

1st September 2023

# **Advocacy for Establishing a Safe Consumer THC Level as a** in CBD Food Products

To the Joint Chairs of the APPG for Industrial Hemp and CBD (by email)

Dear Crispin and Ronnie,

# Synopsis:

I am writing to you on behalf of the HTA and CTA and other Trade Organisations involved in the UK CBD sector who advocate for safe and effective regulation of the burgeoning CBD market in the United Kingdom.

We urge the United Kingdom Parliament to reconsider the current regulatory approach to THC levels in CBD consumer food products, and advocate for establishing an accepted safe level of THC as a food contaminant preventing the total collapse of the UK CBD sector.

As you are likely aware, the Advisory Council on the Misuse of Drugs (ACMD) conducted a comprehensive review in 2016 and further reiterated their findings in 2021, where they explicitly stated that the risks associated with THC consumption are lower than those posed by alcohol and tobacco use. Moreover, CBD products are increasingly used as a food ingredient, and food supplements for therapeutic purposes and contribute significantly to the overall well-being of many UK citizens.

The current UK CBD market has demonstrated significant value, contributing substantially to the national economy, and providing a broad range of potential benefits for consumers. It is important to recognise this growth and support the industry with evidence-based regulations that encourage safe and responsible product development, while providing consumers with product choice and access to effective CBD products.

One key issue that warrants consideration is the current approach to setting limits for THC levels in consumer CBD products. The global regulatory landscape varies, with the United States 0.3% THC level and Europe from 0.25 to 1% THC levels. Australia and New Zealand have strict regulations around THC in food, aligning closely with global Codex standards. Hemp seed foods were legalised in 2017 but must contain no more than 0.5% THC in the oil and 50 mg/kg in solid food.



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The base problem for the CBD industry is that no `safe level for THC as a food contaminant' has been set. This means the FSA CBD Novel Foods Process and the entire legitimate CBD Industry is in limbo and has been for 3 years since the Novel Foods Process began!

To date NO level of THC as a contaminant in foods has been set, and this is causing the entire UK CBD industry estimated to be worth £2 Bn with £400 M in tax revenues and 25,000 permanent jobs by 2027 to be very close to collapse.

Should the ACMD 2021 recommendations be accepted the UK would become one of the strictest regimes for THC in the entire World, and all whole plant full-spectrum CBD products, that UK consumers prefer, would be removed from the FSA NF Public list overnight, leading to a complete collapse of this sector, and potentially serious fall-out for the FSA which we would hope to avoid.

Foreign companies are selling CBD consumer products via the internet straight to UK consumers without any safeguards for consumers or assured product quality. This is a disgrace - and the UK is not receiving ANY benefit of this in the form of tax income, jobs or industry growth or export potential.

No product innovation, brand marketing or investment can be made whilst the CBD Novel Foods pathway remains stalled. With this uncertainty comes higher perceived Risk profiling from Banks, Insurance and Investors - with Bank accounts being closed and no chance of investment even for regulated suppliers on the CBD Novel Foods Public List.

The requirement for (rare) Toxicology Data Sets relating to CBD has created a near monopoly (due to capital R&D costs alone) for the EIHA Toxicology Data. Again, this is not ideal, and many CBD food ingredients may not fit this data. Given the FSA uniquely have over 20 toxicology data sets, taking a sensible view regarding THC as a contaminant in foods can be extrapolated from this data.

The fact that organisations wishing to join the CBD NF process cannot remain on sale whilst the application is in process is a problem and encourages the illicit sale of these products outside the regulated process, particularly as enforcement is practically nil.

The CBD NF process has been cumbersome far too lengthy. Nor is it suited to new entrants, as they cannot have products on sale during the approval process.

The industry plea is that a sensible `operable' safe level for THC as a food contaminant be set - using international standards considered `safe for consumption' which lie somewhere between 0.4% and 0.8% to be reviewed yearly, and so permit the UK CBD industry to thrive, whilst discouraging grey imports and offering consumers product choice and more importantly safe consumption of CBD as a food ingredient.

Currently the FSA are using a `1mg in a closed container' determinant for THC in a food ingredient, which is a measurement unit not suited to a food ingredient or daily intake.



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### The UK CBD Industry recommends the following measures:

- 1. Accept a THC or controlled drugs contaminant level in CBD foods and ingredients at accepted international levels of between 0.4% and 0.8% in foods, supported by further product safety trials, rigorous testing and quality assurance protocols (such as HACCP Hazard Analysis and Critical Control) as part of the FSA Novel Foods Approvals process. This will permit the sector to grow and enable the FSA NF process to continue to food product Approval stage.
- 2. Engage with industry stakeholders and relevant regulatory authorities to ensure the adoption of this standard, including the Food Standards Agency (FSA), Department for Business, Energy, and Industrial Strategy (BEIS), Department for Health and Social Care (DHSC), and Department for Environment Food and Rural Affairs (DEFRA).
- 3. Encourage further research on the safety and efficacy of CBD products, including potential interactions with THC, other cannabinoids, and other food ingredients, handling, storage, and packaging materials.
- 4. The FSA is sitting on the UKs largest library of proprietary data and toxicology data relating to CBD and cannabinoid derivative products which the EFSA and FDA do not have. There are over 20 independent full toxicology reports available to the FSA as part of the Novel Foods process primarily related to CBD. This gives the UK government scientific committees an international advantage in being able to review this data and set safe `contaminant levels for controlled drugs in foods.'
- 5. The Toxicology committee of the FSA, ACMD and other regulatory and scientific parties should be able to have full access to review this data and create a method for data sets to be reviewed and commercialised in a compliant way.

We believe that adopting an operable `contamination level for THC' in CBD Food products and in foods and ingredients to include whole plant foods, will strike a balance between ensuring consumer safety support the growth of the UK CBD industry. This regulatory approach is supported by evidence (not available to the ACMD in 2020) and international standards and will contribute to a more consistent and harmonised global market for CBD products.

# **Background to HTA and CTA:**

I am Marika Graham-Woods, the Executive Director for the Hemp Trades Association (HTA) and Cannabis Trades Association (CTA) based in the UK. Our members companies are involved in Industrial Hemp, CBD ingestibles, supplements, cosmetics, and general wellness products, and Medicinal Cannabis companies operating legally under UK Regulations, or who are coming into regulatory compliance with our help.





The CTA has just around 200 members based in the UK, or trading into the UK, who are involved the manufacturing, distribution, or sale, of safe regulated hemp and cannabis products to consumers, and for medicinal cannabis to patients. Over 150 of our members are involved in CBD products sold to consumers. We encourage membership from outside the UK, including from Commonwealth members wishing to sell compliant products to UK consumers and patients.

# **Background to CBD:**

CBD (cannabidiol) is a non-psychotropic wellness product which cannot make a person `high'. The active molecule which makes a person `high' is THC (Tetrahydrocannabinol). CBD full spectrum whole plant products (preferred by UK consumers) are extracted from low THC-bearing whole plant hemp. It is impossible to strip THC out completely from CBD as it is a naturally occurring substance, however levels are so low that they are referred to as a `contaminant' in food ingredients, with no discernible psychotropic effect.

A recent You Gov Poll indicates that over 18 million Britons have consumed CBD products over the last year. CBD ingestible oils and products are regulated as a foodstuff under Food Law as part of the Food Standard Agency (FSA) Novel Foods Process begun in 2020 for consumer CBD products.

Medicinal Cannabis is derived from Cannabis Plants and is a highly stripped-down ultra-processed isolated product which usually contains high levels of THC (the psychoactive ingredient) required to treat serious health conditions. Medicinal Cannabis and rigorously regulated from seed, growing conditions to final medicine by the Home Office and MHRA (Medicines and Healthcare Products Regulation Agency) and requires full double-blind human trials befitting a medicinal drug.

Ultra processed Isolated CBD is stripped back to remove all but traces of THC and has the advantage of making it easy to add and combine with other molecules for medicinal purposes. Ultra processed isolated CBD forms the basis of the results and recommendations in the 2021 ACMD report, leaving out full whole plant full spectrum CBD derived from hemp, with its non-psychoactive levels of naturally occurring THC.

#### The Problem Today for UK CBD industry:

Currently the UK Government has not set a `safe limit' for THC as a `contaminant' in foods.

This is hampering the whole of the UK CBD industry, which is regulated by the Foods Standards Agency, as CBD foods, supplements and as a food ingredient is considered a food ingredient safe for ingestion by consumers.

The effect of the Home Office adopting the 2021 ACMD Report Recommendations for CBD as a food ingredient based on ultra-processed isolated CBD, would be to close down over 50% of the regulated UK CBD food sector, listed on the Food Standards Agency Novel Foods Public List, overnight!



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The 2021 ACMD recommendations if adopted by the Home Office would render the UK Consumer CBD Industry completely uncompetitive and would have the effect of immediately closing down up to 60% of the UK Consumer CBD industry with immediate effect. The CBD sector is estimated to be worth around £2 Billion by 2027, representing ca £400 Million in Tax revenues, and 25,000 jobs associated with the sector. (See APPG for CBD Products Report 2022 `A Plan for a Legal and Regulated UK Hemp and Cannabis Sector').

In the meantime, the length of time the FSA Novel food process, started in 2020, has had the effect of causing companies to continue to collapse. To date not a single UK CBD Product has been `Approved' as a foodstuff or food additive in over 3 years by the FSA due to inaction in setting a safe THC level as a contaminant in foods.

UK-based CBD Companies are finding it impossible to get inward investment, or be attractive to takeover bids, and often find their Bank Accounts frozen or closed due the over-emphasised Risk profiling of Banks caused by the vacuum of the Government over setting an sensible level for THC in finished consumer CBD food product.

UK companies are moving their businesses out of the UK due to the poor regulatory environment for CBD products. The international migration started in 2021 and is accelerating. Tenacious Labs (Secretariat to this APPG) have moved their main company to Jersey as an example.

Over 50% of smaller CBD Companies and Retailers have failed since 2018, and this encouraged dumping of low quality, cheap ultra-processed isolated CBD into the UK market, with absolutely no consumer protection, and little consumer choice whilst damaging the existing legitimate CBD market including whole plant products.

Research at Companies House on organisations with `CBD, Hemp, Cannabis or Canna' in their company names show there has been a 66% decline in active UK companies listed at Companies House since 2020, when the FSA Novel Foods Process began. Government inertia has opened up the sector to illegal operators who care only for quick profit, and not one iota for Consumer Safety.

Acceptance of the ACMD 2021 recommendations would have the effect of reducing this by over 50% more, effectively **closing the CBD food sector** and forcing businesses to supply products outside regulated pathways (illegally) or from production sites in foreign countries, probably online, not benefitting the UK, jobs, taxes or industry, or safeguarding UK consumers.

# Failings of the 2021 ACMD Report:

The ACMD 2021 Report has major failings in relation to CBD as a food ingredient regulated by the FSA.

It is based on reporting on ultra-processed CBD using toxicology data supplied for a medicinal drug, not a food and does not include whole plant full plant full-spectrum CBD, and so the recommendations are not comparable or reflect the CBD Food sector as a whole.



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The 2021 ACMD recommendations are based on the LOWEST possible effect when the Home Office requirement on the ACMD was to find the MAXIMUM safe level of THC for human consumption. This has set the bar extremely low. In fact, if the ACMD Report were adopted the UK would be one the strictest in the World in regard to `safe THC levels' and strangle all possibility of sector growth.

Another clear failing in the 2021 ACMD Report is the Risk Factor of 20, compared to a Risk factors of 5 applied to alcohol, and 4.5 applied to Opiates!

This cannot be a sensible measure of Risk given the World has an epidemic of Opiate Abuse and CBD as foods and `Wellness' products have no discernible psychoactive effects from the naturally occurring low levels of THC they contain.

The Advisory Council on the Misuse of Drugs (ACMD) conducted a comprehensive review in 2016 and further reiterated their findings in 2021, where they <u>explicitly state</u> that the risks associated with THC consumption are lower than those posed by alcohol and tobacco use. Moreover, CBD products are increasingly used for therapeutic purposes and contribute significantly to the overall well-being of many UK citizens.

Since the ACMD 2021 Report was published, the scientific community and academic studies have moved on, with studies on the effect of CBD and THC in animals and humans. The FSA though the Novel Foods process is sitting on an incredible toxicology data sets relating to CBD which should be reviewed by government scientific committees.

The current UK CBD market has demonstrated significant value, contributing substantially to the national economy, and providing a broad range of potential benefits for consumers. It is important to recognise this growth and support the industry with <u>evidence-based</u> regulations that encourage safe and responsible product development, while protecting consumers and providing them with access to a range of effective CBD products.

#### **Evidence-Based Recommendations having reviewed pivotal reports:**

- 1. "The classification of cannabis under the Misuse of Drugs Act 1971" (Advisory Council for the Misuse of Drugs, March 2002) provided initial groundwork for understanding cannabis and its classification.
- 2. "ACMD Report Phytocannabinoids" (27 April 2016) underscores that, in clause 2.9: 5mg of THC is equivalent to one standard unit of alcohol. A standard unit of alcohol is 8mg, suggesting that THC up to such levels does not impair driving any more than the legal alcohol limit for drivers in the UK.
- 3. "Drug Licensing Factsheet- Cannabis, CBD and other cannabinoids" provides comprehensive details on cannabis licensing, reflecting our evolving understanding.
- 4. World Health Organisation's document from the 41st ECDD meeting (24 January 2019) emphasised the re-evaluation of cannabis and related substances, whilst considering new scientific findings and wider societal implications.



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### **Recommendation reasoning:**

- 1. Establish a safe THC contaminant level in CBD foods, food supplements and food ingredients based on a review of the existing unique toxicology data held by the FSA as part of the Novel Foods process. In setting a THC contaminant level in CBD foods and ingredients at accepted international levels of between 0.4% and 0.8% in foods will ensure the UK CBD food sector can grow and be internationally competitive. This level should be reviewed annually, supported further data sets as they become available, government scientific committee analysis and further rigorous trials, testing and quality assurance protocols.
- 2. Engage with industry stakeholders and relevant regulatory authorities to ensure the adoption of this standard, including the Food Standards Agency (FSA), Department for Business, Energy, and Industrial Strategy (BEIS), Department for Health and Social Care (DHSC), and Department for Environment Food and Rural Affairs (DEFRA).
- 3. Encourage further research on the safety and efficacy of CBD products, including potential interactions with CBD & THC and other food additives and review THC levels based on new data and scientific findings regularly (annually).
- 4. Adopting an acceptable level for THC for finished CBD food towards the upper acceptable European Level strikes a balance between ensuring consumer safety whilst supporting the growth of the UK CBD industry and allowing the FSA Novel Foods process to continue to product Approval stage.
- 5. Setting a sensible level of THC in foodstuffs will overnight completely de-risk the CBD sector allowing for investment, product innovation and sector growth whist removing serious banking and insurance issues that have dogged the sector to date due to perceived corporate risk associated with the Proceeds of Crime Act.

A sensible regulatory approach regarding safe consumed levels of THC as a contaminant in foods, supported by evidence and international standards, will contribute to a more consistent and harmonised global market for CBD products.

# The Argument for Revising THC Limits upwards:

# 1. International Alignment:

A standardised UK THC level in foods, aligning closer to the European upper limit, would streamline customs processes and reinforce trade synergies.

#### 2. **Economic Value:**

The CBD industry has witnessed a remarkable surge. As per APPG CBD Report 2022, the UK CBD market is currently estimated to be worth around £2 Billion by 2027, representing ca £400 Million in Tax revenues, and 25,000 jobs associated with the sector. This burgeoning industry warrants regulations that support sustainable growth without



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compromising public health. See APPG for CBD Products Report 2022 `A Plan for a Legal and Regulated UK Hemp and Cannabis Sector'.

#### 3. **Safety Profile:**

Both the WHO and ACMD have consistently noted that the safety profile of cannabis (with high levels of THC), especially when compared to substances like alcohol and tobacco, is relatively benign. It is therefore reasonable to suggest that UK regulatory frameworks for CBD reflect this understanding and are proportionate to the actual risks presented to consumers.

# **Conclusion and Appeal:**

The CTA urges the UK Parliament to heed the findings and recommendations of esteemed bodies like the WHO and the ACMD, aligning our nation's policies with updated evidence and international standards.

A balanced, informed approach about evidence based internationally acceptable levels of THC as a contaminant in foods, food supplements and food ingredients will not only safeguard public health and safety, and consumer choice, but also foster economic growth in the vibrant CBD sector.

Setting an internationally accepted evidence-based contaminant level for THC in foods will help to de-risk the CBD sector to banking, insurance and inward investment and create growth, tax revenues, jobs and export opportunities for the industry.

We remain open for dialogue and further discussion on this crucial matter. Kindly feel free to reach out to me directly at m.woods@cannabistrades.org

Stakeholders in the CBD Industry would appreciate the opportunity to discuss these recommendations with you further. Please feel free to arrange a meeting or for any additional information with the CTA and our industry colleagues.

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Hemp Trades Association and Cannabis Trades Association

