

# The future of CBD oil

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# Introduction CAN

## **Cannabinoid Association of the Netherlands**

### Objectives:

1. To achieve a quality standard for the production and sale of commodity law products\* containing CBD and/or other cannabinoids and terpenes of natural origin.
2. The realization of a legal basis for these products.
3. The promotion of expertise about these products within the entire chain\*\*, in the field of quality, effectiveness, safety and communication.

\* Food, food supplements, cosmetics and other products.

\*\* From grower, manufacturer, importer and distributor to retailer and consumer.

# What is CBD oil?

- 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 strains. The extraction method should be suitable for use in food. The resulting paste may undergo a 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.
- CBD oil is a mixture of CBD paste and an edible oil, such as hemp seed oil, olive oil or coconut oil.

# The current situation in NL

According to the Dutch “Opium Act”, CBD oil is illegal in the Netherlands:

- CBD oil complies to the definition of hemp-oil (Opium Act schedule 1)
- There is no legal maximum value for THC (Opium Act schedule 1)
- Industrial hemp complies to the definition of cannabis. It is not permitted to cultivate, extract, prepare, etc. (Opium Act art 3)
- Only fibre and seed may be gained from industrial hemp (Opium Act decree art 12)

# The current situation in NL

Nevertheless, CBD oil is condoned in the Netherlands as herbal product under the Opium Act, if it complies to the following prerequisites:

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

# NL vs other EU countries

THC limits (August 2019) – subject to change

- Romania: no limit
- Denmark, Spain: 0,2%
- Netherlands: 500 ppm (= 0,05%)
- Germany: 50 ppm
- Switzerland: 20 ppm
- Belgium: 10 ppm
- Italy: 5 ppm
- Czech Republic: 0,15 ppm
- UK: 1 mg per consumer package
- Sweden: 0%

# What does the future hold?

## Amendments to the Opium Act

### Definition of hemp oil (Opium Act schedule 1):

Concentrate of plants of the genus Cannabis (hemp) obtained by extraction of hemp or hashish, whether or not mixed with oil.

# What does the future hold?

## Amendments to the Opium Act

### Definition of hemp oil (Opium Act schedule 1):

Concentrate of plants of the genus Cannabis (hemp), **excluding hemp plants containing not more than 0,2% tetrahydrocannabinol**, obtained by extraction of hemp or hashish, whether or not mixed with oil.



# What does the future hold?

## Amendments to the Opium Act

### Industrial hemp (Opium Act decree art 12):

The prohibitions laid down in section 3(B) of the Act do not apply to hemp apparently intended for the production of fibre or the multiplication of seed for the production of fibre hemp, on the understanding that the exception to the prohibition on the cultivation of hemp only applies to the extent that cultivation takes place in the open air and in the open air.

# What does the future hold?

Amendments to the Opium Act

Industrial hemp (Opium Act decree art 12):

The prohibitions laid down in Section 3, **opening words and under B, C and D** of the Act do not apply to hemp that is apparently intended for the production of fibre or the multiplication of seed for the production of hemp for fibre **and for the production of products containing cannabidiol**, on the understanding that the exception to the prohibition on the cultivation of hemp only applies to the extent that cultivation takes place in the open ground and in the open air.

# Novel Food status

- Extracts of *Cannabis sativa* L. (Hemp) and derived products that contain cannabinoids, such as CBD, are considered novel foods according to the description of "Cannabinoids" in the Novel Food catalogue. In accordance with the Novel Food Regulation, it would not be permitted to market CBD containing products, that are meant for human consumption, without a Novel Food authorization.
- However, CBD-oil is provisionally condoned in the Netherlands, if it complies to the requirements in this industry standard.
- Synthetic cannabinoids are per definition Novel and not permitted for use in food and food supplements.

## Novel Food status

- Dutch Ministry of Health is awaiting the outcome of discussions within the EU Commission, just like most EU countries.
- However, several EU countries have already implemented the NF status, such as: Austria, Germany, Denmark, Poland, Lithuania, Italy, Greece... (source: RASFF portal)
- One application for authorisation of purified CBD is pending at EFSA, and for a number of other CBD products application procedures have been started via the e-submission portal.

# CAN industry standard

1. Purpose
2. Definitions
3. Regulatory status
4. Maximum daily dose
5. Claims
6. Labelling requirements
7. Test procedures

Annex 1: laboratories

[www.cannabinoidenadviesbureau.nl/wp-content/uploads/2019/11/Industry\\_standard\\_CBD\\_oil\\_ENG\\_v1.1.pdf](http://www.cannabinoidenadviesbureau.nl/wp-content/uploads/2019/11/Industry_standard_CBD_oil_ENG_v1.1.pdf)

# CAN industry standard

Cannabinoïden  
Adviesbureau  
Nederland



## 7. Test procedures

#	Parameter	Specification	Method <sup>10</sup>
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. 5 meq/kg	ISO 3960
5 <sup>11</sup>	Heavy metals <sup>12</sup>		
	Lead	Max. 3,0 mg/kg	Regulation (EC) 333/2007
	Cadmium	Max. 1,0 mg/kg	
Mercury	Max. 0,1 mg/kg		
6 <sup>12</sup>	Pesticides	Acc to Regulation (EC) 396/2005	SANTE/11945/2015
7 <sup>12</sup>	Mycotoxins <sup>13</sup>		
	Aflatoxin B1	Max. 2 µg/kg	Regulation (EC) 401/2006
	Aflatoxins B1+B2+G1+G2	Max. 4 µg/kg	Annex II

# CAN industry standard

8 <sup>12</sup>	Polycyclic Aromatic Hydrocarbons <sup>14</sup>		
	Benzo(a)pyrene: Benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene:	Max. 2 µg/kg  Max. 10 µg/kg	Regulation (EC) 333/2007
9 <sup>12</sup>	Dioxins and PCB's <sup>15</sup>		
	Sum of dioxins:	Max. 0,75 pg/g	Regulation (EU) 2017/644
	Sum of dioxins and dioxin-like PCBs:	Max. 1,25 pg/g	
Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180:	Max. 40 ng/g		
10	Microbiology <sup>16</sup>		
	TAMC	Max. 10 <sup>3</sup> CFU/ml	ISO 4833-1
	TYMC	Max. 10 <sup>2</sup> CFU/ml	
	E. coli	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 <sup>17</sup>	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	Acc to company standard	in-house method

# CAN quality mark

Presentation of quality mark to members on December 9!

- Final product analysis and artwork must comply to the requirements of CAN industry standard.
- Final product must be fully traceable to seed (block chain technology)
  - every link in the chain enters its own data (anonymously).



# CAN quality mark

## Protection of quality mark

- Logo registration at BIOP
- Agreement on use of the CAN mark, including penalty clause
- A concise report of every application is published on-line for consumers ([www.cancheck.org/en/](http://www.cancheck.org/en/))
- Independent control through audits

# Expected timelines

- Introduction CAN quality mark (Dec 2019)
- Amendments to the Opium Act (2020)
- Clarification NF status of hemp extracts (?)

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Thank you for your attention!

[www.cannabinoidenadviesbureau.nl](http://www.cannabinoidenadviesbureau.nl)

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