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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 Cannabinoids 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 flowering parts of the hemp plant, derived from one of the EU-permitted (industrial) hemp strains¹, Canadian permitted hemp strains², or USA permitted hemp strains³. De production method should be suitable for use in food⁴. 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 is pure cannabidiol from natural origin, i.e. the hemp plant, and may be added to CBD-paste to increase the natural CBD content, which is limited in a full-spectrum extract due to the maximum allowed THC content (see 3.a). The addition of cannabidiol should be indicated on the label of the final product.

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

3. Regulatory status

a. Dutch "Opium Act"

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

- CBD oil complies to the definition of hemp-oil (Opiumwet schedule 1);
- CBD oil contains traces of THC (Opiumwet schedule 1);
- Industrial hemp complies to the definition of cannabis. 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).

¹ http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/

² https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/producing-selling-hemp/commercial-licence/list-approved-cultivars-cannabis-sativa.html

³ https://www.federalregister.gov/documents/2019/10/31/2019-23749/establishment-of-a-domestic-hemp-production-program

⁴ Directive 2009/32/EC

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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) THC⁵.

b. Novel Food Regulation

As long as CBD oil is covered by the Opium Act, the Novel Food Regulation⁶ does not apply.

Synthetically obtained cannabinoids are per definition considered Novel⁷ and prohibited for use in food and food supplements, unless a Novel Food authorization has been granted.

4. Maximum daily dose

The maximum recommended daily dose = 160 mg CBD⁸. It is also possible to recommend a lower maximum dose, e.g.: do not exceed the recommended daily 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).

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 EFSA⁹. Until now, no claims have been submitted for CBD or hemp extracts.

 $^{^{5} \, \}underline{\text{https://www.rijksoverheid.nl/documenten/wob-verzoeken/2018/01/31/besluit-wob-verzoek-over-over-destof-cannabidiol-cbd}$

⁶ Regulation (EU) 2015/2283 regarding Novel Foods

⁷ http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm# search: Cannabis sativa L., Cannabidiol, Cannabinoids

⁸ https://www.rijksoverheid.nl/documenten/wob-verzoeken/2018/01/31/besluit-wob-verzoek-over-over-de-stof-cannabidiol-cbd

⁹ http://ec.europa.eu/food/safety/labelling nutrition/claims/register/public/?event=register.home

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6. Labelling requirements¹⁰

- 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
- I. Name and address of the food business operator
- m. Statement "Food supplement"
- n. Do not use 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.

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¹⁰ According to EU/1169/2011 and 2002/46/EC

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7. Test procedures

#	Parameter	Specification	Preferred method ¹¹	
1	Appearance	Yellow to orange to dark green	Visual	
1		clear to turbid viscous liquid		
2	Scent	Typical of hemp and the edible oil	Sensory	
	Scent	of choice	Serisor y	
3	Density/Relative density	To be determined in-house for each	Pycnometer/Densitometer	
		specific quality	•	
4	Peroxide value	Max. 20 meq/kg	ISO 3960	
	Heavy metals ¹³			
5 ¹²	Lead	Max. 3,0 mg/kg		
,	Cadmium	Max. 1,0 mg/kg	Regulation (EC) 333/2007	
	Mercury	Max. 0,1 mg/kg		
612	Pesticides	Acc to Regulation (EC) 396/2005	SANTE/11945/2015	
	Mycotoxins 14			
7 ¹²	Aflatoxin B1	Max. 2 μg/kg	Regulation (EC) 401/2006	
	Aflatoxins B1+B2+G1+G2	Max. 4 μg/kg	Annex II	
	Polycyclic Aromatic Hydrocarbons 15			
8 ¹²	Benzo(a)pyrene:	Max. 2 μg/kg		
8	Benzo(a)pyrene, benz(a)anthracene,		Regulation (EC) 333/2007	
	benzo(b)fluoranthene and chrysene:	Max. 10 μg/kg		
	Dioxins and PCB's 16			
	Sum of dioxins:	Max. 0,75 pg/g		
912	Sum of dioxins and dioxin-like PCBS:	Max. 1,25 pg/g	Regulation (EU) 2017/644	
	Sum of PCB28, PCB52, PCB101, PCB138,		Regulation (LO) 2017/044	
	PCB153 and PCB180:	Max. 40 ng/g		
	Microbiology ¹⁷			
	TAMC	Max. 10 ⁴ CFU/ml		
	TYMC	Max. 10 ² CFU/ml		
10	Enterobacterieën	Max. 10 ² CFU/ml	ISO 4833-1	
	Salmonella	Absent in 10 ml	130 4655-1	
	E. coli	Absent in 1 ml		
	S. aureus	Absent in 1 ml		
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 ¹⁸	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	

¹¹ See Annex 1 1 for list of approved laboratories

¹² 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

¹³ 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)

¹⁴ Specifications are based on Ph Eur 6.0 requirements for Herbal Drugs.

¹⁵ Specifications are based on EU 1881/2006 dd. 01-01-2016 as laid down in the Annex (6.1.1).

¹⁶ Specifications are based on EU 1881/2006 dd. 01-01-2016 as laid down in the Annex (5.12).

¹⁷ Specifications are based on Ph Eur 5.1.4 – Category 3 B

¹⁸ Specification is only applicable if the CBD-A content is declared on the label

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Annex 1 - list of laboratories

- 1. The appointed laboratories for tests 11 till 16 are:
 - BrightLabs¹⁹
 St. Jansweg 20
 5928 RC Venlo
 Netherlands

BrightLabs can also perform all other tests, except 7, 8 and 9.

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.

Eurofins PROXY Laboratories¹⁹
 Archimedesweg 25
 2333 CM Leiden
 Netherlands

Proxylab can also perform all other tests, except 8.

CAN members receive a 25% discount on the tests at Proxylab. 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 other tests.

CAN does not (yet) have any agreement with Öhmi regarding a discount for members. 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.

 $^{^{19}}$ 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.

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- 2. The other tests (1 till 10) may 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