products, the Association of Cantonal Pharmacists (KAV) and the Association of Swiss Cantonal Chemists (VKCS). Its content will be modified accordingly as legislation is revised or relevant new scientific findings come to light.

[1] https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/hilfsmittel-und-vollzugsgrundlagen/abgrenzungskriterien.html

[2] https://www.swissmedic.ch/swissmedic/en/home/about-us/nationale-zusammenarbeit/fachgremium-abgrenzungsfragen.html

Note:

1. **This information sheet applies not only to CBD, but to all cannabinoids** of herbal, synthetic or semi-synthetic origin, **provided they are not subject to narcotics legislation**. In this context, the latter refers exclusively to the Narcotics Act (NarcA; SR 812.121) and, for medical purposes, to the Therapeutic Products Act (TPA; SR 812.21).

2. **This information sheet excludes cannabis products with a total THC content of at least 1.0% for medical purposes.**
   Due to the removal of the prohibition in the Narcotics Act on 1 August 2022, cannabis **for medical purposes** with a total THC content of at least 1.0% was reallocated from List d (prohibited narcotics) to List a (substances subject to all control measures) of the Narcotics Lists Ordinance (NarcLO-FDHA; SR 812.121.11). As a result, the use of cannabis for medical purposes with a total THC content of at least 1.0% is subject to regular control measures, like other controlled substances in List a (see Narcotics Control Ordinance, NarcCO; SR 812.121.1). Cannabis plants and parts thereof as well as preparations such as extracts, resins, oils and tinctures and the substances dronabinol and THC have also been reallocated to List a, provided there is an intended medical purpose. The defined limit of at least 1.0% total THC content remains unchanged.

   As a result of the change in the legislation, the cultivation, processing, preparation of and trade in cannabis for medical purposes were made subject to the approval and control system operated by Swissmedic, analogously to other narcotics used for medical purposes (such as fentanyl, methadone and morphine). The handling of cannabis and cannabis products with a total THC content of at least 1.0% for non-medical purposes is still forbidden (for exceptions see Art. 8 para. 5 and Art. 8*a* NarcA).

   More information can be found on the Swissmedic and FOPH websites[3][4].

[3] https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/heilmittel/med-anwend-cannabis.html

[4] https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/besondere-arzneimittelgruppen--ham-/authorised-narcotics/cannabis-agency.html

2 What are cannabinoids?

Cannabinoids are a group of substances that are structurally related to tetrahydrocannabinol (THC) or that bind to cannabinoid receptors. The term cannabinoids originally referred to a unique group of terpene phenol compounds that occur in the cannabis plant (*Cannabis sativa* or *Cannabis indica*).

The subsequent development of synthetic cannabinoids, such as dronabinol, has altered this definition, as has the discovery of endogenous cannabinoids.

Investigations have shown that the cannabis plant produces between 80 and 100 cannabinoids and around 300 non-cannabinoids. The most important and most thoroughly 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 have any corresponding comparable psychoactive effect. It interacts with various receptors and evidently also modulates the psychotropic effect of THC.

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

3 Legal basis according to classification

The range of products that contain CBD or other cannabinoids (or to which CBD or other cannabinoids have been added) 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, smoked tobacco substitutes, scented oils, chewing gums and ointments, some of which are marketed 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 use are not met, a product may not be distributed in Switzerland and therefore may not be placed on the market.

The final products are classified on a case-by-case basis taking account of all the relevant factors, including composition, intended use, dosage, etc. The person who places the product on the market is required to provide information on the intended use (e.g. medicinal product, medical device, foodstuff, cosmetic, chemical). Different enforcement authorities are responsible for control, depending on how the products are classified. In case of doubt, the enforcement authority assigns a product to particular legislation and takes the necessary measures.

Assignment is particularly unclear in the case of products with pure raw materials. Products for which there is no specific applicable law (e.g. Therapeutic Products Act [TPA; 812.21], Foodstuffs Act [FoodA; SR 817.0]) are covered by the Federal Act on Product Safety (ProdSA; SR 930.11) (catch-all legislation).

Raw materials intended for further processing by establishments into final products are subject to the provisions of the Chemicals Act (ChemA; SR 813.1). All other “raw materials” must be placed on the market in compliance with the legislation that corresponds to the intended or presumed use.

Other cannabinoids that are not subject to the Narcotics Act, like CBD, must nevertheless satisfy all the requirements of the legislation or intended use according to which they are to be placed on the market.

4 Overview of the competent authorities

The Federal Office of Public Health (FOPH) is responsible for the registration of smoked tobacco substitutes containing CBD and other cannabinoids in retail packs (in practice: under 250 grams), for exemptions for tobacco products containing large quantities of additives, and for cannabis and cannabis products with a THC content of at least 1.0% without a medical intended use.

If the product is a therapeutic product (medicinal product or medical device), Swissmedic, the Swiss Agency for Therapeutic Products, is responsible.

The cultivation, processing, preparation of and trade in cannabis for medical purposes with a total THC content of at least 1.0% is subject to the approval and control system operated by Swissmedic.

The Federal Food Safety and Veterinary Office (FSVO) is responsible for foodstuffs (including food supplements), cosmetics, utility articles and non-smoked tobacco substitutes (e-cigarettes or liquids for electronic cigarettes, smokeless snus and snuff substitutes containing CBD and other cannabinoids).

The Federal Office for Agriculture (FOAG) handles issues relating to commercial cultivation in the agricultural and horticultural production sectors. These are limited to direct payments legislation, plant health legislation and feed legislation following the revocation with effect from 1 January 2021 of all the provisions of the agricultural seed legislation governing the production and placing on the market of hemp seeds and plants.

5 In what form are products containing CBD and other cannabinoids supplied?

5.1 As a raw material

Raw materials (in the form of substances or preparations) are governed by the provisions of the chemicals legislation. They are used to prepare products and are therefore typically marketed to manufacturers. The manufacturers are responsible for correct preparation in compliance with the specific legal requirements governing their products.

If the intention is to distribute raw materials to the general public, the distributor (who is the manufacturer under the terms of the Chemicals Ordinance) must exercise self-supervision in reviewing beforehand the possible and probable uses that could occur.

If this review identifies uses that are subject to special legislation, or if such uses appear plausible, the requirements of this legislation must be observed.

5.2 As ready-to-use products

Products containing CBD and other cannabinoids are also supplied in ready-to-use form, whether as therapeutic products, foodstuffs, cosmetics, utility articles (excluding cosmetics), tobacco substitutes or as chemicals, e.g. scented oil. Ready-to-use products or finished products are understood to be products in the form in which they are supplied directly to the commercial or individual end user or are designated for them[5].

In order to decide which legislation is applicable, it is necessary to consider all the properties and claims, both implicit and explicit, relating to a product in an overall assessment and to weigh them up on a case-by-case basis. Some suppliers state on their websites that the products may not be used for medical purposes for legal reasons. Other websites, on the other hand, include links to sites describing medical uses of cannabis. Therapeutic claims are evidently being made for such products, and they are therefore subject to the legislation governing therapeutic products.

The legal requirements for the various product categories and their marketability are described below.

[5] This means that they are intended for the "end user" as defined in Article 1 paragraph 5 of the CLP Regulation and may not be placed on the market in another form.

5.3 Products sold as therapeutic products (medicinal products, medical devices)

5.3.1 Medicinal products

In accordance with Article 4 paragraph 1 letter a TPA (SR 812.21), ready-to-use products containing CBD and other cannabinoids with a medical intended use are regarded as medicinal products and, in accordance with Article 9 paragraph 1 TPA, may not be placed on the market without authorisation.

Establishments which prepare, distribute or dispense medicinal products containing CBD and other cannabinoids always require a corresponding licence from Swissmedic or the canton in addition.

Epidiolex® was approved by the FDA on 28 June 2018, making it the first CBD monopreparation in the world to receive regulatory approval. This product was additionally authorised in Switzerland on a prescription-only basis on 10 February 2021 under the proprietary name Epidyolex®. The following has to be considered:

- CBD has a different activity profile from THC and is therefore not suitable as a substitute for THC;
- When a medicinal product is approved, its efficacy and safety are only reviewed and authorised in specific indications. The FDA only approved Epidiolex® for the adjuvant treatment of two rare forms of epilepsy in 2018; Epidyolex® was authorised in Switzerland in 2021 for the adjuvant treatment of convulsions associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients from 2 years of age. Further information on dosage, adverse drug reactions (ADR), extension of the indications, etc. can be found in the corresponding Information for healthcare professionals[6].

[6] Swissmedic: https://www.swissmedicinfo.ch/?Lang=EN
FDA: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf

In accordance with Article 9, paragraph 2 letter a TPA and taking into account the respective provisions of the legislation governing therapeutic products, medicinal products containing CBD may be prepared and dispensed in pharmacies. In addition to the general requirements applicable to the preparation, validation and filling of prescriptions, the following should be considered:

1. A doctor's prescription must be present.
2. The prescription should be issued by a specialist in the indications for which currently authorised medicinal products have been approved.
3. If, in justified individual cases, a doctor issues a prescription for a different indication, the prescription should only be filled (prepared and dispensed) consultation with the respective doctor and it should be documented accordingly.

If a medicinal product is prepared in a pharmacy using a magistral formula, the following position papers, which can be found at www.kantonsapotheker.ch must be taken into account:

- Position paper 0021 Cannabis medicinal products (current version)
- Position paper 0020 Formula medicinal products, manufacture and placing on the market (current version)

Medical devices

Products containing CBD and other cannabinoids with a medical intended use, the primary effect of which in or on the human body according to its intended use is **not** achieved by pharmacological, immunological or metabolic means, but the mode of action of which is supported by the CBD or other cannabinoids contained in the product, may comply with the definition of a medical device as stipulated in Article 3 of the Medical Devices Ordinance (MedDO; SR 812.213).

The classification of medical devices containing CBD and other cannabinoids is guided by Article 15 MedDO in conjunction with Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (EU-MDR).

If multiple classification rules apply to a device, the strictest rule applies, meaning that the device will be placed into the highest applicable class.

For medical devices containing CBD or other cannabinoids, classification rules 14 and 21 of Annex VIII EU-MDR must also be taken into particular account. The two classification rules listed here are not exhaustive[7].

Medical devices may generally contain plant extracts which provide colour or flavour, for example. In all cases in which medical devices may contain pharmacologically active substances or plant extracts, the manufacturer must perform a case-by-case assessment of whether the product must be classified as a medicinal product or a medical device and, if it is a medical device, the class to which it belongs. This also applies to CBD or other cannabinoids since these may have a pharmacological, if not a psychoactive, effect.

Article 45 paragraph 2 TPA and Article 21 paragraph 2 MedDO require anyone who places a medical device on the market (e.g. manufacturers or importers) to perform an assessment of and/or be able to demonstrate conformity with the fundamental safety and performance requirements (more detailed information on the obligations of economic operators can be found in the information sheet "*Obligations Economic Operators CH*[8]").

The conformity assessment procedure is based on Articles 52 and 54 and Annexes IX-XI EU-MDR (Art. 23 MedDO), the necessary certificate(s) on Annexes IX-XI EU-MDR (Art. 25 para.1 MedDO) and the declaration of conformity on Annex IV EU-MDR (Art. 29 para. 2 MedDO).

Contact

Swissmedic, Swiss Agency for Therapeutic Products
https://www.swissmedic.ch/swissmedic/en/home.html

[7] Please refer to the 22 classification rules in Annex VIII of Regulation (EU) 2017/745 (EU-MDR)

[8] https://www.swissmedic.ch/dam/swissmedic/en/dokumente/medizinprodukte/mep_urr/mu600_00_016d_mb_pflichten_wirtschaftsakteure_ch.pdf.download.pdf/MU600_00_016e_MB_Obligations_Economic_Operators_CH.pdf

5.4 Products sold as foodstuffs

Article 4 paragraph 1 of the Foodstuffs Act (FoodA; SR 817.0) defines foodstuffs as 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 FoodA).

It is a basic precondition that foodstuffs must be safe (Art. 7 FoodA). 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; SR 817.02]).

However, foodstuffs that were not 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 licensed by the FSVO or authorised by the European Commission. These foodstuffs are classed as novel foods (Art. 15 FUAO), a category that includes cannabinoids such as CBD and extracts of *Cannabis sativa* L. and derivatives containing cannabinoids that are used in/as foodstuffs (e.g. hemp seed oil with added CBD, food supplements with CBD).

Products derived from *Cannabis sativa* L. or from parts of the plant which were documented as safe and in use for human consumption to a significant degree in the EU prior to 15 May 1997 are not considered to be novel foodstuffs in Switzerland provided the plant *Cannabis sativa* L. fulfils the requirements of Article 15 paragraph 1 letter d no. 2 FUAO. This applies in particular to hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds. Furthermore, in Switzerland herbal tea obtained from the leaves of the cannabis plant *Cannabis sativa* L. is not considered to be a novel foodstuff. The latter may be used to flavour foodstuffs without a licence. The precondition for this is that the herbal tea is used as an aqueous infusion and in no other form (e.g. concentrated or as a syrup).

As part of the authorisation procedure for novel foodstuffs, 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 classified as a foodstuff and is not subject to therapeutic products legislation (Art. 2 para. 4 let. d FoodA).

If they are subject to food legislation, products with cannabinoids added as pure substances may not currently be placed on the market. Such products are subject to the Novel Food Regulation (Art. 15-19 FUAO). To date, no such products have been authorised as Novel Foods. Unregulated or unapproved novel foods may neither be placed on the market (Art. 16 FUAO) nor used as food ingredients (Art. 18 FUAO).

To date numerous applications have already been submitted in the EU for CBD to be authorised as a novel foodstuff. The European Commission has passed on these applications to the EFSA for assessment of the harmlessness to health of the consumption of CBD by humans. The Scientific Committee of the EFSA identified numerous gaps in the data concerning the impact on health of consuming CBD. Assessment of CBD as a novel foodstuff will therefore be suspended in the EU until these data gaps have been filled by the applicants.

Switzerland has also assessed the health risks of CBD as a novel foodstuff and published the findings in the “FSVO Briefing Letter: Cannabidiol (CBD) in foodstuffs and effects on the liver” dated

3 December 2021. Safety concerns exist in Switzerland too, and it is currently not possible to produce a final assessment of the safety of CBD as a foodstuff.

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

The presence of CBD or other cannabinoid is indicated on the labelling of a product derived from *Cannabis sativa* L. by means of the word "contains...". Depending on the specific case, this word and others with the same meaning may be considered as nutritional or health-related information or an indication of the presence of an ingredient in a product.

If this indication is considered to be nutritional information, it must fulfil the conditions for use of the information “contains...” described in Annex 13 of the FDHA Ordinance on Information on Foodstuffs (FoodIO; RS 817.022.16).
In order to use information of this type for a cannabinoid such as CBD contained in the ingredient *Cannabis sativa*, it must be possible to demonstrate that a quantity of the corresponding cannabinoid 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 to be non-specific health information, for example if it is present in combination with certain graphic elements. According to Article 34 paragraph 2 FoodIO, information of this type is only permitted if it is accompanied by authorised health-related information in keeping with Article 31 paragraph 3 FoodIO, or by health-related information as described in Annex 14 FoodIO. No health-related information is currently permitted for cannabinoids such as CBD. It is therefore currently prohibited to indicate the presence of a cannabinoid if this is considered to be health-related information.

If it is not considered to be either nutritional information or health-related information, it could be considered as an indication of the presence of an ingredient in the product. **Since no cannabinoid is currently authorised as an ingredient in foodstuffs (novel foodstuff), it is not possible at present to indicate the presence of cannabinoids such as CBD in this way**.

Further information

Website on cannabis, hemp extracts and cannabinoids as foodstuffs
https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/bewilligung-und-meldung/bewilligung/cannabis-cannabidiol.html

Contact

Federal Food Safety and Veterinary Office (FSVO)
https://www.blv.admin.ch/blv/en/home.html

5.5 Products sold as cosmetics

General requirements for cosmetics:

A cosmetic product (cf. definition in Art. 53 para. 1 FUAO) must be safe (Art. 15 FoodA). The safety of the individual ingredients must be documented in a safety report (Art. 57 FUAO). Furthermore, references of any kind to effects of cosmetics that lead to the cure, relief or prevention of diseases (e.g. medical or therapeutic properties) are forbidden (Art. 47 para. 3 FUAO).

Specific requirements with respect to CBD and other cannabinoids:
Based on the report from the Federal Council on legal certainty regarding the production, trade in and use of hemp/cannabis products,[9] the interpretation on the use of CBD and other cannabinoids in cosmetics is being modified.

Currently, CBD and other cannabinoids are not specifically regulated as such. However, the use of *"narcotics"* in cosmetic products is prohibited under Article 54 para. 1 FUAO with reference to Regulation (EC) 1223/2009[10]. According to entry no. 306 of Annex II of Regulation (EC) 1223/2009 "*narcotics*" are defined as follows:
"Narcotics, natural and synthetic: All substances listed in Tables I and II of the Single Convention on Narcotic Drugs[11] signed in New York on 30 March 1961". "Cannabis, cannabis resin, cannabis extracts and cannabis tinctures" are listed in this Table I.

However, the Single Convention is not directly applicable (not "self-executing"). Furthermore, the EU legislation does not further specify the Single Convention; rather, it permits the member states to implement the regulations into national law (no uniform interpretation).

Therefore, Switzerland has adopted the Single Convention under its national narcotics legislation. *"Cannabis"*[12] is defined in Annex 1 NarcLO-FDHA. Of relevance is the total THC content of at least 1.0%, regardless of whether CBD or other cannabinoids were obtained from the flowers or leaves of the hemp plant.
For the manufacture of CBD or other cannabinoids for use in cosmetic products, it is irrelevant which part of the hemp plant is used. Rather, none of the intermediate products during the entire manufacturing process can have a THC content of more than 1.0%.

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[9] Report of the Federal Council dated 1 November 2023 in fulfilment of postulate 21.3280 Minder dated 18 March 2021.

[10] Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342 of 22.12.2009, p. 59; most recently amended by Regulation (EU) 2024/858 OJ L of 15.3.2024, p. 1.

[11] Single Convention on Narcotic Drugs, 1961, SR 0.812.121.0.

[12] Hemp plants or parts thereof with an average total THC content of at least 1.0% and all articles and preparations which have a total THC content of at least 1.0% or which have been produced from hemp with a total THC content of at least 1.0%.
With regard to cannabis resin, cannabis extracts and cannabis tinctures, reference is made to the definition of cannabis.

Synthetic CBD and other synthetic cannabinoids are not specifically regulated either. The general legal requirements for cosmetics described above apply.

Furthermore, the safety report to be created for self-supervision (Art. 57 FUAO) must include scientific evidence that the CBD or other cannabinoids, regardless of origin, used to manufacture the cosmetic products do not pose a risk to health and are safe.

A product with a total THC content of 1.0% or higher is subject to the provisions of narcotics legislation.

Following the approval of the general ruling of the Notification Authority for Chemicals of 29 March 2022 on the denaturing of CBD-containing scented oils as chemicals and the recent suspension of the assessment of CBD as a novel foodstuff in the EU, numerous CBD oils are currently being offered on the market as oral care products containing various concentrations of CBD. Products of this kind do not comply with the intended use of a cosmetic and there is considerable potential for misuse.
It is currently not possible to perform an adequate safety assessment of these products. To date, the safety has not been demonstrated in any of the safety reports available to the cantonal enforcement authorities: gaps in the data mean that precisely the same safety concerns exist as those relating to foodstuffs. The placing on the market of such a product for oral administration does not currently satisfy the legal requirements.

Further information

Website on cannabidiol (CBD) in cosmetics
https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/kosmetika-schmuck/kosmetika/cbd-in-kosmetika.html

Contact

Federal Food Safety and Veterinary Office (FSVO)
https://www.blv.admin.ch/blv/en/home.html

5.6 Products sold as utility articles (e.g. liquids for e-cigarettes, tobacco-free snus and snuff substitutes containing CBD and other cannabinoids)

Some shops selling e-cigarettes offer non-smoked tobacco substitutes containing CBD and other cannabinoids. These are classified as utility articles. According to Article 5 FoodA, these are defined as articles that come into contact with mucous membranes. According to Article 61 FUOA, 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 confer pharmacological effects on products may not be added (Art. 61 para. 2 FUAO). Accordingly, it is not permitted to add CBD and other cannabinoids to such products in pharmacologically effective doses. This also applies to information which suggests that the product is a therapeutic product.

Refill containers for e-cigarettes are also governed by the chemicals legislation. This means that the person placing the product on the market must practice self-supervision and fulfil obligations including labelling and registration in the product register (see next section).

Contact

Federal Food Safety and Veterinary Office (FSVO)
https://www.blv.admin.ch/blv/en/home.html

5.7 Products sold as chemicals

The Chemicals Act primarily regulates the packaging and labelling of chemical products. Before placing chemical products on the market, the responsible manufacturer is required to practice self-supervision as regards conformity with chemicals legislation. However, if in the course of self-supervision the presentation of a product is suggestive of or implies uses that would be covered by other legal provisions, its marketability must be assessed according to these provisions (see Art. 1 para. 5 let. c Chemicals Ordinance, ChemO; SR 813.11).

Example: CBD-containing "scented oil" is sold in a cartridge for e-cigarettes: in this case the foodstuffs/utility articles legislation, or the new tobacco law upon entry into force, and not chemicals legislation, forms the basis for the assessment of the product's marketability (see preceding section). For the purposes of practical marketing, marketable cartridges of this kind must be labelled and notified in accordance with chemicals legislation. Further examples could include cannabis oils and cannabis tinctures which are sold without a medical prescription but with the intention of using them orally in the expectation of a pharmacological effect, in which case the therapeutic products legislation would apply.

If the product is subject to the provisions of the ChemO, the manufacturer must assess whether the chemical product may pose a threat to the life or health of humans or the environment. Accordingly, the manufacturer must classify, package and label the product in accordance with the provisions of ChemO and produce a safety data sheet. On 29 March 2022 the Common Notification Authority for Chemicals issued a general ruling requiring CBD-containing products placed on the market under the provisions of the chemicals legislation and intended for the end consumer to be denatured. This affects, for example, products with barely plausible product claims such as "room fragrance", but not CBD intended for consumption as a foodstuff (see section "Products sold as foodstuffs"), therapeutic products (see section "Products sold as therapeutic products (medicinal products, medical devices)"), cosmetics (see section "Products sold as cosmetics") or e-liquids for e-cigarettes (see section "Products sold as utility articles (e.g. liquids for e-cigarettes, tobacco free snus and snuff substitutes containing CBD and other cannabinoids)").

Contact

Common Notification Authority for Chemicals
https://www.anmeldestelle.admin.ch/chem/en/home.html

5.8 Products sold as smoked tobacco substitutes

Cannabis with a total THC content of less than 1.0% is not regarded as having a psychotropic effect and can also be sold as a smoked tobacco substitute. Under the foodstuffs legislation, smoked tobacco substitutes are regulated by the Tobacco Ordinance (TobO; SR 817.06). These rules still apply, although the Federal Supreme Court has established[13] that CBD cannabis products are not tobacco substitutes within the meaning of the Tobacco Taxation Act. The requirements of the foodstuffs legislation still apply. The person or entity placing the product on the market must practise self-supervision (Art. 73 FUAO 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 (Art. 3 para. 2 TobO). The corresponding evidence and documents must be submitted to the FOPH for this purpose. The requirements and the notification form can be found on the FOPH website. Claims for tobacco products which refer in any way to health are forbidden (Art. 17 para. 2 TobO). Responsibility for checking compliance lies with the competent enforcement bodies in the cantons.

Smoked tobacco substitutes must also be notified under the new Tobacco Products Act approved by Parliament in 2021. The approved version of the legislation is available on the FOPH website[14] under *Laws*.

The use of cannabis products with a low THC content may briefly impair the ability to drive. A corresponding warning was therefore incorporated into Article 14 paragraph 1 letter c point 3 of the future Tobacco Products Act. Consumers may also face prosecution abroad because of stricter regulations and different threshold values for THC in cannabis products. The FOPH therefore recommends persons or entities placing products on the market to voluntarily inform consumers accordingly until the Tobacco Products Act comes into effect. Details can be found on the FOPH website linked below and in the Federal Gazette (in the Swiss languages only).

Further information

Federal Office of Public Health (FOPH) https://www.bag.admin.ch/bag/de/home/gesetze-und-bewilligungen/gesuche-bewilligungen/gesuche-bewilligungen-im-bereich-sucht/gesetzliche-vorgaben-tabakprodukte/faq-cbd.html

Federal Gazette 2021 2327 Federal Act on Tobacco Products and Electronic Cigarettes (Tobacco Products Act, TobPA)

Contact

tabakprodukte@bag.admin.ch

[13] Decision of the Federal Supreme Court 2C_348/2019

[14] www.bag.admin.ch > Strategie & Politik > Politische Aufträge & Aktionspläne > Politische Aufträge zur Tabakprävention > Tabakpolitik der Schweiz > Tabakproduktegesetz

5.9 Agricultural production of hemp, hemp seeds and plants

Agricultural production of hemp that is not classified as a narcotic has been permitted since 1 January 2021. All the provisions of the seed legislation governing the production and placing on the market of hemp seeds and plants have been revoked. The provisions of the plant health legislation and the direct payments legislation must be observed with respect to the agricultural production of hemp. If the hemp is intended for use as animal feed, the provisions of the feed legislation apply.

Further information
https://www.blw.admin.ch/blw/en/home/nachhaltige-produktion/pflanzliche-produktion/hanf.html

Contact
Federal Office for Agriculture (FOAG)
https://www.blw.admin.ch/blw/en/home.html

5.10 Procedure for cannabis and cannabis preparations containing CBD and other cannabinoids with a total THC content of less than 1.0%

According to NarcLO-FDHA, cannabis and cannabis preparations with a total THC content of less than 1.0% are not regarded as narcotics, and the exemptions in accordance with Article 8 paragraph 5 NarcA therefore do not apply. Authorisation from the FOPH is therefore not required to handle cannabis with a total THC content of less than 1.0% or cannabis preparations made from hemp with a total THC content of less than 1.0%.

According to Article 8 paragraph 5 and paragraph 8 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, limited medical use or control measures. Following the revision of the Narcotics Act on 1 August 2022, cannabis with a total THC content of at least 1.0% for medical purposes is no longer classified as a prohibited narcotic and is now subject to the approval and control system operated by Swissmedic (see Art. 8 para. 1 let. d NarcA in conjunction with List a of NarcLO-FDHA). You can find further information at the link below.

5.11 Import and export of cannabis and cannabis preparations containing CBD and other cannabinoids with a total THC content of less than 1.0%

Swissmedic cannot issue a no-objection certificate (NOC) 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 the 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 certificate of analysis for the delivery in question issued by a laboratory accredited to ISO/IEC 17025 or by a GMP laboratory must be provided.

Further information

Federal Office of Public Health (FOPH) https://www.bag.admin.ch/bag/en/home/gesetze-und-bewilligungen/gesuche-bewilligungen/ausnahmebewilligungen-bewilligungen-betmg/ausnahmebewilligungen-verbotene-betaeubungsmittel.html

Revised legislation governing cannabis medicinal products

https://www.bag.admin.ch/bag/de/home/medizin-und-forschung/heilmittel/med-anwend-cannabis/gesetzesaenderung-cannabisarzneimittel.html

Contact

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6 Change history

Version	Date	Description
7.0	12.04.24	First version with version control The 7th version of the information sheet contains some changes and further specifications, particularly in the area of cosmetics and medical devices.