KANAVAPE – IS CBD IN EUROPE BACK ON TRACK?

In May we published an analysis of the Judgement of Advocate General Tanchev in respect of the Kanavape case, "*Can the movement of CBD within the European Member States be prohibited it if is derived from prohibited elements of the plant?*" (found here). We observed that there was "good" and "bad" in the provisional Opinion.

In July, in publishing "*Is there a sting in the Kanavape tail?*" (found here), we drew attention to what might be a sharper issue being forced on the back of the provisional opinion: Member States and Commission elements who continued to resist the inclusion of extracts of buds and flowers in consumer products were then utilising a topic that only those who have been involved in the CBD industry from its inception would remember – CBD as a narcotic.

With the publication of the Judgement of the Full Court today, we are able to bring the issue to a conclusion (for now at least).

THE DECISION

1. Approaching the matter in reverse, we will deal with the Court's conclusions first, which are:

    a. CBD is not a drug within the meaning of the Single Convention on Narcotic Drugs 1961;

    b. a Member State may not unilaterally prohibit the marketing of cannabidiol (CBD) lawfully produced in another Member State when it is extracted from the *Cannabis sativa* plant in its entirety and not solely from its fibre and seeds;

    c. a prohibition may be justified by the objective of protecting public health but any such prohibition must not go beyond what is necessary in order to attain that objective; and,

    d. in considering a claim for a prohibition on the grounds of public health justification, it is for the National Court to assess the scientific data available and produced before it in order to make sure (in the light of this Court's conclusion that CBD does not appear to have any psychotropic effect or harmful effect on human health), that the real risk to public health alleged does not appear to be based on purely hypothetical considerations.

OUR THOUGHTS

2. The predictions that we made in our earlier Position Papers (see links above) have transpired to be accurate, with the Full Court undertaking the same analysis, and coming to the same conclusions that we at ***The Canna Consultants*** did:

OUR PREVIOUS ANALYSIS	THE COURT'S DECISION
On a strict interpretation of the 1961 Convention, then the answer to the question [of whether naturally derived cannabinoids are narcotics] is likely to be "yes", because they are "extracts" from the flowering or fruiting tops of the Cannabis plant from which the resin has not been [previously] extracted.	…it is true that a literal interpretation of the provisions of the Single Convention might lead to the conclusion that, in so far as CBD is extracted from a plant of the *Cannabis* genus and that plant is used in its entirety – including its flowering or fruiting tops – it constitutes a cannabis extract within the meaning of Schedule I of that convention and, consequently, a "drug" within the meaning of Article 1(1)(j) of that convention. [Paras 70 and 71]
However, when one considers the extraction techniques that were available in 1961 and asks whether the application of those techniques meant that it was inevitable that the "extracts" referred to within the Convention definition would contain what we would today more readily associate with psychoactive "controlled cannabinoids" (i.e., CBN and THC), one would equally be led to the conclusion that they would.	…CBD… does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data. [Para 72] …the Single Convention is based, inter alia, on an objective of protecting the health and welfare of mankind. It is therefore appropriate to take that objective into account when interpreting that convention's provisions. [Para 73]

To that extent, it can be contended that the "extracts" that were being referred to in 1961 had an inherent "controlled cannabinoid" (THC/CBN) content and if, through the application of modern techniques and processes - unknown, undiscovered and/or unapplied in 1961 - extracts can now be obtained which are free from the "controlled cannabinoids", then those "non-psychoactive, non-controlled Cannabinoids" are (but ought not to be), caught by a definition that was fit for purpose almost half a century ago, but which is perhaps now not so	…an international treaty must be interpreted by reference to the terms in which it is worded and in the light of its objectives. [Para 66] … having regard to the purpose and general spirit of [the 1961] convention, that definition [of cannabis] is intrinsically linked to the state of scientific knowledge in terms of the harmfulness of cannabis-derived products to human health. [Para 74] …since CBD does not contain a psychoactive ingredient in the current state of scientific knowledge… it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of 'drugs' within the meaning of that convention as a cannabis extract. [Para 75]
It is perhaps of some note that products which contain synthetic CBD are not covered by the relevant legal prohibition because they do not have a link to any plant, let alone the prohibited parts of such plants. There is, therefore, currently no inhibitor to their sale in France.	…it does not appear to it to be possible [for the French Government] to rely on the principle of proportionality since… in justifying the prohibition on natural CBD, [it] relies on a prohibition which could not extend to the marketing of synthetic CBD with the same characteristics and effects. [Para 42]

3. While the Court is unable to close off the decision in respect of whether the French authorities can satisfy the National (French) Court that there is evidence to demonstrate that CBD poses a risk to human health, such as to justify the prohibition (because that is a decision which must be made firstly by the French court), the Full Court here could not be more conclusive in its assessment of the position:

"…since CBD does not contain a psychoactive ingredient in the current state of scientific knowledge… it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of 'drugs' within the meaning of that convention as a cannabis extract." [Para 75]

4. Barring any revelatory new scientific data, it is hard to see how the French court could come to any different conclusion than this higher authority and, if it were to do so, one can see that such a decision is not likely to admired, or supported, by the European Court.

WHAT ARE THE CONSEQUENCES FOR THE CBD INDUSTRY?

5. At ***The Canna Consultants*** we are firmly of the view that this Judgement removes the legal objection to the progress of CBD products in Europe and inevitably increases the pressure on the European Commission to remove the present ban on the advancement of the Novel Food assessments of naturally-derived CBD products.

6. However, the lineage between legal judgement and political action is not necessarily always straight or swift and one can see circumstances in which the brakes are not immediately removed. We understand that, without further pressure being brought, the EU Commission may delay any tacking of this issue further until the outcome of the UN vote on the "Cannabis Resolutions" is known in December 2020.

Remember what we always say: Be Careful Who You Listen To.

THE BACKGROUND TO THE CASE AND THE WIDER ISSUES RAISED

(FROM OUR PUBLISHED ANALYSIS IN JULY 2020)

NATIONAL FRENCH LAW

1. French law restricts the elements of the hemp plant within Cannabis-derived products to the fibre and seeds: in essence, it prevents the legitimate marketing of CBD-based products that are derived from the entire hemp plant (i.e. from the buds and flowers).

WHAT WAS THE CASE ABOUT?

2. The hemp was lawfully grown within the EU (but not in France), and the use of the whole plant was lawful in the Member State in which it was extracted and processed.

3. The issue was whether the specific element (the flowering and fruiting tops) of the lawful source that was utilised in the product made the end product itself unlawful, such that the restrictions to the free movement of goods within the European Union (as consequent under French law) were justified on the basis of public health grounds.

APPLICABILITY: TO THIS CASE AND CBD PRODUCTS GENERALLY

4. The question was whether French National legislation (which prohibited the importation of CBD oil from another Member State where that oil was extracted from the whole plant), interfered with the proper functioning of the common organisation of the market in hemp and constituted a quantitative restriction (or equivalent).

5. Under the principles of the Union, Member States are prevented from adopting legislation prohibiting the importation of CBD products from another Member State, where that product is extracted from the whole plant, unless that legislation pursues a genuine and realistic public-interest objective.

6. Legislation that is capable of restricting a fundamental freedom guaranteed by the EU Treaty, such as the free movement of goods, can be justified on grounds of the protection of the health and life of humans only if that measure is appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it.

7. The Advocate General's Opinion was that the French Government had not clearly identified the harmful, in particular psychotropic, effects involved in the use of CBD oil in electronic cigarettes, even less that it had carried out a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.

8. The Advocate General concluded that the relevant Articles preclude legislation which prohibits the importation of CBD oil where it is extracted from the whole hemp plant, since, in the current state of scientific knowledge, it has not been established that CBD oil has psychotropic effects.

THAT SOUNDS LIKE A WIN FOR THE INDUSTRY - WHERE IS THE STING?

9. Recently we were informed by DG SANTE, the Commission's Directorate General for Health and Food Safety responsible for EU policy and food safety and health (and for monitoring the implementation of related laws) that no Novel Food applications for naturally-derived CBD ingredients would be Validated (by EFSA (the European Food Standards Agency)) until after the UN addresses the issue of the classification of Cannabis. It is to be noted that one of the matters placed before the UN for approval includes a proposed footnote defining an acceptable level of THC in CBD products.

10. At ***The Canna Consultants*** we have reason to believe that the Kanavape Opinion has re-ignited a debate which took place at the origins of the Cannabinoid Industry in the European Union, but which was overtaken by the momentum of events and left by the Cannabinoid roadside.

11. It is unclear whether the resurrection of an old issue is fuelled by Member States whose National Legislation would be affected by the Advocate General's Opinion being upheld by the full EU Court, or simply that it has returned the issue to the minds of Europe's policy-makers, but there are clear indications to us that the issue of "Cannabinoids as Narcotics" are back on the agenda.

12. Some readers will remember the debate to which we refer. For other more recent arrivals to the industry (which in reality is most market participants), it may be something that has never required your thought.

CANNABINOIDS: A FOOD OR A NARCOTIC OR A RESIDUE CONTAMINANT?

13. On 28th January 2002 EU Regulation 178/2002 laid down the general principles and requirements of food law, establishing the EFSA and laid down procedures in matters of food safety.

14. Article 2 thereof provided, and continues to provide, the definition of "Food" as follows:

> *For the purpose of this Regulation, "food" means any substances or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.*
>
> *"Food" includes… any substance… intentionally incorporated into the food during its manufacture, preparation or treatment."*
>
> *"Food" shall not include:*
>
> *(g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs 1961, and the United Nations Convention on Psychotropic Substances 1971."*

15. It is therefore a necessary and integral part of the assessment of any food (but particularly a Cannabinoid), to understand the treatment which the substance or compound is given by the two Conventions referred to.

THE 1961 SINGLE CONVENTION ON NARCOTIC DRUGS

16. On 13th March 1961 seventy-three States Adopted a Single Convention on Narcotic Drugs at the United Nations Headquarters. The Convention that they each signed, with amendments, remains applicable to this day.

17. Article 1 of the 1961 Convention defines:

    a. "Cannabis" as "*the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated*"; and,
    b. A "Drug" as any of the substances in Schedules I and II, whether natural or synthetic.

18. Schedule 1 identifies Cannabis, Cannabis Resin and "***Extracts and Tinctures"*** thereof, but neither "Extracts" nor "Tinctures" are defined further.

COULD THE THREAT BE A CATALYST FOR CHANGE?

19. This document is intended to do no more that bring to the attention of market participants what we at ***The Canna Consultants*** believe to be the re-awakening of the "all cannabinoids are narcotics" debate within the echelons of power within the institutions of the Union. It is not the appropriate vehicle to consider the issue in-depth, nor to undertake a full analysis of the proposed amendments to the 1961 Convention. However, we do not want to raise what could be perceived as a seismic shift to the detriment of the Cannabinoid industry in Europe and say nothing now about why we do not think that that will be the case.

20. It is true that if the narrow interpretation of the definition within the 1961 Convention was adopted more widely by other States it would be a body-blow for the whole industry, but we believe that the issue could instead be used as a catalyst to drive compromise on the proposed amendments.

21. The most significant opposition to the proposed amendments concern the proposed footnote and the acceptance therein of a 0.2% THC level in cannabinoid products. Reduction of that figure to a ratio which was acceptable to those nations who would otherwise vote down the proposal, in return for the latter's acknowledgment that the definition of "extracts" should be brought into the modern age could present a satisfactory compromise to both sides.

DOES IT HELP IF "UNWANTED" CANNABINOIDS ARE RESIDUES OR CONTAMINANTS?

22. While we are addressing the 1961 Convention and the approach of the European food safety regulators, we have become aware of a second, parallel approach within the Union which is gaining traction – and which we have previously seen deployed in Member States who caused the withdrawal of CBD products from sale earlier this year, not because of the novel food issue, but because of the levels of THC within products (See our two articles **here** and **here** from February 2020 concerning the action taken by one such Member).

23. Leaving aside how much people would like there to be an acceptable and defined 0.2% level of permitted THC content in Cannabinoid products, there is no such level in law in many countries – if there were there would be no need for the proposed footnote addition to the 1961 Convention discussed above.

24. If the proposed footnote amendment to the 1961 Convention is passed, the issue will disappear, but if the vote is again delayed (which is not unlikely given the current priorities of the World's Nations) or the proposed amendments are unsuccessful, then irrespective of the above potential issue of "all cannabinoids are narcotics", there will continue to be the "latent THC issue".

25. We referred earlier to the definition of "Food" in Article 2 of Regulation 178/2002 which, when defining "Food", also provides, that *"Food" shall not include: (h) residues and contaminants."*

26. We know that due to the feeding of hemp biomass to cattle we now have what is, unless the practice is prohibited, an effectively permanent contaminant level of THC within milk and the onward food-chain. Therefore, it would seem that an argument that there can be no acceptable level of THC contamination in food products, would be an academic one.

27. If that is correct, then one could suggest that a sensible approach would be to then define what an acceptable level of controlled cannabinoid presence (THC/CBN) could be in foodstuffs generally, or in cannabis-derived products specifically.

28. Given that no-one seriously believes that individuals consume cannabinoid products which contain technically measurable, but pharmaceutically insignificant amounts of controlled cannabinoids (THC/CBN) in order to achieve psychoactive results, then one could quite properly define them as "residues" of the natural origin of the end product or undesired "contaminants" to that product.

29. To do so would not offend food law and regulation and if agreement could be found for the level at which acceptability was defined, then it is unlikely to have unintended consequences for those government departments charged with the control and eradication of narcotic drugs. The question within this debate would be – what is an "acceptable" level below which the presence of "controlled cannabinoids" could be deemed an acceptable contaminant?

30. One can almost hear the choral cries of the large elements of the European industry to suggest that that acceptable contaminant level should be "0.2%". Given that the EU Commission has fundamental objections to the proposed footnote amendment to the 1961 Convention, at ***The Canna Consultants*** we feel that that is an unlikely to be an acceptable level. From what we understand, it is more likely to be at, or around, the level to be found as a contaminant level in milk stocks – in part because whether they like it or not, those who would otherwise contend for "zero tolerance" are somewhat undermined by the ubiquity of that contamination.

31. If the levels were set with this as a context benchmark then the effect would be to further fracture the industry, with naturally-derived cannabinoid isolates and synthetic cannabinoids being the only production methods presently likely to be able to achieve the required levels of purity.

32. Depending upon the approaches taken and tactics deployed by those governments and/or food regulators who still wish to eradicate, or at least limit, the burgeoning cannabinoid industry (whether that is permanently or just until more is known about the compounds involved), the industry as a whole may be faced with some very tough choices, and consumers with significantly fewer product lines than they presently enjoy.

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