

FAO: Paul Tossell

Team leader, Radiological, GM, Novel Foods and Feed Additives
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By email & post

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Date 26 March 2019

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Without prejudice

Dear Sirs

CBD Products

We have been instructed to represent Cannabis Professionals' (**CannaPro's**) interests, in respect of your correspondence with Mr Peter Reynolds of CannaPro on the Food Standards Agency's (**FSA**) classification of Cannabidiol (**CBD**) products as "Novel Foods".

CannaPro have a number of members who are certified by them to supply CBD products and as such they have requested that we write to you on behalf of all members of CannaPro.

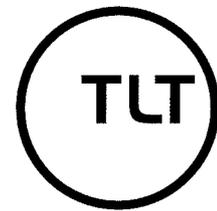
In light of the approach that you have taken in classifying all of CannaPro's certified businesses' products as novel foods, we consider our client has grounds to challenge the decision, and should any associated loss be suffered as a result of this misclassification, to make a claim for compensation under Article 1 of the First Protocol of The Human Rights Act 1998 (**the Act**).

In addition to this, we are advising our client of their position in relation to potential judicial review proceedings in connection with the decision you have taken.

In view of this, we write to draw to your attention the detrimental effects of your actions to date, and we invite you to declassify CBD products as novel foods, and revert to their previous classification as a food supplement.

1 Current position

- 1.1 Your website's current guidance states that food businesses have not been able to show that there was a significant history of consumption of CBD products in food and food supplements prior to May 1997 in the European Union (**EU**), and consequently the EU Novel Food Catalogue has been changed to include CBD Products as a novel food.



- 1.2 Our client has communicated with you previously on this point, most recently being your email of 22 February 2019. Despite the wording on the FSA website outlining that no evidence has been provided, and a decision has been made, your email outlines that you are anticipating evidence being provided by our client in relation to the history of CBD consumption. Please also refer to paragraphs 5.1 and 5.6 for further confirmation that evidence has previously been provided.
- 1.3 You outline that the FSA are considering how to move forward, by meeting with relevant industry representative bodies, local authorities and other stakeholders in order to determine how to achieve compliance in the marketplace.
- 1.4 Our client has made it clear to the FSA, during various email exchanges, that many businesses within the industry are still unclear as to how to proceed, and as a result are incurring significant costs in contingency planning. Arguably, contrary to your statement as outlined at 1.3, there are many stakeholders that the FSA has not considered nor kept informed during this process. The first many knew of the changes was when The Daily Mail newspaper published an article reporting on the classification.

2 Your classification of CBD Products as Novel Foods

- 2.1 Our client has already outlined in their email correspondence with you, the significant impact this misclassification could have on its customers. CBD Products are known for their therapeutic properties, and removing them from the market would have a detrimental knock on effect too, for example, the National Health Services (**NHS**). Consumers, who are successfully managing health conditions with CBD products, would have to then struggle to find an alternative and consequently utilise the resources of the NHS to do so.
- 2.2 The purpose of the Novel Foods category is to ensure and deal with safety surrounding new food types, especially as products within this category are usually deemed to be entirely "new" and consequently it is not always known the extent to which they could pose a safety risk to human health.
- 2.3 CBD Products do not satisfy the characterisation of this category. The World Health Organisation in their 2017 report pronounced CBD as safe and outlined that it does not create adverse health effects. This contradicts the legal basis for a requirement to submit an application for a novel food product, which is in place to ensure that such novel food is indeed safe.
- 2.4 In addition to the above, we submit that there is no element of novelty surrounding CBD products. The plant itself has been cultivated and consumed for thousands of years.
- 2.5 We submit that the above factors clearly outline that the FSA's decision to classify CBD Products as novel foods is incorrect.

3 General classification

- 3.1 You have come to the conclusion that all CBD Products will satisfy the definition of a novel food. This classification has been adopted without specific reference to CannaPro's certified businesses' particular product ranges.
- 3.2 Your guidance, and European case law (C-383/07 M-K Europa GmbH), states that you reach a determination on whether a product is or is not a novel food on a "case by case

basis" rather than on a generic basis in terms of composition. The various products marketed by CannaPro's certified businesses present different characteristics and therefore should be properly considered on a case by case basis rather than the general approach that has been taken here.

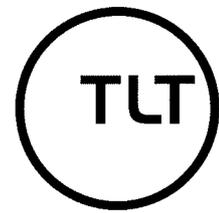
- 3.3 In the circumstances we submit that you have not considered our client's products on a case by case basis, and therefore your decision as to classification of CBD Products as novel foods is incorrect.

4 No prior notification or communication

- 4.1 Our client did not receive any information or notification prior to the amendment to the EU Novel Foods Catalogue being published. However, the FSA clearly knew about the change, given that the entity petitioned for the update.
- 4.2 Please confirm what information was provided to manufacturers and suppliers of CBD Products prior to classification, and the amendment being published.

5 Historic use

- 5.1 The FSA have requested evidence to show that there was a significant history of consumption of CBD Products in food and food supplements prior to May 1997 in the EU.
- 5.2 The European Food Safety Authority (**EFSA**) has previously supported the view that Cannabis Sativa L. was on the market as a food ingredient and was consumed to a significant degree before 1997. It was also clear that it was never their intention to limit this opinion to seed only. It is therefore unfortunate that the FSA is attempting to backtrack on these previously firmly held conclusions.
- 5.3 Further to this, the FSA have confirmed previously in written correspondence dated September 2018, that there was evidence of consumption within the EU prior to 1997 with regards to Cannabis Sativa L. The FSA outlined that "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 cannabiniol and cannabiniin) in the EU, prior to 15 May 1997, and therefore it does not fall within the scope of the novel foods regulation." In addition, the FSA confirmed that they were aware of a significant history of use of the plant as a whole (Cannabis Sativa L. plant) in the EU prior to 1997, and therefore ruled the entire plant as not falling within the Novel Foods Regulation.
- 5.4 Recital 17 of the Novel Food Regulations exempts CO₂ and Ethanol extractions from being considered Novel. The result of this being that as Cannabis Sativa L. is not novel, and the other ingredient e.g. CO₂, when dealing with extraction is also not novel, then the resulting food cannot be novel. Both CO₂ and Ethanol have a vast history of use across the food supply chain.
- 5.5 The legislation, at Recital 17, outlines that where food is "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." Consequently, it is obviously not the intention of the Novel Food Regulations to deal with foods that are produced from non-novel food ingredients, even



if the composition of these elements is slightly different. CBD Products, therefore, should not be considered novel in nature.

- 5.6 In addition to the above points, the plant itself has been cultivated and consumed for thousands of years, and should in no way be labelled novel. Evidence has previously been assessed, considered and the relevant ingredients declared not to be novel in nature, nor deemed unsafe, the main purpose for food products to be declared novel. It would therefore be impossible to suggest that this evidence is no longer relevant, or that the same conclusions should not be drawn.

6 CBDA oil

- 6.1 Our client considers that products containing CBDA oil are not covered by your classification of CBD products as they can be distinguished as a different and precursor product. Please confirm.

7 Hemp Flowers

Our client considers that Hemp Flowers in their natural state, not advertised or promoted as having food properties, are not covered by your classification of CBD Products. Please confirm.

8 Financial implications

- 8.1 We draw your attention to the fact that all certified businesses of CannaPro, have significant financial interests at stake, as does the industry as a whole with a wide range of CBD Products. Your classification of the products it sells has clearly had, and will continue to have an impact on this.
- 8.2 For reference, our client has estimated that CannaPro's certified members have a monthly turnover in the region of £2,000 to £1 million per member per month. Consequently, should our client, or any of its members, suffer any associated loss as a result of any misclassification of their products as novel foods, they will be seeking compensation. As per the figures referenced above, any such claim would be significant.
- 8.3 We are sure that the FSA can appreciate that due to the detrimental effect such a misclassification could have on the industry as a whole; an industry-wide claim for associated loss may also be pursued.

9 Next steps

- 9.1 On behalf of our client and for the numerous reasons presented above we invite you to suspend your decision immediately and reconsider your classification of CannaPro's certified businesses' products as novel foods in the circumstances.
- 9.2 Our client also wishes to underline the fact that it has a very supportive and loyal customer base who will be impacted by your decisions in respect of the classification of the CBD Products as novel foods.

9.3 As mentioned above, to the extent that CannaPro or any of their certified businesses, suffer any associated loss as a result of any misclassification of their products as novel foods, we are instructed to seek to recover it.

We look forward to hearing from you as a matter of urgency.

Yours faithfully

A handwritten signature in black ink that reads "Duncan Reed". The signature is written in a cursive style with a large, looped initial "D".

Duncan Reed
Legal Director
for TLT LLP