



ALL PARTY PARLIAMENTARY GROUP FOR CBD PRODUCTS

What regulatory changes the secretariat advisory board members, and the secretariat for the APPG for CBD products advocate for.

Right for UK: Consumers | Legislation & Regulation | Industry (inc. farming)

Agreement: 4/6/2022

The Secretariat Advisory Board members (SAB) - *members that represent all sectors and sizes of the industry* - are experts within the UK CBD products industry as well as the wider UK cannabis industry including consumers, patients, hemp farmers and all the service and supply side companies associated with the industry.

The SAB recommend and advise the Secretariat - *Tenacious Labs, a pioneering multimillion pound cannabinoid group wholly owned by Delarki, a search fund targeting Generation Y and Z audiences that includes funding from Meritus, a multi-generational Bermuda-based trust that manages monies predominantly from a private shareholding in Bacardi* - for the APPG for CBD products.

There are six key regulatory changes that the SAB and the Secretariat advocate for; that with the right checks and balances:

- ! Protects consumers and patients
- ! Encourages competition and significantly expands sources of supply
- ! Supports existing UK hemp farmers and easily enables new farms to enter
- ! Continues supply of whole plant hemp extract, full-spectrum and broad-spectrum products
- ! Enables the environmental benefits from growing hemp to be unlocked
- ! Creates revenue growth for companies of all sizes triggering investment, employment and tax receipts

Six key regulatory changes

- 1) Novel Foods - replace with a Certificate of Analysis (COA) led approach
- 2) Controlled cannabinoid limit (i.e. THC) in final product - set at a ratio of 10% THC:CBD
- 3) Allow UK hemp farmers to harvest the flowering tops (leaf & flower) of hemp plants grown in the field and/or extract/supply British extraction companies
- 4) Hemp seed selection - allow non-EU approved hemp seeds
- 5) Controlled cannabinoid limit in the field - to be set at 1%
- 6) Synthetic CBD - products to be clearly labeled

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Appendix 1 - Novel Foods - Replace with a Certificate of Analysis (COA) led approach

A certificate of analysis (COA) is a report that should be produced by an independent laboratory on the finished product. Minimum reporting level: Potency; i.e. cannabinoids contained within said product and results displayed as mg/g, % and the Limit of Quantification (LOQ). (See appendix 8 for an example.)

COAs are transparent and make all products equal.

COAs directly benefit consumers.

Gold standard full-panel COAs test for and report on: Potency, Heavy Metals, Pesticides, Residual Solvents, Microbiological, Mycotoxins, Terpenes and Flavonoids.

'Novel Foods' - January 29th 2019 the European Union (EU) specifically, the European Foods Standards Agency (EFSA) announced/added hemp extracts and hemp-derived products containing cannabinoids including CBD to a list known as Novel Foods.

Inclusion in The Novel Food Catalogue does not create Law.

The Novel Food catalogue is a EU guideline document developed by the European Commission and it is not, legally binding.

On the 31st of January 2020 the UK stopped being a member of the European Union (EU) enabling the UK to do things differently, better, more efficiently and that applies to self-generated EU bureaucracy that has left the UK lagging behind other countries.

On the 13th February 2020 the UK Food Standards Agency (FSA) stated that all CBD products on the UK market must have a novel food application through the validation phase of the review process before 31 March 2021.

The FSA chose to inherit this costly and counterproductive approach from the EU rather than build upon post-Brexit freedoms most likely due to a lack of experience and understanding of the hemp farming industry as a whole and CBD products.

A novel food application involves the creation of a **very large dossier** of complex and costly information that **serves no benefit to the end consumer** and is a process that is flawed from the outset:

Anti-competitive. Novel Food Primary Dossier applications are initially required and only large multi-national corporations have the capital, resource, infrastructure and scale to submit these to the FSA. **This approach significantly limits, controls and monopolises the supply**; many excellent international small hemp farmers, hemp CBD producers are now excluded and **there is absolutely no possibility of the creation, the innovation of a UK hemp CBD product industry**; think UK artisan bread, chocolate producers, small batch regional wine producers, craft beer producers this could be applied to CBD oil producers, CBD product producers, hemp farmers.

No transparency, governance, accountability, regulatory oversight including auditing of the process, appeals process with independent adjudication that is fair, open and consistent.

No benefit to the environment. With the majority of hemp CBD products being imported, there is no benefit to CO2 emissions. Hemp grown in the UK could significantly support the Governments decarbonisation plan - hemp absorbs more CO2 than any other plant, up to 15 tonnes per hectare.

Completely disproportionate approach that is not in the public interest. Novel Food dossiers are made up of:

- ! Dossier:
 - o Primary: 180 pages, appendices: 300 pages, drafted by a team of 2-4 specialists including;
 - academics, researches, scientists,
 - product & production specialists

- with on going support and funding required.
- ! Cost:
 - Primary dossier: between £350k & £1m
 - Secondary dossier: £10k-£30k
- ! Should include (per hemp ingredient):
- ! Preamble:
 - Company
 - Products
 - Examples
- ! Applicant
- ! Characterisation of the novel food, technical & scientific data
- ! Key dates
- ! Legal position of products
- ! Safety
- ! Products
- ! Production process
- ! Compositional data, cannabinoid profile
- ! Pathogenic microbiology
- ! Stability
- ! Specifications
- ! History of use (written by an academic; duplication across all applications)
- ! Proposed uses, use levels and anticipated intake
- ! Target population
- ! Absorption, distribution, metabolism and excretion (inc. scientific studies)
- ! Nutritional information
- ! Toxicological information:
 - Genotoxicity and Sub-chronic toxicity (rat study),
 - Hepatotoxicity,
 - Immunotoxicity.
 - 90-day toxicity data that can cost between £300k & £1m
- ! Allergenicity
- ! Conclusion

The premise of the Novel Food application process is safety however a COA achieves this incredibly efficiently and is a direct benefit for consumers.

For the avoidance of doubt, whole-plant extract is not a novel food and therefore does not fall part of the novel food process, guidance unlike synthetic CBD.

Appendix 2 - Controlled cannabinoid limit in final product - Set at a ratio of 10% THC:CBD

Any cannabinoid that is a cannabinol derivative is currently illegal in the UK. At present there are twelve cannabinoids classified as controlled substances, simplified as THC, CBN & THCV.

The 1mg rule

Regulation 2 (Interpretation) of the The Misuse of Drugs Regulations 2001 (MDR) provides that some products may, in limited circumstances, be considered 'exempt' from control, notwithstanding their 'controlled drug' content.

The regulation¹ sets out:

An "exempt product" means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where

- a) the preparation or other product is not designed for administration of the controlled drug to a human being or animal;
- b) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and
- c) no one component part of the product or preparation **contains more than one milligram of the controlled drug**

Example: A 10ml bottle of CBD oil should not contain more than 1mg total of the controlled cannabinoid. This is expressed as a percentage of 0.01% on a COA.

Limit of Quantification (LoQ) is important to ensure that the lowest concentration of a cannabinoid can be determined.

If a COA only has a LoQ of 0.05%, controlled cannabinoids could be displayed as non-detect when in fact they are present.

Anecdotally, it is widely acknowledged that hemp seed oil (available in supermarkets) contains controlled cannabinoids and significantly more than 1mg.

January 2021 Kit Malthouse MP - Minister of State for Crime and Policing - wrote to Professor Owen Bowden-Jones Chair, Advisory Council on the Misuse of Drugs (ACMD) stating:

Government wishes to explore the possibility of creating a specific exemption in the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') for CBD products which contain no more than a 'defined trace' percentage of controlled cannabinoids.

The 'defined trace' will be determined following further scientific testing advice.

The AMCD to advise on the "maximum dose for any non-negligible effect for controlled cannabinoids".

So, the amendment of the regulations for CBD products is underway however and the updating of the limit of controlled cannabinoids is yet to be set.

The ACMD/ Professor Owen Bowden-Jones has yet to advise.

Switzerland has set the THC/controlled cannabinoid limit at 1% for CBD products.

Australia has set the THC/controlled cannabinoid limit at 1% for CBD products.

US hemp farmers expect the THC/controlled cannabinoid limit to be raised from 0.3%>1%

¹ <https://www.legislation.gov.uk/uksi/2001/3998/regulation/2/made>

The European Industrial Hemp Association (EIHA 2017) proposed, after an extensive review of the literature on the topic of THC consumption and effects, a Lowest Observed Effect Level (LOEL) of 2.5mg of THC intake per person twice daily (Sarmiento et al. 2015). A total daily intake of 5 mg THC (2 x 2.5 mg) results in a LOEL of 0.07 mg THC/kg body weight (BW) per day assuming a body weight of 70kg.

Based on a 10ml bottle of CBD oil containing 1% THC (100mg) with an average of 40 servings (0.25ml) per bottle = 2.5mg of THC per serving being consumed.

Appendix 3 - Allow UK hemp farmers to harvest the flowering tops of hemp plants grown in the field and/or extract/supply British extraction companies.

When a hemp crop is ready for harvesting, a UK farmer may process the plant for seed and fibre/stalk only. The flowering tops - where the CBD is pressed/extracted from the trichomes - must be destroyed. It is crucial that the Government reforms Home Office licenses in order for UK hemp farmers to extract CBD from the hemp plant and this does not include any additional requirements i.e. security than already exists. This does not exclude the right to grow hemp plants in a greenhouse/indoors.

No English, Welsh, Scottish or Northern Ireland farmer can grow hemp for the production of CBD products unless they have spent circa £20-30 million and 2-5 years building a secure production facility that has the correct Home Office licenses in place **to produce a 'sample'!** which can be tested and then included in a novel food dossier application (see Appendix 1) that could then take 12-24 months to be assessed. **As it stands today, 99.9% of all hemp CBD products purchased by UK consumers - that's a +£690m p.a. industry - is imported from either, the EU, America, Switzerland, Israel and China sources/grown hemp; there is and there will be no domestic farming and production for hemp CBD products in the UK.**

Appendix 4 - Hemp seed selection - Allow non-EU approved hemp seeds

The Home Office provides licenses for the cultivation of hemp, defined as cannabis plants with a low level of tetrahydrocannabinol (THC). UK farmers can grow hemp under license. The variety of hemp that can be grown must come from an approved EU certified seed that will produce a plant with less than 0.2% THC. There are 81 EU certified seed varieties available for farmers to choose from however none are ideal for the UK climate.

Appendix 5 - Controlled cannabinoid limit in the field - Set it at 1%

Hotter temperatures and drought conditions naturally increase THC concentration in all hemp varieties.

The UK is stuck at 0.2% THC (dry weight) for hemp and still restricted to certified EU varieties. If a hemp crop tests over the allowed legal dry-weight limit then it has to be destroyed. All ten Scottish farms growing hemp (Finola seed variety) is often tested over the 0.2% THC limit and therefore has to be destroyed.

Switzerland is already at 1%, setting the THC limit for industrial hemp at 1% in 2011²

Italy raised the limit to 0.6% so that Italian farmers were not breaking the regulations and that law enforcement didn't have to take a 'blind eye' approach with selective discriminatory enforcement because THC levels of 0.2% were rarely achieved.

World Health Organization (WHO) expert committee on drug dependence identify and acknowledge 1%³. Hemp plants grown for fibre or oil, of limited intoxicant ability, Δ^9 -THC usually comprising less than 0.3% (dry weight) of upper third of flowering plants (sometimes up to 1%).

Australia has already made the amendment to 1%. Industrial Hemp Amendment Bill⁴ 2018 initiated the amendment of the Industrial Hemp Act 2004 to increase the permitted level of tetrahydrocannabinol (THC) in industrial hemp to no more than 1%.

Hemp farmers in America expect the THC limit to be raised to 1% due to hemp crops testing over the 0.3% limit.

The EU has raised (Oct. 2020) the THC limit in hemp from 0.2% to 0.3% but hemp farmers in the EU are still restricted to certified EU varieties. The limit was 0.5% in 1984. (See Appendix 1 - Certificate of Analysis/COA)

² <https://hemptoday.net/switzerland-moves-to-allow-production-marketing-of-planting-seeds/>

³ 2.5.1 <https://www.who.int/medicines/access/controlled-substances/Cannabis-and-cannabis-resin.pdf>

⁴ <https://www.parliament.wa.gov.au/parliament/bills.nsf/BillProgressPopup?openForm&ParentUNID=765A8A8EEADCCBEF4825826C001824A7>

Appendix 6 - Synthetic CBD – products to be clearly labeled

For the avoidance of doubt, the majority of CBD products are made from natural CBD obtained from the hemp plant. Synthetic CBD products are made using chemical or biological processes in a lab, such as using yeast, and should be labeled accordingly.

Appendix 7 - CBD food supplement product descriptions

Consistency in the communication of the different types of CBD food supplement products is key to ensure there are minimal misunderstandings.

Whole plant hemp extract - all parts of the plant

Full-spectrum - whole plant with naturally occurring levels of controlled cannabinoids

Broad-spectrum - whole plant with trace levels of controlled cannabinoids

Narrow-spectrum - whole plant with one or two cannabinoids

No-spectrum, isolate - pure single cannabinoid

Appendix 8 – Certificate of Analysis *example*

Signatures

Organisation: European Industrial Hemp Association
Representative: Catherine Wilson
Signature:
Date:

Organisation: European Industrial Hemp Association
Representative: Tony Reeves
Signature:
Date:

Organisation: British Hemp Alliance
Representative: Rebekah Shaman
Signature:
Date:

Organisation: Charlottes Web
Representative: Jade Proudman
Signature:
Date:

Organisation: Cannabis Industry Council
Representative: Charles Clowes
Signature:
Date:

Organisation: Cannabis Industry Council
Representative: Jamie Bartley
Signature:
Date:

Organisation: Cannabis Industry Council
Representative: Prof. Mike Barnes
Signature:
Date:

Organisation: Scottish Hemp Association
Representative: Kyle Esplin
Signature:
Date:

Organisation: Tenacious Labs
Representative: Nick Morland
Signature:
Date:

Organisation: Cannabis Trade Association
Representative: Sian Phillips
Signature:
Date:

Organisation: Cannabis Trade Association
Representative: Marika Graham-Woods
Signature:
Date: