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Products containing cannabidiol (CBD)

Overview and implementation guide

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Introduction

A wide range of cannabidiol-containing products are available in Switzerland. These products are regulated in a number of Federal Acts. Unlike THC (tetrahydrocannabinol), CBD is not subject to the Narcotics Act (NarcA, SR 812.121) because it does not produce a comparable psychoactive effect.

This Information sheet provides an overview of the available CBD-containing raw materials and products 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 observed. The reader is referred to the report “Criteria for the demarcation of therapeutic products from foodstuffs for products for oral use” 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 technical platform for demarcation 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.

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

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 are present in the plant mainly as carboxylic acids.

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 psychoactive effect. It interacts with various receptors and evidently also modulates 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 be demonstrated only inadequately.

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, 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.

Overview of the competent authorities

The Federal Office of Public Health (FOPH) is responsible for the registration of tobacco substitutes containing CBD 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 %. If the product is a therapeutic product (medicinal product or medical device), Swissmedic, the Swiss Agency for Therapeutic Products, is responsible. The Federal Food Safety and Veterinary Office (FSVO) is responsible for foodstuffs and e-cigarettes or liquids for electronic cigarettes containing CBD.
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.

In what form are CBD-containing products supplied?

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.

As ready-to-use products

CBD-containing products 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[2].

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.

[2] 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.

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 since these frequently raise queries.

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

a) Medicinal products

In accordance with Article 4 paragraph 1 letter a TPA (SR 812.21), ready-to-use CBD-containing products 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 CBD-containing medicinal products 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 also authorised in Switzerland 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[3].

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 exceptional, justified cases, a doctor issues a prescription for a different indication, the prescription should only be filled (prepared and dispensed) after consultation with the respective doctor and it should be documented accordingly.
4. The medicinal product must be prepared with CBD that has been produced in compliance with the relevant GMP requirements to a quality standard that meets the requirements of monograph C-052 Cannabidiol of the current German Drug Codex DAC/NRF as a minimum.
5. Preparation at the pharmacy level must comply with the GMP requirements of the current Swiss pharmacopoeia (Pharmacopoea Helvetica, Ph. Helv., GMP for small quantities of medicinal products).

[3] Swissmedic: https://www.swissmedicinfo.ch/#section1
FDA: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf

b) Medical devices

A CBD-containing product 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 products, but the mode of action of which is supported by the CBD contained in the product, may comply with the definition of a medical device as stipulated in Article 1[4] of the Medical Devices Ordinance (MedDO; SR 812.213).

The classification of a CBD-containing medical device is guided by Article 5 MedDO and Annex IX of Directive 93/42/EEC (MDD)[5], and in particular by Rule 13 in Annex IX MDD, which states: *"All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC [sic. source document cites Directive 65/65/EEC], and which is liable to act on the human body with action ancillary to that of the devices, are in* ***Class III****."*

The current MedDO and MDD will be superseded by new medical device regulations with effect from 26 May 2021 (new MedDO and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [MDR]). However, the classification of a CBD-containing medical device remains unchanged since the following continues to apply under Rule 14 of Annex VIII MDR: *"All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, [...] and that has an action ancillary to that of the device, are classified as* ***class III****."*

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 since it is known to have a pharmacological, although not a psychoactive, effect.

Article 45 paragraph 2 TPA and Article 9 paragraph 2 MedDO[6] require anyone who places a medical device on the market (e.g. manufacturers or distributors) to be able to demonstrate that the fundamental requirements are met and the claimed efficacy and performance exist. The conformity assessment procedure, the necessary certification and the declaration of conformity are based on Annex 3 MedDO (Art. 10 para. 1 MedDO[7]).

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

[4] Medical devices are defined in Article 3 MedDO with effect from 26 May 2021.

[5] With effect from 26 May 2021, classification is governed by Article 15 MedDO and Annex VIII MDR.

[6] Regulated in Article 21 paragraph 2 MedDO with effect from 26 May 2021.

[7] With effect from 26 May 2021 the conformity assessment procedure stipulated in Article 23 paragraph 1 MedDO is based on Articles 52 and 54 and Annexes IX–XI MDR.

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).

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 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 the CBD contained in the ingredient *Cannabis sativa*, it must be 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 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 CBD. It is therefore currently not permitted to indicate the presence of CBD 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. CBD is not currently authorised as an ingredient in foodstuffs (novel foodstuff). It is therefore not possible at present to indicate the presence of CBD in this way.

Further information

Website with information about 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

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:
CBD may be used in cosmetics if it is synthetically prepared or obtained from various parts of the cannabis plant (a plant of the genus Cannabis).

- Synthetic CBD is not specifically regulated. However, the general legal requirements for cosmetics described above are applicable.
  The following applies to the use of parts of the cannabis plant in cosmetics:
  The cannabis plant is regulated in accordance with Article 54 paragraph 1 FUAO, which refers to the list of prohibited substances in Annex II of Regulation (EC) 1223/2009[8] on cosmetic products under Reference number 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[9]. 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 flowering or fruiting tops) from which the resin has not been extracted, irrespective of the use to which they are put.
  The use of *"cannabis"* (buds and fruiting tops from which the resin has not been extracted) and products prepared from them (e.g. hemp extracts, CBD) in cosmetics is forbidden. Seeds and leaves not accompanied by the flowering or fruiting tops, on the other hand, are not covered by the term *"cannabis"* and may be used in cosmetics. *"Cannabis resin"* refers to the resin that has been separated from the cannabis plant, in raw or purified form. The definition of *"cannabis resin"* covers the whole plant and therefore also the leaves. The resin obtained from the cannabis plant (no matter from which parts of the plant) may therefore not be used either in cosmetics or to obtain CBD (cf. Annex 5 of the Narcotics Lists Ordinance; NarcLO-FDHA; SR 812.121.11).

  The justification for this regulation is that the resin of the cannabis plant contains a high concentration of cannabinoids and therefore potentially also its CBD extracts or tinctures. Furthermore the general legal requirements for cosmetics described above apply.

In all cases it is recommended to request information relating to the extraction of CBD (the parts of the cannabis plant used and the preparation process if CBD is obtained from the cannabis plant) and the safety of the product (CBD and THC content). A product with a total THC content of at least 1.0% is subject to the provisions of the Narcotics Law.

[8] 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) 2020/1684 OJ L 370 of 13.11.2020, p. 42.

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

Contact
Federal Food Safety and Veterinary Office (FSVO)
www.blv.admin.ch

Products sold as utility articles (e.g. CBD-containing liquids for e-cigarettes)

Some shops offer CBD-containing liquids for e-cigarettes. 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 to liquids for e-cigarettes in pharmacologically effective doses. This also applies to information which suggests that the product is a therapeutic product.

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

Contact
Federal Food Safety and Veterinary Office (FSVO)
www.blv.admin.ch

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”. 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 ChemO).
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 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 the Chemicals Ordinance (ChemO; SR 813.11) and compile a safety data sheet. If the presentation is not suggestive of any other use, CBD-containing products such as perfumed oils may well be placed on the market legally under the terms of the chemicals legislation.

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

Products sold as 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[10] 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 FoodA 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. 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.

It is currently not clear whether use of cannabis products with a low THC content can impair the ability to drive. 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 inform consumers accordingly. Details can be found on the FOPH website linked below (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

Contact
tabakprodukte@bag.admin.ch

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

Agricultural production of hemp, hemp seeds and plants

Agricultural production of hemp that is not classified as a narcotic is permitted from 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 considered 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)
www.blw.admin.ch

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

According to list D of the Narcotics Lists Ordinance (NarcLO-FDHA; SR 812.121.11), 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%. NarcLO-FDHA defines cannabis resin (hashish) as a forbidden substance irrespective of its THC content. Consequently, authorisation from the FOPH is always required to handle this substance no matter what its THC content.

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.

Import and export of cannabis and cannabis preparations containing CBD and 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-verbotene-betaeubungsmittel.html

Contact
betmg@bag.admin.ch