1. Purpose

The purpose of this industry standard is to establish a quality standard for CBD isolate as a raw material for the food/supplements and cosmetics industry.

2. Definition

CBD stands for cannabidiol. CBD isolate is (pure) CBD of natural origin. CBD isolate is extracted from the above-ground parts of the hemp plant (flower and/or leaf), originating from (industrial) hemp species that contain less than 0.3% THC[1], including: EU permitted hemp species[2], Canadian permitted hemp species[3], or USA permitted hemp species[4]. The production method should be suitable for use in food[5].

3. Regulatory status

a. Dutch "Opium Act"

Although cannabidiol is not included in the schedules of the Opium Act, the production of CBD isolate in the Netherlands falls under the Opium Act and is illegal according to the Act:

- CBD isolate may contain traces of THC (Opiumwet schedule 1);
- The definition of cannabis applies to industrial hemp. It is not permitted to cultivate, extract, prepare, etc. cannabis (Opiumwet art 3);
- Only fibre and seed may be gained from industrial hemp (Opiumwetbesluit art 12).

Nevertheless, CBD isolate is condoned in the Netherlands in herbal products/food supplements under the Opium Act, if it complies to the following prerequisites:

- CBD isolate is manufactured from permitted industrial hemp species.
- The final product does not contain more than 0.05% (w/w) THC[6].

b. Novel Food Regulation

As long as CBD isolate is covered by the Opium Act, the Novel Food Regulation[7] does not apply.

Synthetically obtained cannabinoids are per definition considered Novel[8] and prohibited for use in food and food supplements, unless a Novel Food authorization has been granted.

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[1] https://www.europarl.europa.eu/doceo/document/TA-9-2020-0289_EN.html
[2] http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/ (choose: Agricultural plant species, and subsequently at species: A-85)
[3] https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/producing-selling-hemp/commercial-licence/list-approved-cultivars-cannabis-sativa.html
[4] https://www.federalregister.gov/documents/2019/10/31/2019-23749/establishment-of-a-domestic-hemp-production-program
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009L0032
[6] besluit-wob-verzoek-over-over-de-stof-cannabidiol-cbd, 2018 (https://rijksoverheid.archiefweb.eu/#archive search: cannabidiol)
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1449760581954&uri=OJ%3AJOL_2015_327_R_0001
[8] http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm# search: Cannabis sativa L., Cannabidiol, Cannabinoids

c. Cosmetics Regulation

CBD isolate is subject to the provisions of Annex II/306[9] if extracted from the flowering parts of the hemp plant. If extracted from the leaves and free of THC, it is permitted for use in cosmetics[10], as well as CBD of synthetic origin[11].

4. Maximum daily dose

The maximum recommended daily dose = 160 mg CBD[12]. It is also possible to recommend a lower maximum dose.
Each label should contain the maximum recommended daily dosage, stated as the number of drops, capsules, etc.

5. Claims

No medical claims and no health claims are permitted. Not on the primary or secondary packaging, nor on any marketing material, including flyers, leaflets, ads, websites, blogs, etc.
Health claims are only permitted for ingredients that have been submitted to and approved by EFSA[13]. Until now, no claims have been submitted for CBD or hemp extracts.

In case an approved health claim is used, proof of the concentration/quantity of the relevant ingredient in the final product must be provided with the application for the quality mark.

6. Labelling requirements

The labelling requirements for CBD oil and CBD capsules are included in the relevant industry standards[14].

[9] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223
[10] https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=97599
[11] https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=93486
[12] besluit-wob-verzoek-over-over-de-stof-cannabidiol-cbd, 2018 (https://rijksoverheid.archiefweb.eu/#archive search: cannabidiol)
[13] http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home
[14] https://www.cannabinoidenadviesbureau.nl/en/diensten/keurmerk/

7. Test procedures[15]

#	Parameter	Specification	Preferred method
1	Appearance	White to light yellow crystalline powder	Visual
2	Scent	Odourless to light terpenic odour	Sensory
3	Melting point	63 – 69 °C	Melting point apparatus
4	Specific rotation	-130,0 ~ -140,0 °	Polarimeter
5	Total ash content	Max 0,3%	Ph Eur 2.4.16
6	Water content	Max. 1%	Karl Fisher
7	Heavy metals [16]		
	Lead Cadmium Mercury	Max. 3,0 mg/kg Max. 1,0 mg/kg Max. 0,1 mg/kg	Regulation (EC) 333/2007
8	Pesticides	Acc to Regulation (EC) 396/2005	SANTE/11945/2015
9	Microbiology[17]		
	TAMC TYMC Enterobacteria Salmonella E. coli S. aureus	Max. 10^4 CFU/ml Max. 10^2 CFU/ml Max. 10^2 CFU/ml Absent in 10 ml Absent in 1 ml Absent in 1 ml	ISO 4833-1
10	Residual solvents	Acc to Ph Eur 5.4	Ph Eur 2.4.24
11	Content CBD	97,5 – 102,5%	in-house method
12	Content THC	Max. 0,05% (w/w)	in-house method
13	Fingerprint cannabinoid profile (chromatogram)	Acc to company standard	in-house method

[15] See Annex 1 1 for list of approved laboratories

[16] Specifications are based on EU 1881/2006 dd. 01-01-2016 as laid down in the Annex (3.2.21, 3.1.22, 3.3.3)

[17] Specifications are based on Ph Eur 5.1.4

Annex 1 – list of laboratories

1. The appointed laboratories for tests 10 till 13 are:

   - BrightLabs[18]
     St. Jansweg 20
     5928 RC Venlo
     Netherlands

   BrightLabs can perform all tests.
   CAN members receive a 25% discount on the tests at BrightLabs. The reporting lead-time is 7 working days after receipt of the samples. The discount is not applicable in case of a lead-time of 5 working days. An additional discount is applicable if all tests are performed by Brightlabs.

   - Eurofins PROXY Laboratories[18]
     Archimedesweg 25
     2333 CM Leiden
     Netherlands

   Proxylab can perform all tests.
   The reporting lead-time is 10 working days after receipt of the samples.

   - ÖHMI Analytik GmbH
     Berliner Chaussee 66
     39114 Magdeburg
     Germany

   Öhmi can also perform all tests.
   The reporting lead-time is 7 working days after receipt of the samples. For a lead-time of 24 hours a surcharge of 100% is calculated and for 48 hours there is a surcharge of 50%.

   - Dept of Food Analysis and Nutrition (UAPV), UCT Prague
     Technická 3
     16628 Praha 6
     Czech Republic

   CAN does not (yet) have any agreements with UAPV about analyses, prices and lead times.

[18] No “Opiumontheffing” is required of the client if the sample contains less than 0,05% (w/w) THC. Samples that contain more than 0,05% (w/w) THC are reported with IGJ.

2. The other tests (1 till 9) may for example also be performed by any of the following laboratories. These laboratories do not perform the assays on cannabinoids and only and only test if the assays have already been performed and the sample does not contain more than 0,05% THC!

   - NutriControl
     N.C.B. laan 52
     5462 GE Veghel
     Netherlands

   - NofaLab
     Jan van Galenstraat 41/51
     3115 JG Schiedam
     Netherland