

Application for consultation to determine the status of a novel food, pursuant to Article 4(2) of the above Regulation

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Recipient Member State: UK Food Standards Agency (FSA)

Name and description of the novel food concerned:

The food is a CBD isolate (purity is >98%) dissolved in MCT oil (medium-chain triglyceride). The concentrations of CBD in the product are 500mg, 1000mg and 1500mg per 10ml. The CBD is extracted using ethanol as the solvent. The product is intended to be used as a food supplement.

The dossier highlights no suggestion that this should not be considered as food. No medicinal or drugs considerations were highlighted. No information is highlighted to suggest that the isolate is performing a technical function in the food and therefore should be considered as an additive.

Status – Novel food

Novel food category (where applicable)-

(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;

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 ██████████ Cannabidiol 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.

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Conclusion

An enquiry on the novel food status from the applicant was considered by the UK under Regulation 2015/2283. The UK has reached a view based on the evidence provided and after discussion with Member State colleagues, that for the reasons below, it would be considered a novel food;

- A history of consumption had not been demonstrated for the CBD isolate
- That the final product was different from the starting material and that there may be differences in exposure because of the concentration of the CBD component.

In the UK most forms of CBD are currently considered food.. This may not be the case in other Member States which may class CBD as a medicine or as a narcotic drug. It is advisable to consult relevant national authorities for confirmation of the correct regulatory regime CBD falls within the scope of, in a particular Member State.

The UK has reviewed the information and arrived at an opinion of novel.

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