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# Novel Food Regulations

Submissions on behalf of

**The Cannabis Trades Association**

Dated 8<sup>th</sup> March 2019

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# NOVEL FOOD REGULATIONS

## 1. Background

- 1.1. We are instructed by the Cannabis Trades Association UK (“CTA”) to represent them at the forthcoming European Food Safety Authority (“EFSA”) committee meeting at the European Commission in Brussels on 12<sup>th</sup> March 2019. We provide these written submissions in advance of the oral submissions we propose to make at the committee meeting.
- 1.2. The CTA was founded in October 2016 by seven business owners operating in the UK CBD wellness sector. At that time the Medicines and Healthcare Regulation Authority (“MHRA”) was considering oversight of the UK CBD industry. Following representations by the CTA, the MHRA agreed that CBD products were not medicines and therefore would not fall under their jurisdiction. This is also the position in every other Member State, except Belgium. The CTA remained in place and has become the largest hemp trade association in Europe.
- 1.3. At present the CTA has more than 700 full members. Over 90% of the membership is located in the UK. However, there is a proportion of members situated in EU27 countries. These are associate members sell their products into the UK.
- 1.4. The CTA continues to work with all sectors of the hemp and cannabis industry to promote good practice, provide practical advice and ensure consumers of legal cannabis and hemp products have access to top quality information. They have engaged consistently with the MHRA and the Food Standards Agency (“FSA”) and have been added as recognised Stakeholders to the official guidance given by both authorities. The CTA is committed to raising and maintaining standards in the industry to ensure that only safe and legal products are available to consumers.

## 2. The 'CBD' Industry

- 2.1. The CBD industry has grown substantially across Europe in the last few years. CBD products are marketed as nutritional supplements CBD is in fact hemp oil extract. Within the extract is cannabidiol, which is a naturally occurring cannabinoid from the hemp plant. Cannabidiol is commonly known as 'CBD'. Although referred to in modern marketing as CBD, these products are simply hemp oil extracts which contain CBD.
- 2.2. The products are made using *Cannabis Sativa L*, more commonly known as Hemp. This strain of the cannabis plant is a high-CBD, low-THC variety. THC is a psychoactive cannabinoid which is a controlled drug in the UK. It should be noted that all parts of the plant including seed contain CBD. Regulations across Europe allow for THC content of 0.2% or less. Therefore, Hemp extracts are produced to have THC levels below the permitted amount.
- 2.3. A recent report on "Extracts and tinctures of cannabis" from the WHO Expert Committee on Drug Dependence described the hemp products as follows:

"Hemp seeds possess an extremely high nutritional value due to a high content of unsaturated fatty acids (about 80% of fatty acids) and proteins (about 25%). It is not to be ruled out that other minor components, such as terpenes and cannabinoids, could contribute to the surprising beneficial effects of hemp seeds." – Page 21

"Hemp seed oils are widely sold for human food" – Page 24<sup>1</sup>

- 2.4. Hemp products are sought after by the public. The products are ingested either by way of a tincture or oil, or inhaled by way of a vaping device. There is no evidence that these products have caused harm.

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<sup>1</sup> <https://www.who.int/medicines/access/controlled-substances/Extracts-and-tinctures.pdf>

### 3. Novel Food Catalogue

- 3.1. The Novel Food Regulations ((EU) 2015/2283) (the “NFR”) requires that ‘novel’ foods obtain authorisation before being sold as a foodstuff within the EU. A Foodstuff can be considered ‘novel’ if it was not consumed by humans to any significant degree prior to May 1997.
- 3.2. The CJEU considered the position of novel foods under the predecessor to the NFR in Case C-383/07 M-K Europa GmbH & Co. KG v Stadt Regensburg, where it stated that:

“In order to decide whether that food product should be classified as a novel food... the competent national authority must proceed on a case-by-case basis, taking into account all the characteristics of the food product and of the production process.”

- 3.3. The NFR requires that novel foods be authorised at community level. It provides for an authorisation procedure and the keeping of a ‘union list’ of authorised novel foods, which is described by EFSA as the Novel Food Catalogue.

#### *Cannabis sativa L*

- 3.4. The entries on the novel food catalogue in relation to cannabis sativa L. previously stated (since 2007) that:

“Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, Regulation (EC) No 258/97 is not applicable to most foods and food ingredients from this plant. It is an annual herb, usually erect belonging to the Cannabaceae Family. Native to Central Asia and long cultivated in Asia, Europe and China. It’s a multiple-use plant, furnishing fiber, oil, medicine and narcotics. Fibers are best produced from male plants. Leaves are added to soups in southeast Asia. Most varieties contain cannabinal and cannabinin.” [bold emphasis added]

- 3.5. It followed that hemp extract (or CBD oil) was not generally considered to be a novel food because it was widely used before 1997 and neither the propagation or extraction methods are in any way new. It is simply the marketing of the product, as CBD oil, that had changed.

3.6. The entry under *Cannabis sativa L.*, now reads:

“In the European Union, the cultivation of *Cannabis sativa L.* varieties is permitted 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 % (w/w). Some products derived from the *Cannabis sativa* plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.”

3.7. It follows that products derived from cultivated cannabis sativa L, including hemp oil, are not considered novel foods because of a long-accepted history of usage within the EU and across the globe. It is submitted that CBD oil falls within this category because it is propagated and subjected to a traditional extraction process that results in a food that has an identical chemical profile to hemp seed oil that has been in use for generations.

#### *Cannabinoids*

3.8. The recent entry on the Novel Foods Catalogue for Cannabinoids reads:

“Without prejudice to the information provided in the novel food catalogue for the entry relating to *Cannabis sativa L.*, extracts of *Cannabis sativa L.* and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are considered as novel.”

3.9. The information accompanying this entry reads that *“this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.”*

3.10. This change was not the subject of any industry or sectoral consultation. It has caused considerable confusion across the EU about which hemp extract products are to be considered novel foods and therefore require authorisation. The new entry is confusing because most traditional hemp seed oils contain cannabinoids. There can be more than 100 cannabinoids in products extracted from cannabis. Cannabidiol is one such cannabinoid. It is present in CBD oil, but was also present in hemp oil.

3.11. It is accepted that the novel foods catalogue is not binding and is only 'advisory'. However, it is being treated by national regulators as a binding statement of the legal position. For example, in the UK the Food Standards Agency recently tweeted on 30<sup>th</sup> January 2019:

"There has been a recent change to the EU Novel Food Catalogue which affects some cannabidiol (CBD) products. Food businesses have not been able to show there was a significant history of consumption of these products in food and food supplements prior to May 1997 in the EU."

3.12. This approach of national regulators completely fails to take into account (a) that the catalogue is not designed to be a binding statement of law and (b) regulators ought to adopt a case by case assessment for each product. This is particularly important with CBD oil, which is typically extracted methods that fall out of the scope of novel food regulations.

## 4. Main submissions

4.1. There are three primary submissions that the CTA makes in relation to the sale of CBD products:

- (a) There is a long history hemp extract oils containing CBD being consumed in the EU before 1997.
- (b) Where the active cannabidiol component has not been specifically isolated, CBD oil is essentially hemp extract oil. It is propagated in the same way that hemp oil has been for decades and subjected to non-novel extraction process
- (c) In any event, CBD products are *“isolated from or produced from”* hemp plants that have been propagated using *traditional propagation methods* for the purposes of article 3(2)(a)(iv) of the NFR.

## 5. History of hemp extract oil consumption in the EU

5.1. Article 3(2)(a) of the NFR defines novel food to mean *“any food that was not used for human consumption to a significant degree within the Union before 15 May 1997”*. The current entry for Cannabis sativa L on the novel food catalogue accepts that hemp extract products have long been consumed in the EU.

*“Some products derived from the Cannabis sativa plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel.”*

5.2. There is a long history of hemp extract consumption by humans in the EU prior to 1997. The UK FSA’s position has been made clear in correspondence sent to businesses in the UK. One such email received from the FSA by a CTA member states:

*“From a novel foods perspective, the UK is aware that a significant history of consumption exists for industrial hemp strains of Cannabis sativa L (Hemp, marijuana) as foodstuffs and food ingredient (plants, beans and oils with no content - or low- of cannabinoil and cannabinin) in the EU, prior to 15 May 1997, and therefore it does not fall within the scope of the novel foods regulation.”<sup>2</sup>*

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<sup>2</sup> Email from FSA Novel Food department to CTA member dated 17<sup>th</sup> September 2018

## 6. CBD Oil is essentially hemp extract oil.

- 6.1. CBD oil is made from a strain of the *Cannabis sativa* L plant with very low levels of Tetrahydrocannabinol ('THC'). It is propagated using the same methods that hemp has been propagated for many decades. Once the hemp plant has been cultivated, the extraction process typically involves parts of the plant being steeped in ethanol or pressurised carbon dioxide. This traditional process normally extracts many of the active cannabinoids in the plant and results in the production of an oil that is effectively the same as hemp oil. Extraction solvents are expressly excluded from the scope of the NFR.<sup>3</sup>
- 6.2. **A video presentation showing the extraction process for hemp oil will be shown during the course of oral submissions.** It should be noted, however, that EU food law considers that "*distillation/rectification*" and "*Extraction. Incl. solvent extraction in accordance with Directive 88/344/EEC*" to be "*traditional food preparation processes*".<sup>4</sup>
- 6.3. Importantly, this traditional extraction process does not result in the *isolation* of the active component, cannabidiol. It is possible to isolate the cannabidiol from the other cannabinoids in a hemp extract using different processes, such as partition chromatography. However, many CBD products do not isolate cannabidiol and will contain many different cannabinoids, as does hemp extract oil.

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<sup>3</sup> Falling within Directive 2009/32/EC (see Recital 5 of the NFR).

<sup>4</sup> See articles 3(2)(d)(i), 4 8 and Annex II of Regulation (EC) 1334/2008 on flavourings etc

## 7. Propagation methods

7.1. It is important to understand that the definition of novel food *additionally* requires that the food falls within one of the categories set out in article 3(2)(a)(i) to (x).<sup>5</sup> The most relevant category in relation for CBD oils is article 3(2)(a)(iv) which states:

“(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

- traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
- non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances”

7.2. The Novel Foods Catalogue accepts that hemp (*Cannabis sativa* L) has been propagated and safely consumed within the EU before 1997. The hemp plant that is used to make CBD oil is *propagated* using “*traditional propagating practices*”. Those *propagation* practices have not materially changed from those used in the production of hemp extract oils over decades. It follows that where CBD products have been “*isolated from or produced from*” hemp plants propagated using traditional practices, they are not novel foods under the NFR.

7.3. This reflects recital 17 of the NFR which states:

“Food produced exclusively from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food or their amount, should not be considered to be a novel food. However, modifications to a food ingredient that has not yet been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation.”

CBD products are produced “*exclusively*” from *Cannabis sativa* L, which does not “*fall within the scope*” of the NFR because, it is accepted, that it was used “*for human consumption to a significant degree within the Union*”.

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<sup>5</sup> See para 21 of Case C-448/14, *Davitas GmbH v Stadt Aschaffenburg and Landesanstalt für Lebensmittelsicherheit Bayern*.

- 7.4. It should also be pointed out that even if hemp was produced by *“non-traditional propagating practices”* a hemp extract would only become a novel food if those practices caused *“significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances”*.

## 8. Conclusion

- 8.1. It is submitted that the novel foods catalogue ought to be amended by the removal of the entry in relation to cannabinoids and the reinstatement of the previous entry in relation to Cannabis Sativa L set out at paragraph 3.4 above.

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