## 1. Purpose

The purpose of this industry standard is to warrant transparency for the consumer regarding the quality of CBD oil on the Dutch market. Members of CAN (the Cannabinoid Association of the Netherlands) whose products comply with the standard may request the CAN hallmark for these products.

## 2. Definitions

CBD is the abbreviation of Cannabidiol. CBD-paste is an extract of the aerial parts of the hemp plant (flower and/or leaf), derived from (industrial) hemp varieties containing less than 0.3% THC[1], such as: 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]. The resulting paste may undergo further processing steps, such as a heating step to convert CBD-A into CBD and a winterization step to remove chlorophyll and bad-tasting fatty acids and waxes.

The resulting paste is a full-spectrum extract: the full spectrum of cannabinoids which is found in the plant, is found in the extract in the original ratio. The final product may be labelled as **full-spectrum**.

A full-spectrum paste can also be further processed, thus removing THC. The resulting product is a broad-spectrum extract: the full spectrum of cannabinoids, which is found in the plant, except THC, is found in the extract in the original ratio. The final product may be labelled as **broad-spectrum**.

CBD isolate can also be added to CBD-oil to increase the natural CBD content, which is limited in a full-spectrum product due to the maximum permitted THC content (see 3.a). The definition of CBD isolate is included in the industry standard for CBD isolate[6]. Cannabidiol should then be included in the ingredient declaration of the final product.

CBD oil is a mixture of CBD paste and an edible oil, such as hemp seed oil, coconut oil, MCT oil, etc.

[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] https://www.cannabinoidenadviesbureau.nl/en/diensten/keurmerk/

## 3. Regulatory status

### a. Dutch "Opium Act"

In the Netherlands, CBD oil falls under the Opium Act and is illegal according to the Act:

- The definition of hemp oil applies to CBD oil (Opiumwet schedule 1);
- CBD oil 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 oil is condoned in the Netherlands as an herbal product/food supplement under the Opium Act, if it complies to the following prerequisites:

- CBD oil is manufactured from permitted industrial hemp strains.
- CBD oil does not contain more than 0.05% (w/w) THC[7].

### b. Novel Food Regulation

As long as CBD oil is covered by the Opium Act, the Novel Food Regulation[8] does not apply.

Synthetically obtained cannabinoids are per definition considered Novel[9] and prohibited for use in food and food supplements, unless a Novel Food authorization has been granted.

### c. Cosmetics Regulation

Hemp extracts, CBD oil and CBD isolate are subject to the provisions of Annex II/306[10] if extracted from the flowering parts of the hemp plant. If extracted from the leaves and free of THC, they are permitted for use in cosmetics[11], as well as CBD of synthetic origin[12].

## 4. Maximum daily dose

The maximum recommended daily dose = 160 mg CBD[13]. It is also possible to recommend a lower maximum dose.
Each label should contain the maximum recommended daily dose stated as the number of drops. The number of drops is dependent on the quality of the CBD oil (extraction method, strength, choice of edible oil) and the dropper (drop size).

[7] besluit-wob-verzoek-over-over-de-stof-cannabidiol-cbd, 2018 (https://rijksoverheid.archiefweb.eu/#archive search: cannabidiol)
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1449760581954&uri=OJ%3AJOL_2015_327_R_0001
[9] http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm# search: Cannabis sativa L., Cannabidiol, Cannabinoids
[10] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223
[11] https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=97599
[12] https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=93486
[13] besluit-wob-verzoek-over-over-de-stof-cannabidiol-cbd, 2018 (https://rijksoverheid.archiefweb.eu/#archive search: cannabidiol)

## 5. Claims

Medical claims are not permitted. Not on the primary or secondary packaging, nor on any marketing material, including flyers, folders, advertisements, websites, blogs, etc.
Health claims are only permitted for ingredients that have been submitted to and approved by EFSA[14]. 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[15]

a. Name of the product
b. List of ingredients in descending quantity, per annex VII (EU/1169/2011)
c. Allergen declaration, per annex II (EU/1169/2011)
d. Net quantity
e. The CBD percentage in the final product
f. Date of minimum durability, per annex X (EU/1169/2011)
g. Batch code
h. Storage conditions
i. Instructions for use (e.g. shake well and drop under the tongue)
j. Dosage recommendation for daily consumption
k. A warning not to exceed the stated recommended daily dose
l. Name and address of the food business operator
m. Statement “Food supplement”
n. A statement to the effect that the product should not be used during pregnancy or breastfeeding
o. A statement to the effect that food supplements should not be used as a substitute for a varied diet
p. A statement to the effect that the product should be stored out of the reach of young children
q. No statement regarding the THC percentage

When products are made available on-line (via internet) the required information must also be made available, except for the batch code and date of minimum durability. This can be provided directly with the product or accessible via a hyperlink. Consumers must be able to see this product information online before purchase.

[14] http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home
[15] According to EU/1169/2011 and 2002/46/EC

## 7. Test procedures[16]

| # | Parameter | Specification | Preferred method |
|---|---|---|---|
| 1 | Appearance | Yellow to orange to dark green clear to turbid viscous liquid | Visual |
| 2 | Scent | Typical of hemp and the edible oil of choice | Sensory |
| 3 | Density/Relative density | To be determined in-house for each specific quality | Pycnometer/Densitometer |
| 4 | Peroxide value | Max. 20 meq/kg | ISO 3960 |
| 5[17] | Heavy metals [18] | | |
| | Lead<br>Cadmium<br>Mercury | Max. 3,0 mg/kg<br>Max. 1,0 mg/kg<br>Max. 0,1 mg/kg | Regulation (EC) 333/2007 |
| 6[17] | Pesticides | Acc to Regulation (EC) 396/2005 | SANTE/11945/2015 |
| 7[17] | Mycotoxins [19] | | |
| | Aflatoxin B1<br>Aflatoxins B1+B2+G1+G2 | Max. 2 µg/kg<br>Max. 4 µg/kg | Regulation (EC) 401/2006 Annex II |
| 8[17] | Polycyclic Aromatic Hydrocarbons [20] | | |
| | Benzo(a)pyrene:<br>Benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: | Max. 2 µg/kg<br>Max. 10 µg/kg | Regulation (EC) 333/2007 |
| 9[17] | Dioxins and PCB's [21] | | |
| | Sum of dioxins:<br>Sum of dioxins and dioxin-like PCBS:<br>Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180: | Max. 0,75 pg/g<br>Max. 1,25 pg/g<br>Max. 40 ng/g | Regulation (EU) 2017/644 |
| 10 | Microbiology [22] | | |
| | TAMC<br>TYMC<br>Enterobacterieën<br>Salmonella<br>E. coli<br>S. aureus | Max. $10^4$ CFU/ml<br>Max. $10^2$ CFU/ml<br>Max. $10^2$ CFU/ml<br>Absent in 10 ml<br>Absent in 1 ml<br>Absent in 1 ml | ISO 4833-1 |
| 11 | Residual solvents | Acc to Ph Eur 5.4 | Ph Eur 2.4.24 |
| 12 | Content CBD | Label declaration +/- 10% (w/w) | in-house method |
| 13 | Content CBD-A[23] | Label declaration +/- 10% (w/w) | in-house method |
| 14 | Content THC | Max. 0,05% (w/w) | in-house method |
| 15 | Content THC-A | Max. 0,05% (w/w) | in-house method |
| 16 | Fingerprint cannabinoid profile (chromatogram) | Acc to company standard | in-house method |

[16] See Annex 1 1 for list of approved laboratories
[17] These tests do not have to be performed in the final product if they have been performed in the paste and the results comply to the specifications
[18] 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)
[19] Specifications are based on Ph Eur 6.0 requirements for Herbal Drugs.
[20] Specifications are based on EU 1881/2006 dd. 01-01-2016 as laid down in the Annex (6.1.1).
[21] Specifications are based on EU 1881/2006 dd. 01-01-2016 as laid down in the Annex (5.12).
[22] Specifications are based on Ph Eur 5.1.4
[23] Specification is only applicable if the CBD-A content is declared on the label

**Annex 1 – list of laboratories**

1. The appointed laboratories for tests 11 till 16 are:

   - BrightLabs[24]
     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[24]
     Archimedesweg 25
     2333 CM Leiden
     Netherlands

   Proxylab can perform all tests, except 8 and 9.
   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.

[24] 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 10) 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