

Implications of the ECJ ruling on the organisation of the European Common Market

March 14th, 2022



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CJE judgment in case C-663/18 (the "Kanavape case") of November, 20th, 2020

Key principles of the judgment:

1

CBD, extracted or isolated from the cannabis sativa plant, is not an agricultural product and is not a narcotic substance

2

It is permissible to use the whole hemp plant to obtain CBD and e x t r a c t s

3

N a t i o n a l r u l e s
p r e v e n t i n g t h e
m a r k e t i n g o f C B D
p r o d u c t s e x t r a c t e d f r o m
t h e w h o l e p l a n t a n d n o t
o n l y f r o m c e r t a i n p a r t s ,
l e g a l l y p r o d u c e d i n a
M S , v i o l a t e A r t i c l e s 3 4
a n d 3 6 T F E U

Why?



The rationale of the judgement:

- ✓ A comparative reading of the SC and Community law shows that there are no limits in Community law on the use of the hemp plant in its entirety
- ✓ Hemp is an agricultural product according to the TFEU with its own common market organisation under Reg. (UE) n. 1307/2013 and Reg. (UE) n. 1308/2013
- ✓ The assessments on the impact on public health have already been made by the EU when the hemp plant is qualified as an agricultural product (and an industrial plant), so MS cannot impose limitations on the basis of general precautionary requirements (see Italy and Spain), but only on the basis of proven scientific evidence (principle already affirmed by the ECJ in the "Hammerstein case" in 2003 against Sweden)

Then...

Any public health issues will have to be assessed on the finished product in its individual uses (e.g. food, Novel Food, cosmetics, feed) but not on the use of the whole plant which is an agricultural product

For regulatory purposes no botanicals have divisions between plant parts (flowers/stem/seeds/leaves), not even opium!. Any restrictions are IN THE FINISHED PRODUCT. Safety is measured on the finished product



EUROPEAN COMMISSION
DIRECTORATE-GENERAL II
INDUSTRY
Industrie-Unternehmens-Verwaltung
Foodstuffs - Leguminosae, scientific and technical aspects
Head of Unit

03-02-1998 001908

Brussels,
DGII/II-IGS&K D(98)

Subject: Your request for information about the opinion of the Standing Committee for Foodstuffs concerning hemp products.

Dear Mr Kreutner,

According to your request of 26 January 1998, we can inform you that the Standing Committee for Foodstuffs agreed on 18 December 1997 that hemp flowers used for the production of beer-like beverages are considered to be food ingredients and not additives since they are used in the same manner as hop flowers.

Secondly, it was decided that foods containing parts of the hemp plant do not fall under the scope of the Regulation (EC) 258/97.

Yours sincerely,


E. GAERNER

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In 1998 hemp flowers were allowed as food ingredients and foods containing parts of the hemp plant were not considered novel foods !



The regulatory framework in some Member States

L'Arrete du 30.12.2021 had established that the production of the entire hemp plant for the production of hemp extracts, which would be lawful up to the threshold of 0.3% THC, was entirely lawful, subject to the provisions of Articles 14 and 15 of Regulation (EC) No 178/2002 and Article 4 of Regulation (EC) No 767/2009.

Decree suspended by the Council of State

France



The regulatory framework in some Member States:

Croatia and Czech Republic



It has been clarified that the industrial production and use of the entire hemp plant with a THC content of up to 0.2% is permitted; below this THC threshold, hemp sativa L. does not fall within the scope of the Croatian Narcotics Act.



Hemp extracts, tinctures and plants with a THC content of less than 1% are excluded from the scope of the Narcotic Substances Act - In § 2, letter a) ; 3. In § 2, letter d) of the Act of the Parliament of the Czech Republic of September, 14 th, 2021 in force since January, 1st, 2022.

The regulatory framework in some Member States:

Lithuania



Law on the use of hemp plant of the Republic of Lithuania, which came into force on the 1st of November of 2021 allows the use of the whole hemp plant (flowers, leaves, stem) for the hemp plant products*.

*Hemp plant products – food stuffs, feed, cosmetics and other products with hemp plant made of hemp plant products intended for the final consumption.

The regulatory framework in some Member States:

Belgium and Luxembourg

Belgium has qualified cannabis and cannabis products (inflorescences, e-liquid) with THC content up to 0.2%. *“comme autres tabacs à fumer”* and, as such, subject to the relevant tax regime.

Luxembourg too has included these products in the *“Taxation de produits à base de cannabis susceptibles d’être fumés ou vaporisés”*



The regulatory framework in some Member States:

Italy, Spain and Portugal



In these MS there are restrictive interpretations that the production of flowers and leaves for the sole purpose of extraction of API by pharmaceutical workshops authorised by the respective Medicines Agencies, effectively excluding other lawful uses for the extracts.



In Italy a draft decree on medicinal plants has been approved (awaiting publication in the Official Gazette), which states that the use of hemp is limited to seeds and derivatives, excluding flowers and leaves.





The implications for the Common Market

The risk of a «two-speed» Europe

The risk of distortion of the common market and
competition

What can be done?

Opportunity to affirm the centrality of Europe and protect the common market

A unified and organic solution at EU level with the adoption of appropriate regulatory instruments binding on MS on the basis of the interpretation provided by the CJEU regarding the lawfulness of the production, processing and use of the whole hemp plant (including flowers and leaves) as an agricultural product for industrial purposes and for the production of extracts containing cannabinoids.

To bring this general provision on the hemp plant as an agricultural product and industrial plant into line with the sectoral regulations in force for the various uses (food, food supplements, cosmetics, feed, inhalation product, pharmaceuticals, etc.)

The various issues (already pending with the competent European authorities) concerning the safety of the product for human or animal consumption can be addressed here through toxicological studies, such as, for example, the studies promoted by EIHA on the applications of CBD isolates and extracts (the so-called 'full spectrum') as novel foods or zootechnical additives



The hemp plant in its entirety is an agricultural product. The extracts are products that have to be regulated according to the (existing) sector regulations for the various uses.

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Thanks for your attention !



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