

Article 4 Submission: Novel Food Status of Whole-Plant CBD Extracts



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1. Scope of Response

This submission concerns **whole-plant hemp extracts** (full-spectrum and broad-spectrum) containing up to **10% CBD**, produced through **traditional processes** (cold press, expression, tincturing, ethanol extraction, evaporation).

It does **not** defend isolated cannabinoids or highly selective extracts.

It should also be noted that historically the term '*hemp oil*' was used to describe oils derived from the aerial parts of the plant, including flowering tops, through pressing or tincturing. What is now described as '*whole-plant CBD oil*' is in fact the same product line, long recognised under the name '*hemp oil*', and cannot reasonably be redefined as novel

2. The FSA's Own Article 4 (FOI 00026)

In its Article 4 response to Marry Jane GmbH [1], the FSA concluded CBD isolate in MCT oil was **novel** because:

- No evidence of consumption of **CBD isolate** prior to 1997 was provided.
- Isolate exposure differs substantially from that in hemp oils.

However, in the same document, the FSA acknowledged:

- **Cold-pressed hemp oil has a history of consumption.**
- **Ethanol extraction was used pre-1997 and is not a novel process.**

This distinction is crucial: if cold-pressed and ethanol-extracted oils were already accepted as traditional, then whole-plant hemp extracts made with those processes cannot be classed as novel.

3. EIHA FOI Evidence (FOI 2413 & FOI 2545)

Industry evidence submitted to the FSA and EFSA, disclosed through multiple FOIs, demonstrates both historical use of hemp flower in foods and formal recognition of hemp extract beverages prior to the 15 May 1997 cut-off.

- **FOI 2413 Annex C (2019) [2]:**

Recorded discussions between the FSA and the European Commission acknowledged that

hemp flowers had been used in teas, brewing, and lemonade flavouring prior to 1997. This confirms that hemp flower was directly used in food and drink, not only hemp seed or oil.

- **FOI 2545 Annex C (2019) [3]:**

Contained evidence of **certificates of marketability** for hemp soft drinks, issued in 1997 by the German authorities and endorsed by the UK Home Office. This establishes that hemp extract beverages were lawfully traded across EU borders **immediately prior to the regulatory cut-off date.**

Together, FOI 2413 and FOI 2545 demonstrate:

1. **Pre-1997 consumption of hemp flower in foods and beverages.**
2. **Official recognition and authorisation of hemp extract beverages on the market in 1997.**

This twin body of evidence shows without ambiguity that hemp flower and whole-plant derivatives were part of the human food chain prior to 1997, meeting the first limb of the Monk Fruit/Davitas test.

4. Legal Principles

- **Monk Fruit case (Davitas, C-448/14) two-limb test, clarified further by C-383/07 (M-K Europa) [4]:**
 - Limb 1: Consumption pre-1997 — **satisfied** (see above evidence).
 - Limb 2: Falls into a novel food category — **not applicable** to whole-plant hemp, since processes are traditional and no molecular novelty is introduced.
- **Recital 19, Reg. 2015/2283 [5]:**
 - Explicitly states that Food Business Operators' (FBOs) evidence of first marketing should be relied upon. Such evidence was provided but not properly considered. [2] [3]
- **Medicinal and holistic evidence both count.** Case law makes clear that medicinal use can be relied on as proof of consumption when assessing food history.

5. The Cold Press Misdefinition

The FSA has attempted to restrict “cold press” to seed-only oils [6]. This is inaccurate:

- Historical pharmacopoeia and industry catalogues demonstrate pressing and tincturing of **flowers and leaves.**
- To exclude flowers from “cold press” is a retrospective redefinition that conflicts with both evidence and historic consumption.

Restricting ‘cold press’ to seed alone ignores historical references to expression and tincturing of flowers and leaves, as documented in pharmacopoeia and industry catalogues.

6. MDR vs. General Food Law

- **Isolates and selective extracts:** These should appropriately fall under the Misuse of Drugs Regulations (MDR) 2001. Once cannabinoids are isolated or concentrated to purity, there is a genuine risk of encountering or extracting controlled cannabinoids in isolation. This is a legitimate concern of **drug law**, not food law.
- **Whole-plant hemp extracts:**
 - Hemp derivatives containing up to **0.2% THC** are recognised in EU and UK law as **hemp, not narcotic**.
 - Under *Kanavape* (C-663/18), products derived from hemp grown lawfully cannot be considered narcotics. [7]
 - **General Food Law (Reg. 178/2002)** requires food authorities to define safe levels where compounds are present in food. Hemp extracts at $\leq 0.2\%$ THC fall within this remit. [8]
- **Therefore:** MDR applies only where cannabinoids are deliberately isolated or selectively enriched beyond natural ratios. For whole-plant hemp derivatives ($\leq 0.2\%$ THC), food law governs — not MDR.

7. Proportionality & the 50 µg THC Limit

The FSA's imposition of a **50 µg per-serving THC limit** is not grounded in food law. [9]

- Food law requires evidence-based safety thresholds, not arbitrary importation of drug-law rules.
- Cannabinoids in whole-plant products are intrinsic constituents, not contaminants, unlike in isolates or selective extracts, and their presence cannot be regulated as contaminants without contradicting General Food Law. .
- MDR already governs controlled cannabinoids in isolation. Applying drug-law thresholds to lawful hemp foods is **ultra vires**.

The ACNFP/COT (2025) position establishes 1 µg/kg bw/day as the safe upper limit for THC. This evidence-based benchmark supersedes the FSA's arbitrary 50 µg/serving limit, which is not grounded in food law

8. Conclusion

On the basis of:

- The FSA's own acknowledgement of traditional processes;
- Historical and modern industry evidence (EIHA, FOI 2545);
- Established case law (Monk Fruit, Davitas, Kanavape);
- The clear division between isolates (MDR) and whole-plant derivatives (General Food Law);

There is **no shadow of a doubt** that hemp flower and whole-plant derivatives up to **0.2% THC** should be defined as **not novel foods**.

9. Annex: Evidence of Historical Consumption of Hemp Extracts

Product / Preparation	Process	Date / Period	Evidence	Notes
Cold-pressed hemp oil	Expression (cold press)	Pre-1997 (acknowledged)	FOI 00026: FSA accepts cold-pressed hemp oil as traditional [1]	Historic consumption of hemp oil; not to be confused with hempseed oil
Ethanol tinctures / fluid extracts	Alcohol extraction	19th c. pharmacopeias; pre-1900	British Pharmacopeia; Parke-Davis catalogue (1902) [10] FOI 2545 Email 5 [3]	Standardised strengths; widely marketed.
Solid, powdered & resinous extracts	Evaporation of tinctures	19th–20th c.	Parke-Davis catalogue (Barcelona, 1902) [10]	“Pure extract” = uncompounded cannabis extract, not isolate
Compressed hemp tops	Mechanical compression	1902 (Parke-Davis)	Riboulet-Zemouli 2024 citing archival catalogue [10]	Retail packs of raw flower sold alongside extracts
Hemp bread	Home cooking	From 552 AD	Cultural documents and recipes [11] FOI 2413 Annex C [2]	Svaneti cuisine; hemp flower central to traditional diet
Chocolate-coated tablets / pills	Solid oral dosage forms	Early 1900s	Parke-Davis catalogue [10]	Palatability preparations; edible form of hemp extract
Extract in cocoa butter	Lipid carrier	Late 19th–early 20th c.	Dausse laboratories; Riboulet-Zemouli 2024 [10]	Precedent for modern CBD in lipid carriers
Hemp teas, brewing, lemonade flavouring	Infusion & flavouring	Pre-1997	FOI 2413 Annex C (EU/FSA discussions) [2]	Confirms flower used in beverages pre-1997
Hemp soft drink (Germany/UK)	Hemp extract beverage	Certificates dated 1997	FOI 2545 Email 5 [3]	Marketed and certified by Home Office & German authorities

10. Additional Information

10.1: On 7 January 2019, Love Purple People Ltd received an enforcement letter from Islington Trading Standards (Ref: RJ/NR).

The ruling stated that **CBD was novel**, but that **hemp oil was legal**.

You asked whether [redacted] could cold press *Canabis sativa* L and sell it. This would be Hemp Oil, which is legal. However, it would not be CBD which is an extract, as set out above. An extract may result in a higher level of CBD than the source especially if, for example, it has been added to hemp oil.

Points to note:

- The letter makes no mention of seed oil. The response is unambiguous: hemp oil, in general, was accepted as legal.
- A recurring misconception surfaces — likely influenced by the FSA — suggesting that **cold pressing is not an extraction method**. This contradicts historical definitions and pharmacopoeia practice.
- The letter further states: *“In the UK, the plant can only be cultivated under licence but we need to distinguish between the plant and extracts of the plant. *** ***** is selling extracts of the plant.”* This shows a regulatory contradiction: **raw hemp is treated as a drug, whereas extracts of that ‘drug’ are accepted as food**.
- The full response indicates that the EU Novel Foods Catalogue had already been internally updated to show CBD as novel **11 days before the public EU announcement on 18 January 2019**.

CBD is listed in the EU Novel Food Catalogue under this description *“Extracts of *Canabis Sativa* L in which cannabidiol (CBD) levels are higher than the CBD levels in the source *Canabis sativa* L are novel in food. CBD is one of the cannabinoids in *Cannabis sativa* plant. In the EU, the cultivation of the *Canabis sativa* L varieties is granted provided they are registered in the EU’s Common Catalogue of Varieties of Agricultural Plant Species and the tetrahydrocannabinol (THC) content does not exceed 0.2 % of the plant.”* In fact, in the UK, the plant can only be cultivated under licence but

- CBD is explicitly recognised as *“one of the cannabinoids in Cannabis.”*
- Whilst 0.2% THC is mentioned in regards to hemp, there is no mention of the Misuse of drugs Regulations 2001 or the 1mg rule.

Conclusion

Taken together, the enforcement letter and accompanying notes demonstrate that UK regulators themselves have, at times, recognised **hemp oil as legal** without restricting the definition to seed alone. At the same time, they acknowledged CBD as a constituent cannabinoid of cannabis while attempting to reframe its status in the EU Novel Foods Catalogue ahead of formal announcements. This evidence further supports the position that *whole-plant hemp oils are not novel foods*, and that subsequent efforts to redefine them as such are inconsistent and retrospective.

10.2 Body and Mind Bothanicals (BMB)

In 2022 to 2023 a key worker for BMB submitted questions to the FSA regarding the legitimacy of whole-plant products.

Dear [REDACTED]
Your query to our application service was:
"Hi, we are making cold pressed hemp oil from hempseed and hemp tea. We are not separating any compounds from the plant or using any solvents.. I believe this would not be novel and would just like clarification."
Hemp and related products, such as cold-pressed oils, are not novel because there is evidence to show a history of consumption before May 1997. Providing that you are not extracting or isolating from the plant then the cold press as you have confirmed would not be novel.
We have closed this application in our application service.
Kind regards,
Regulated product approvals team
Regulated Products Approvals
Food Standards Agency
The content of this message is graded as OFFICIAL unless otherwise specified above or within attached documents

Dear [REDACTED]
Thank you for submitting your application to the Regulated Products Application Service.
After consideration we do not believe your application requires the Article 4 process, however we can answer your query.
The use of Hemp does have a history of consumption and is not considered to be novel. We assume that the plant is dried, milled and made into a tea/infusion. If this is the case then it would not be considered to be a novel food and therefore does not require authorisation. You must however be aware that, like all foods sold in the UK, such products should comply with General Food Law, not be injurious to human health and must have the necessary import documentation/authorisation.
It should also be clearly labelled and inform consumers as to the exact nature of the food.
We hope this helps with your enquiry.
Best wishes,
Regulated products approvals team
Regulated Products Approvals
Food Standards Agency

Points to note:

- It's clearly stated that "Hemp and related products, such as cold-pressed oils, are not novel."
- A clear distinction is made between the isolation of active compounds vs. the use of the whole-plant.
- It further shows that an application [Article 4] was rejected because of the FSA pre-existing stance on the novel status of hemp and related products.
- It is further stated that the whole-plant, dried and milled, is not novel when used for tea and/or infusions.
- It's also stated that not novel foods are subject to General food Law, but, there is no mention of the Misuse of Drug Regulations 2001.

Conclusion

These communications reinforce that the FSA has, at least internally, accepted that cold-pressed hemp oils and whole-plant preparations do not fall under novel foods. By distinguishing isolates from whole-plant use, and by applying General Food Law rather than drug law, the FSA's own correspondence undermines its public position that all CBD-containing products are novel. This inconsistency highlights the retrospective and selective application of novel food regulation to hemp products.

10.3 FSA Article 4 submitted in October 2018

The following is an excerpt of the Article 4 submission from the FSA to the EU that started CBD Novel Foods

Reasons statement:

History of consumption

Hemp oil which contains CBD and is produced by cold pressing has a history of consumption. MCT also has a history of consumption. Ethanol extraction process was used in the EU prior to May 1997 and is not considered a novel process. The main issue is whether the CBD isolate has a history of consumption prior to May 1997. The applicant has not provided any evidence that its CBD isolate product was on the market in the EU prior to 15 May 1997.

The CBD in the final product is in a more concentrated form than that naturally occurring in hemp and is a purer substance. This will lead to greater exposure when consumed.

Consultations with other Member States carried out since 2015 have been unable to confirm a significant history of consumption of CBD extracts with a purity of <98%. Member States were consulted on Marry Jane GmbH Cannabidol hemp oil and agreed that it was novel but in some Member States it was classed as a medicine or as a narcotic drug in which case it was outside the scope of food law in these Member States.

This document was commissioned by Marry Jane, a company based in Switzerland, in 2015. [1]

In 2017 the FSA stated to the Cannabis Trades Association that CBD isolate was novel, but whole-plant products were not novel.

That intent is matched by that which you can see above.

Below is the refined version that was ultimately published by the EU in January 2019. [12]

Reasons statement:

History of consumption

The issue is whether the CBD isolate has a history of consumption prior to May 1997. The applicant has not provided any evidence that its CBD isolate product was on the market in the EU prior to 15 May 1997.

Consultations with other Member States carried out since 2015 have been unable to confirm a significant history of consumption of CBD extracts with a purity of >98%. Member States were consulted on [REDACTED] Cannabidol hemp oil and agreed that it was novel but in some Member States it was classed as a medicine or as a narcotic drug in which case it was outside the scope of food law in these Member States.

Conclusion

The FSA's draft Article 4 submission in October 2018 acknowledged that hemp oil produced by cold pressing had a history of consumption and was therefore non-novel. The question raised was specific to CBD isolate, not the legitimacy of whole-plant hemp oils.

By January 2019, the EU's refined version had expanded this position to state that all CBD extracts were novel. Rather than challenge this shift, the FSA accepted the new definition without public or industry consultation. The same pattern can be seen in their later acceptance of updated EU definitions for non-novel hemp products, again adopted without transparent consultation in the UK.

This demonstrates that the FSA was not merely following EU direction but was complicit in cementing a broader interpretation that retrospectively reclassified whole-plant hemp oils as novel. Such conduct is inconsistent with Recital 19 of Regulation 2015/2283, which requires food authority decisions to be based on evidence of prior consumption submitted by food business operators.

11. Annex Narrative Summary

The table on the previous page summarises clear and direct evidence of hemp extract consumption from the 6th century through to the late 20th century, encompassing both medicinal and food contexts.

A. Traditional Processes

Cold pressing, ethanol tincturing, and evaporation were recognised historical processes. The FSA itself (FOI 00026) acknowledged cold pressing and ethanol extraction as non-novel.

B. Whole Plant vs. Isolates

Historical catalogues show 'pure extracts' meant uncompounded whole-plant cannabis extract, not isolated cannabinoids. These processes preserved natural ratios of phytocannabinoids.

C. Cultural Continuity

Evidence spans formal pharmaceutical catalogues (Parke-Davis, Dausse) and cultural practices such as Svaneti hemp bread. Teas, brewing (including beer), and cocoa butter extracts show overlap between dietary and medicinal use.

D. Pre-1997 Authorisations

Certificates of marketability issued in 1997 for hemp soft drinks in Germany and the UK confirm that hemp extract beverages were lawfully traded immediately prior to the 15 May 1997 cut-off.

Conclusion

This combined evidence leaves no shadow of a doubt: hemp flower and whole-plant derivatives, prepared by traditional processes, were consumed long before 1997 and must be defined as not novel foods under Regulation 2015/2283.

12. Case Studies and Contradictions in Enforcement

Three cases — *Patel v R*, *R v Jersey Hemp*, and *Charlotte's Web* — illustrate the consequences of leaving hemp regulation to overlap between food law and drug law. When set against the FSA's shifting positions from 2020–2024, these cases demonstrate selective enforcement, regulatory capture, and inconsistency amounting to unreasonableness.

1. *Patel v R* [2025] EWCA Crim 1149 [13]

- **Facts:** Patel imported CBD hemp products between August 2020 and January 2021. Several consignments were seized, testing “<1% THC.” Most seizures occurred pre-Brexit, overlapping with *Margiotta* [2023], which recognised hemp <0.2% THC as a lawful agricultural product under EU law. At arrest in January 2021, Patel had only ~70 g of material in his possession.
- **Outcome:** Patel pled guilty and received suspended sentences. On appeal, the Court of Appeal dismissed his reliance on *Margiotta*, ruling that EU law ceased to have direct effect after 31 December 2020. Crucially, no tests were ever carried out to establish whether the material was under 0.2% THC.
- **Significance:** Hemp was treated as “cannabis” by default, using a crude “<1%” testing standard that erased the EU definition of hemp. The decision shows how criminal law collapses nuance and disregards proportionality.

2. *Jersey Hemp* (Judicial Review, 2023) [14]

- **Facts:** Jersey Hemp's broad-spectrum products were accepted onto the FSA's novel foods list. Following Home Office intervention under MoDR, those products were forced off the market despite that acceptance.
- **Outcome:** A judicial review found that MoDR had been misapplied. Jersey Hemp was compensated for its losses.
- **Significance:** Even FSA-approved products were vulnerable to Home Office override, showing that food law was subordinated to drug law.

3. *Charlotte's Web* (Withdrawal, 2023) [15]

- **Facts:** Charlotte's Web's products, some containing up to 0.2% THC, were authorised by the FSA in 2022 under a novel foods application. After the Jersey Hemp case, those products were voluntarily withdrawn from the public list in November 2023. Evidence suggests Home Office engagement influenced this decision, though it was not formally disclosed.
- **Significance:** The FSA authorised products that arguably breached MoDR, then avoided enforcement when the issue became politically sensitive. This reflects selective enforcement and inconsistent application of guidance.

4. The FSA's Changing Positions

2020 Statement:

The FSA published guidance in 2020 clarifying that the “1 mg rule” did not apply to foods intended for consumption.

This recognition has led to the frequently cited “1 mg rule,” which stipulates that controlled substances such as THC must not exceed 1 mg in any given product. While this rule is often associated with the burgeoning CBD industry in the UK, it is pertinent to clarify that it doesn't apply to products intended for consumption (UK Food Standards Agency, 2020).

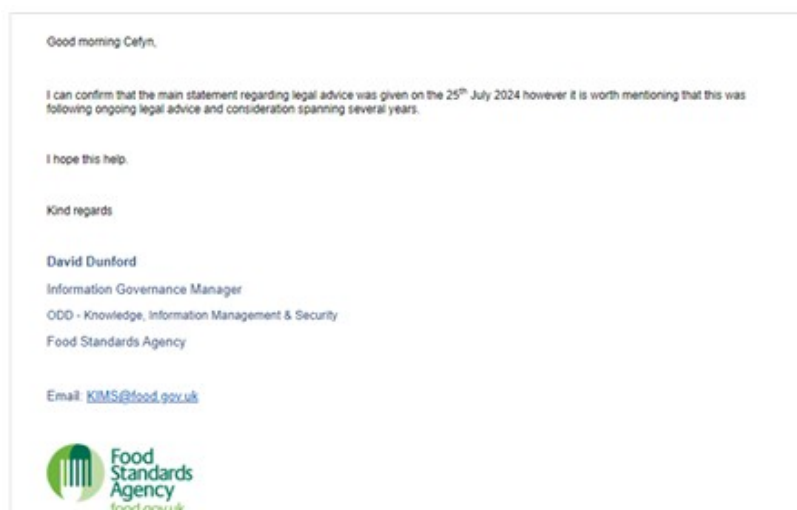
FOI Response:

When later asked under Freedom of Information whether this statement existed, the FSA did not confirm or deny. Instead, they stated the following:

“We have been unable to find this page on food.gov (or in the National Archive) with this url published between 2019 and 2020 and can find no reference to the text included. It would be unexpected for us to add a reference like that for our own work as this would be unnecessary and out of context. If you do have any further information relating to this page, we can consider this further.” [16]

2024 Dunford Confirmation:

In 2024, the FSA accepted legal opinion that the Home Office controls the interpretation of controlled cannabinoids in food. This was a direct reversal of its 2020 position, formalising a creeping reality that had already shaped Patel, Jersey Hemp, and Charlotte's Web.



5. Common Threads

1. **Selective Enforcement** – Patel’s products were tested only to “<1% THC,” ignoring the 0.2% threshold; Jersey Hemp was forced out despite FSA approval; Charlotte’s Web was authorised then quietly withdrawn.
2. **Home Office Override** – Each case shows the Home Office asserting primacy over hemp regulation, whether in courts, through MoDR, or via quiet market pressure.
3. **Regulatory Drift** – The FSA’s own positions shifted from distancing food law from the 1 mg rule (2020) to fully conceding Home Office ownership (2024), with FOI obfuscation in between.

6. Relevance to Article 4

This pattern demonstrates irrational and inconsistent decision-making. The FSA contradicted its own published guidance, failed to enforce MoDR consistently, and eventually ceded control of cannabinoids in food to the Home Office. This regulatory capture has left businesses subject to criminal sanction, market exclusion, and arbitrary enforcement.

Article 4 clarity is essential to restore independence to food law. Recognising whole-plant hemp and associated products as non-novel foods would provide certainty, prevent selective enforcement, and ensure they are judged under food law, not drug law.

13. Additional Information: Safety Evidence vs. FSA Position

A review of toxicology data associated with CBD Novel Food Applications [17] demonstrates that **whole-plant extracts present a safer toxicological profile than isolated or synthetic CBD**. The studies consistently highlight:

- **Higher NOAELs** (No Observed Adverse Effect Levels) for whole-plant extracts compared to isolates.
- **Better tolerance** in both short- and long-term animal studies when cannabinoids are present in their natural matrix.
- **Absence of mutagenic activity** in bacterial assays across multiple whole-plant preparations.

These findings support the long-standing understanding that cannabinoids function within a synergistic matrix, mitigating risks associated with isolated compounds.

By contrast, the FSA's response to that review [18] makes clear that their toxicological approach is guided by the **“simplest scientific case.”** In practice, this has meant:

- **Defaulting to single-molecule toxicology** (i.e. CBD isolate) as the reference standard.
- **Applying uncertainty factors derived from isolate studies** directly to all CBD-containing products, regardless of extraction method.
- **Overlooking the evidence that whole-plant extracts do not share the same adverse effect profile.**

This disconnect between evidence and regulatory practice highlights a fundamental flaw: the FSA's methodology is appropriate only if CBD is treated as a contaminant in food. It is **not appropriate** for assessing the safety of traditional whole-plant preparations, which have distinct compositional and toxicological characteristics.

Therefore, reliance on the “simplest case” undermines both consumer safety and regulatory proportionality, and ignores the established precedent that **hemp derivatives, when consumed in their traditional forms, are not novel foods**

14. FAQ's

Why 10% CBD?

CBD was discovered in 1940 [19]. An extract of wild hemp was used which produced 33% by weight after isolation. Whole-plant preparations up to 10% CBD are therefore within natural ranges consistent with historic practice.

What about controlled cannabinoids (including CBN)?

CBN was first identified in hemp in 1898 [20]. THC was discovered in 1964 in cannabis [21]. THC is already accepted in hemp ($\leq 0.2\%$) which has a history of consumption predating both the discovery of CBN and the creation of drug laws that mention cannabis and hemp.

It is reasonable to assume that hemp cultivated before the 1993 and 1997 definitions often exceeded these later thresholds, yet still formed part of the food chain without being considered narcotic

Is there evidence of continued use?

Yes. Pharmacopoeias, commercial catalogues (e.g., Parke-Davis), and cultural food records (e.g., Svaneti hemp bread, teas, beverages) confirm continuity of use across centuries and into the 20th century. [1][2][3][7][10][11]

Aren't extracts different from raw hemp?

Traditional processes such as cold pressing, tincturing, and evaporation were documented long before 1997 and are acknowledged by the FSA itself [1]. These are not novel technologies; they are consistent with historical food and pharmacopeial practices.

Furthermore, case law [4] shows that extracts created by those methods and that are unselective in nature are as legitimate a food as the source food used to create them.

Does medicinal use count as evidence for food use?

Yes. Case law [4] makes clear that medicinal and holistic evidence may be relied upon as proof of prior consumption when assessing food history. Hemp derivatives therefore satisfy the test.

15. Companies attached to this Article 4

The Hemp Hound Agency has been given the Authority to Act on behalf of the following companies:

Allworld Products

Big Chief Hemp

Bnatural

Brown's CBD

CBD Brothers

CBD One

CBD-UK

Crop England

Happy Hemper

Hempen Organic

Jersey Hemp

Naturally Pure Lab

Naturecan

Orange County

Ortis Wellbeing (Under Construction)

Project Forty8 (Under Construction)

Mr A. Sheppard (Company under consideration dependent on Article 4 outcome)

Confirmation of that Authority to Act has been attached to the application

The submission will be added to as several companies have expressed an interest and have given permission but are yet to sign an Authority to Act document.

16. Reference Index

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