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LEGAL FRAMEWORK FOR CANNABIS APPLIED IN FOOD AND PHARMA

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health
food
technology

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Introduction
Axon Lawyers

- **Who are we?** Amsterdam based *life sciences law firm* with international focus
- **What do we do?** Assisting high tech, science-based companies marketing innovative food products, medicinal products and medical devices
- **What's the offer?** Offering unique life sciences expertise on an EU-wide level through Alliance of European Life Sciences Lawyers and other close collaboration with peers
- **What more?** Reporting current life sciences developments at 2 blogs:

medicaldeviceslegal

Food Health Legal
legal and regulatory blog

Agenda

Legal framework for Cannabis applied in food and pharma

- Difference between these two applications
- Current legal framework for application of Cannabis in food + impact of latest changes
- Legal framework for application of Cannabis in pharma + upcoming tender

Difference between Cannabis in pharma and in food

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Cannabis in pharma

Application of medicinal Cannabis

- Medicinal Cannabis does not actually cure any disease, but according to scientific evidence it can alleviate suffering from certain diseases – see information below (source www.jellinek.nl).

MEDICINALE CANNABIS

Cannabis wordt bij een aantal aandoeningen ook gebruikt als medicatie. Er zijn voldoende wetenschappelijke gegevens beschikbaar die aantonen dat cannabis werkt bij:

- pijn, spierkrampen en spiertrekkingen bij MS of ruggenmergschade
- misselijkheid, verminderde eetlust, vermagering en verzwakking bij kanker en aids
- misselijkheid en braken als gevolg van medicatie of bestraling bij kanker, hepatitis C- of hiv-infectie en aids
- chronische pijn (voornamelijk als de oorzaak in het zenuwstelsel zit bijvoorbeeld door beschadiging van een zenuwbaan, fantoompijn, aangezichtspijn of chronische pijn die blijft bestaan na het genezen van gordelroos)
- syndroom van Gilles de la Tourette
- therapieresistent glaucoom

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Cannabis in food

Alleged effects of Cannabis in food

- Stress reduction
- Good night rest
- Energy & resistance

Industrial hemp fibre is virtually THC free and therefore has no psychoactive effect. The leaf and flower buds contain very beneficial substances such as cannabinoids and terpenes. CBD (cannabidiol) is one of several substances which is extracted and has great health-promoting properties. A small selection: CBD reduces stress, ensures a good night's sleep, provides energy and increases resistance.

HEMP FLAX® Nature wins!

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Legal framework for Cannabis in food

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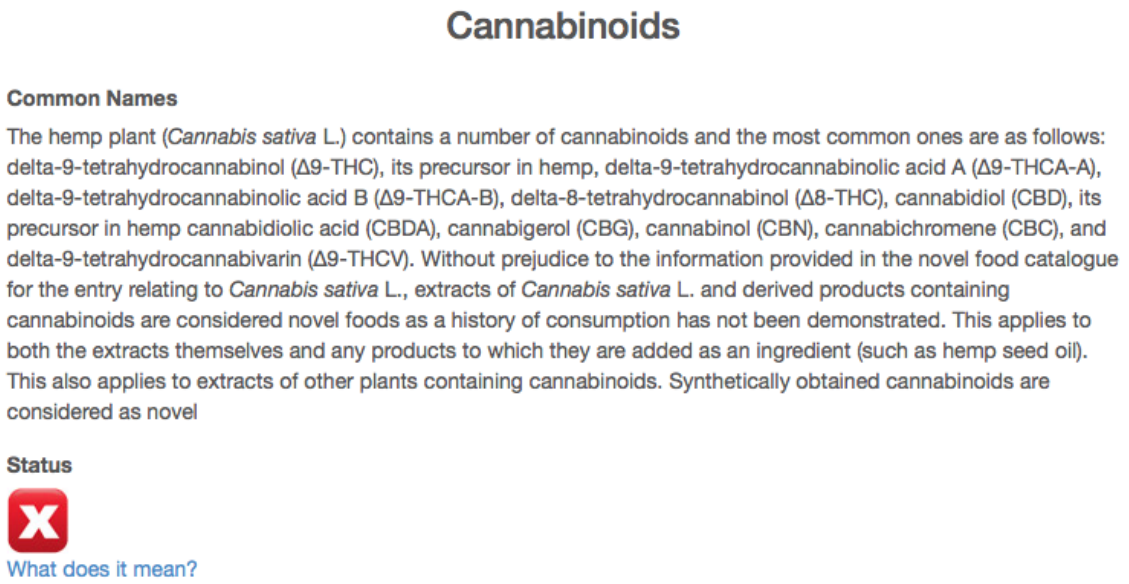
Old and new regulatory framework

Change in legal framework of CBD foods

- CBD food products (mostly supplements) used to be “regular” food products, not requiring any prior market authorization.
- Since change in Novel Food catalogue, CBD food products were brought into realm of Novel Food framework. What happened?



Cannabinoids

Common Names

The hemp plant (*Cannabis sativa* L.) contains a number of cannabinoids and the most common ones are as follows: delta-9-tetrahydrocannabinol (Δ9-THC), its precursor in hemp, delta-9-tetrahydrocannabinolic acid A (Δ9-THCA-A), delta-9-tetrahydrocannabinolic acid B (Δ9-THCA-B), delta-8-tetrahydrocannabinol (Δ8-THC), cannabidiol (CBD), its precursor in hemp cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (Δ9-THCV). Without prejudice to the information provided in the novel food catalogue for the entry relating to *Cannabis sativa* L., extracts of *Cannabis sativa* L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel

Status

What does it mean?

Implications of new framework

Novel Food if history of safe use cannot be demonstrated - and the other way round!

Cannabis sativa L.

Common Names

In the European Union, the cultivation of *Cannabis sativa* L. varieties is permitted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % (w/w). Some products derived from the *Cannabis sativa* plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities

Status

What does it mean?

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Various options for CBD food products

Establishing safe food use and other options

- For some elements of the Cannabis plant (e.g. leaves and flower) history of safe food use can be construed. In the affirmative, no NF application is being required.
- In case no history of safe food use can be established, remaining options are:

1. File Novel Food application
2. Rely on third party NF authorization
3. Consultation procedure at Member State level in case of uncertainty NF-status

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Implications of change in legal framework

Application for NF authorization

- Contrary to former NF-Regulation, generic authorizations under current NF-Regulation.
- Apart from protection of confidential information or data protection, no commercial monopoly.
- In order to share the investment, joint applications can be made for instance by industry organizations.

Summary of the dossier (18.10.05)

Applicant: Belgian Insect Industry Federation (BiiF), 15 rue Fernand Bernier, 1060 Saint-Gilles, Belgium

Food category: *Tenebrio molitor* for consumption as a food and as an ingredient in additional food groups

Implications of change in legal framework

Rely on third party NF authorization

- Currently the entire CBD scene is watching the one and single pending application for CBD food supplements applied for by the Czech company Cannabis Pharma.
- If EFSA grants a positive opinion and a NF-authorization is granted, any third party can market a CBD food supplement with the same specs and for the same targeted audience.
- The same goes for any other potential third party authorization for a CBD food product, so watch that Union list of authorized Novel Foods.

Summary of the dossier: (-)-trans-cannabidiol

Applicant: Cannabis Pharma, s.r.o., Masarykova 1595/54, 415 01 the Czech Republic

This is an application for authorisation to place on the market (-)-trans-cannabidiol (CBD) as a novel food in food supplements in the European Union (EU) intended for the adult population and excluding pregnant and lactating women.

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Implications of change in legal framework

Consultation procedure at Member State level

- Based on Implementing Regulation 2018/456 a request for determining the NF status of a food can be filed at MS level. Big pro: EC is bound by MS decision on non-novelty of food product.

Article 4

Content and presentation of a consultation request

1. The consultation request shall be submitted electronically to the recipient Member State and shall consist of the following:

(a) a cover letter;

(b) a technical dossier;

(c) supporting documentation;

(d) an explanatory note clarifying the purpose and relevance of the submitted documentation.

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Implications of change in legal framework

Consultation procedure at Member State level

- Relatively quick procedure: national authorities should decide within 4 months after receipt request (in principle including potential requests for additional information).
- Protection of confidential information possible to certain extent. If request for confidentiality is not granted: consultation request can be withdrawn.
- Outcome published at Commission website (currently 31 publications, 5 not novel). For the entries not considered novel, a history of food use in the EU < 1997 was established.

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Enforcement re. CBD food products

What types of enforcement can FBOs meet when marketing CBD foods?

(1) Marketing CBD foods without required Novel Food authorization

(2) Marketing CBD foods in violation of applicable labeling and advertising rules

▶ Each type of exposure comes down to violation of a EU legal norm.

▶ Enforcement however takes place on a national MS level > for proper risk assessment, consult local expert.

Takeaway: proper labeling is of the essence, also for online sales.

NVWA

Cannabis in food

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Cannabis derived food products – what's the current state of play?

Posted: February 25, 2019 | **Author:** Karin Verzijden | **Filed under:** Authors, cannabidiol, cannabis, Enforcement, Food, Health claims, novel food | Comments Off on Cannabis derived food products – what's the current state of play?

Recently, CBD food products were qualified as Novel Foods requiring a market authorization. The lively trade in these products therefore currently seems to be at risk. However, not all cannabis derived products are Novel Foods. What is the current state of play regarding these products and how is enforcement going to look like?

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Legal framework for Cannabis in pharma

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Cannabis under the Dutch Opium Act

Controlled substances

- Under Dutch Opium Act Cannabis is considered be “controlled substance”.
- Our Opium Act contains two Annexes: List I (hard drugs) and List II (soft drug). In fact, hemp is defined in List II as follows:

> elk deel van de plant van het geslacht Cannabis (hennep), waaraan de hars niet is onttrokken, met uitzondering van de zaden

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Restrictions & sanctions re. Cannabis

Despite Cannabis being a soft drug – severe sanctions under Dutch Opium Act

- Art. 3 Dutch Opium Act prohibits the following acts re. controlled substances: importing / exporting / cultivation / processing / manufacturing / selling / delivering / transport.

- Available sanctions for trading a *large quantity* of Cannabis include imprisonment up to six years or a fine up to a maximum of € 83.000,00.

- "Large quantity" defined in art. 1.2 Opium Act Decree": > 500 g hemp
  > 200 hemp plants

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Office of Medicinal Cannabis

Role of the Health Ministry

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

Limited number of exemptions under Dutch Opium Act

- Dutch Health Minister is responsible for cultivation of sufficient hemp in the NL for scientific research re. hemp / hashish / hemp oil and for production of medicinal products.
- Via the Office of Medicinal Cannabis (OMC), exemptions are granted for scientific research or the production of medicinal Cannabis, both under very strict conditions.
- OMC thereby plays a pivotal role in any legal cultivation of Cannabis.

The Office of Medicinal Cannabis (OMC) is the government office which is responsible for the production of cannabis for medical and scientific purposes. Pharmacies, universities and research institutes can get legal medicinal cannabis from us.

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Research with Cannabis

Applicable requirements to obtain research exemption (Beleidsregels Opiumwetontheffingen)

- Necessity for exemption must be demonstrated.
- Scientifically justified objective, backed by for instance research protocol for clinical trial or for breeding of hemp plants.
- Applicable quality requirements (GMP or GLP) or certification standards (e.g. ISO) must be met and appropriate safety (anti theft) measures must be put in place.
- Screening of the applicant ("*verklaring omtrent gedrag*") in order to prevent potential criminal applications.

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Cannabis for medicinal purposes

Upcoming tender for manufacturing medicinal Cannabis

- Currently only a single manufacturer of medicinal Cannabis: Bedrocan. This will most likely change in future, as a tender for election of new growers has been launched.
- NB Former tender was launched on 28 February 2018, but withdrawn on 28 June 2018, as OMC realized the tender requirements were not proportionate to intended purposes.
- New tender opened on 11 July 2019.

Levering medicinale cannabis van farmaceutische en constante kwaliteit

Selectieleidraad

ten behoeve van het

CIBG

(Bureau voor Medicinale Cannabis)

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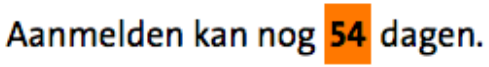
Tender procedure growing medicinal Cannabis

Purpose & procedure tender

- Selection of up to two companies for the supply of medicinal Cannabis of constant pharmaceutical quality. Deadline for application initially 25 November 2019. Extension:



(info Tendernet.nl 27 November 2019)

- Harvest will be purchased by OMC, who will conclude framework agreement with selected entity/entities as of 1 April 2021 for 4 years (two 12 months extensions feasible).

- Actual tender phase preceded by selection phase (Q1 2021): selection based on exclusion grounds and suitability requirements set out in Uniform European Tender Document.

- Screening of applicant under Act for the Promotion of Integrity Evaluation by public authorities (“*Wet Bibob”).*

Suitability requirements tender procedure

Qualifiers and the challenging thereof

- Demonstrable experience with legal cultivation of > 2 varieties Cannabis / other plants to be used as raw materials for herbal medicinal preparations ("*kruidengeneesmiddele*n").
- Demonstrable experience with compliance with GMP / GAP / GACP in such cultivation.

▶ These qualifiers and any other tender requirements may be subject to Q&A, as published in Informative Memoranda ("*Nota van Inlichtingen*") on an anonymous basis. Latest version: 7 November 2019.

▶ Any questions not addressed in Informative Memoranda should be addressed in summary relief proceedings ("*kort geding*") ultimately within 10 days after 2nd Informative Memorandum.

Material requirements medicinal Cannabis (1)

Current and future varieties medicinal Cannabis

Currently, the following 5 varieties are available:

Product	% THC	% CBD	Afzet nationaal	Afzet internationaal
Bedrobinol®	circa 13,5	< 1	5%	3,75%
Bedrocan®	circa 22	< 1	65%	85%
Bediol®	circa 6,3	circa 8	14%	3,75%
Bedica®*	circa 14	< 1	11%	3,75%
Bedrolite®	< 1	circa 9	5%	3,75%

Any applicant under the tender procedure will have to offer at least the following 2 varieties:

Variëteit	% tetrahydrocannabinol (THC)	% cannabidiol (CBD)
1	≥ 18,7 en ≤ 25,3	≤ 1
2	≥ 5,3 en ≤ 7,2	≥ 6,8 en ≤ 9,2

- Bedrocan
- Bediol

Sales levels and price

This in an overview of the sales of medicinal Cannabis. Against this background, OMC will purchase from winner(s) of tender procedure > **250 kg** against fixed price of € **2,35 / g**.

Jaar	Verkoop aan binnenland (hoeveelheid in kg)	Verkoop aan buitenland (hoeveelheid in kg)	Verkoop aan binnenland en buitenland (hoeveelheid in kg)
2010	101,5	18,5	120,0
2011	120,0	40,0	160,0
2012	161,9	48,1	210,0
2013	215,2	74,8	290,0
2014	134,2	280,8	415,0
2015	309,9	370,1	680,0
2016	569,1	480,9	1.050,0
2017	637,0	1.045,0	1.682,0
2018	552,8	2.051,2	2.604,0

Conclusion

- Application of Cannabis in food substantially differs from application in pharma.
- Both applications however require rigorous safety substantiation: for most Cannabis food products via Novel Food proceedings (if applicable) and for Cannabis pharma products via GMP.
- Contrary to Cannabis pharma market, the Cannabis food market is not completely regulated, leaving room for any (serious) player to enter this market.

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