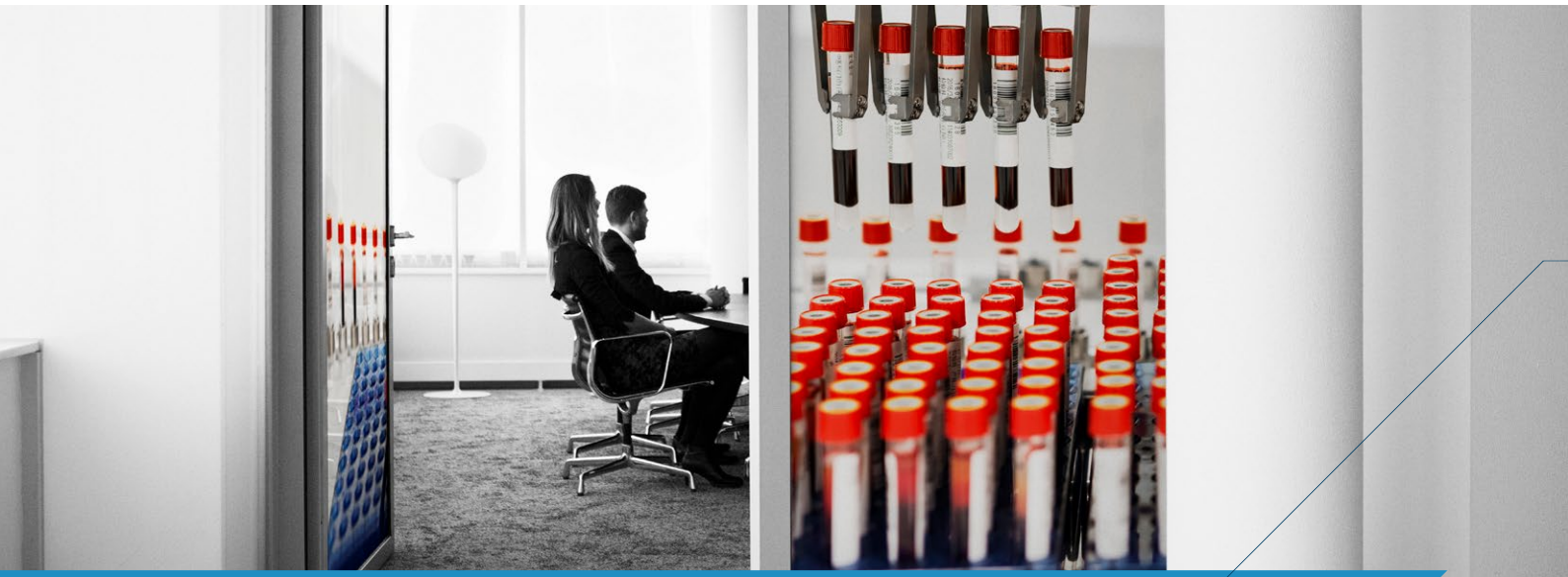
HOUTHOFF



CBD PRODUCTS IN THE NETHERLANDS

This factsheet discusses the rapidly evolving legal framework for non-medical cannabidiol ("CBD") in the Netherlands, including the latest developments.

CBD is one of the cannabinoids that can be derived from the hemp plant. CBD is considered, together with tetrahydrocannabinol ("**THC**"), to be an essential component for the medical use of marijuana. In the Netherlands, the market for medical marijuana, including medical CBD, is highly regulated. The state essentially holds a monopoly on producing, trading and delivering medical marijuana to patients.

The market for non-medical CBD is quite different. Nevertheless, it has so far not achieved its full potential because of legal uncertainties about CBD's status. A recent and long-awaited judgment by the Court of Justice of the EU ("**CJEU**") in the Kannavape case has changed this. By confirming that CBD extracted from hemp does not qualify as a 'narcotic drug', the CJEU has increased the chances of further development of the non-medical CBD market in the EU.

PRODUCTS CONTAINING CBD EXTRACTED FROM THE HEMP PLANT

The Dutch Opium Act ("**DOA**") prohibits selling or warehousing products included in 'list I' and 'list II' of the DOA. List II includes the product 'hemp' and defines it as "any part of the plant of the genus Cannabis (hemp), from which the resin has not been removed, with the exception of seeds." List I includes 'hemp oil'. The DOA defines 'hemp oil' as "a concentrate of plants of the genus Cannabis (hemp) obtained by extraction of hemp or hashish, whether or not mixed with oil".

CBD is neither defined nor listed in the DOA as a banned substance. However, it follows from the definitions of 'hemp' and 'hemp oil' that CBD extracted from hemp falls within the scope of the prohibition on selling or warehousing under the DOA.

Despite these restrictions, to our knowledge, there has not been any enforcement in the Netherlands related to selling or warehousing CBD products containing no more than 0.2% THC. However, the Netherlands Food and Consumer Product Safety Authority (*Nederlandse Voedsel- en Warenautoriteit*) has imposed penalties for these products in cases where sellers have made unsubstantiated health benefit claims.

SYNTHETIC CBD

Technically, under Dutch law, there is currently no restriction on selling or warehousing products containing synthetic CBD. After all, the synthetic variant does not fall under the above-mentioned definitions of 'hemp' or 'hemp oil'. However, it is necessary to prove the CBD's synthetic origin to benefit from this 'legislative gap', which in practice may be challenging.

In the Netherlands, medical specialists have raised specific health concerns about the safety of synthetically produced CBD. Under the Commodities Act Decree on General Product Safety (Article 2 and Article 3), producers, distributors and retailers have a shared responsibility to ensure product safety. Products that are unsafe for use may not be marketed or, if already on the market, must be recalled. The prohibition on marketing unsafe products is enforced by the Netherlands Food and Consumer Product Safety Authority.

In addition, the 'legislative gap' might soon be closed. The State Secretary of Public Health, Welfare and Sports and the Minister of Justice submitted a draft bill for consultation to amend the DOA, aiming to add a 'list Ia'. This draft bill is part of a broader effort to cover a variety of so-called 'designer drugs' that currently fall outside the DOA's scope. 'List Ia' includes, among others, synthetic CBD. The draft bill is expected to be presented to the Dutch parliament at the beginning of 2021.

FOOD PRODUCTS

Under the novel food catalogue drawn up by the European Commission ("**Commission**") to apply the novel food regulation (Regulation 2015/2283), food products that include cannabinoids, including CBD extracted from hemp and the synthetically made variant, are considered 'novel foods'. This means that these products must acquire Commission authorisation before being marketed. The market access restriction under the novel foods regulation in relation to the sale of food products containing CBD applies in all EU Member States.

To date, several requests for market authorisation for food products containing CBD have been submitted to the Commission. None of these requests have been formally approved.

In addition, in early July 2020, the Commission's Directorate-General for Health and Food Safety communicated to certain applicants under the novel foods regulation that it might adopt a position in which food products containing CBD derived from the hemp plant would not be authorised for sale in the EU, as they can be assimilated to narcotic drugs. This information was only circulated to applicants whose CBD was plant-derived – as opposed to CBD obtained by full chemical synthesis.

TOWARDS A BRIGHT FUTURE FOR THE CBD MARKET?

The Commission's communication on the status of hemp-derived CBD is illustrative of the legal uncertainty about CBD's legal status. This uncertainty has in the meantime been addressed by the CJEU's judgment in the Kannavape case.

The CJEU's major finding was that the CBD at issue – hemp-derived CBD from the whole cannabis sativa plant as opposed to solely from the fibre and seeds – does not qualify as a narcotic drug. This is because based on the information available to the CJEU, the CBD has no scientifically proven psychotropic effect or harmful effect on human health.

In addition, the CJEU held that the CBD does not classify as a narcotic drug under international conventions and that, contrary to narcotic drugs, the CBD at issue can rely on the Treaty on the Functioning of the European Union provisions. Therefore, a Member State may not restrict its marketing if it is lawfully produced in another Member State, unless the restriction can be justified by the objective of protecting public health and the restriction does not go beyond what is necessary to attain it. The CJEU further emphasised that there is only a lawful justification for a marketing prohibition if the risk alleged for public health appears sufficiently established based on the latest available scientific data.

The CJEU's judgment has two consequences.

- First, Member States infringe EU law if their national legislation restricts the marketing of hemp-derived CBD – i.e. the prohibition applicable to CBD under the DOA – that has lawfully been produced in other Member States, unless a justification for the restriction can be provided based on the latest scientific data available. In national proceedings, national provisions that are contrary to EU law must be declared inapplicable by domestic courts. As emphasised by the CJEU, it is for domestic courts to assess the relevant restrictions and possible justifications. However, in view of today's publicly available scientific evidence, it is questionable whether prohibiting marketing of hemp-derived CBD, which constitutes the most restrictive restriction, can be justified. In this respect, it is also relevant to note that the World Health Organisation has recommended that CBD not be internationally scheduled as a controlled substance, because CBD "does not have psychoactive properties and has no potential for abuse and no potential to produce dependence". In addition, Member States infringing EU law may face infringement procedures by the Commission.
- Second, it is questionable whether the Commission's Directorate-General for Health and Food Safety can uphold its announced position on the narcotic status of hemp-derived CBD in relation to the applications under the novel food regulation.

In conclusion, the latest judgment by the CJEU might create new perspectives for the development of the CBD market in the Netherlands and the EU.CBD market in the Netherlands and the EU.

If you have got any questions, please contact Bram Caudri, Greetje van Heezik, Fleur Tuinzing-Westerhuis and/or Lorenzo Fiorilli.

BRAM CAUDRI
ADVOCAAT | PARTNER
T +31 6 5161 7840
b.caudri@houthoff.com

GREETJE VAN HEEZIK
ADVOCAAT | COUNSEL
T +32 4 7586 8593
g.van.heezik@houthoff.com

FLEUR TUINZING-WESTERHUIS
ADVOCAAT | COUNSEL
T +31 6 4397 5040
f.tuinzing@houthoff.com

LORENZO FIORILLI
ADVOCAAT | ASSOCIATE
T +32 4 9452 3891
l.fiorilli@houthoff.com