Frequently Asked Questions: Cannabidiol[1]

What is the procedure for authorizing cannabidiol as a food supplement and/or food ingredient in the EU?

The European Commission considered that cannabidiol (CBD) qualifies as a novel food (NF) under EU legislation (EU 2015/2283) since significant human consumption of CBD prior to 15 May 1997 was not demonstrated.

An applicant who intends to place any NF on the EU market should apply to the European Commission (EC) for an authorisation. After verifying the application, the EC mandates EFSA to perform a scientific safety assessment of the health risks for consumers.

The EC decides whether or not to authorise a NF and its conditions of use, taking into account EFSA's scientific advice. Member States (MS) and the EC may also determine specific labelling requirements for a NF where appropriate.

Only NFs that are included in the EU's positive list of authorised NFs may be placed on the EU market in accordance with the conditions of use and specified labelling requirements.

More information related to preauthorization and EFSA's role can be found here.

What is the expected time frame for EFSA's risk assessments?

EFSA's Panel on Nutrition, Novel Foods and Food Allergens (NDA) should finalise their risk assessments within nine months from the date of the receipt of a valid novel food application from EC. If during this time frame EFSA identifies the need for additional information, the risk assessment is placed on hold until the applicant submits the requested additional information and data.

Which guidance documents does EFSA use?

For its risk assessments of novel foods, EFSA follows:

- "Guidance on the preparation and submission of an application for authorisation of a NF in the contest of Regulation (EU) 2015/2283".

Additional sectorial EFSA guidance may also be applicable when appropriate including:

- "Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health"
- "Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles"
- "Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment"
- "Clarification of some aspects related to genotoxicity assessment"
- "Genotoxicity assessment of chemical mixtures"

[1] only the questions received during the info session and that fell within the EFSA remit have been included in the FAQ on CBD. Any regulatory-related question including authorization and marketing of products should be addressed to the European Commission

- "Guidance on aneugenicity assessment".

Does EFSA differentiate between CBD extracted from hemp and synthetic CBD?

The identity, production process and composition of a NF are of paramount importance for the safety assessment of the NF. The production process has a direct impact on the composition of the final product and the presence of small particles. Regardless of the production process used to obtain a CBD-based NF, the resulting product can range from a highly pure CBD product to a less pure CBD product. Purity as well as the presence of other components and/or contaminants and/or small particles in the final product impact on the toxicological profile of the NF.

Does EFSA consider other cannabinoids in its safety assessments?

Applicants are responsible for performing the qualitative and quantitative characterisation of all substances present in the NF and addressing the safety of all constituents, including all cannabinoids present in the NF.

What kind of toxicological data does EFSA consider?

In accordance with the Guidance on Novel Foods, EFSA considers the toxicological data provided by each applicant and the data available in the peer-reviewed literature.

Does EFSA consider the data on Epidyolex® relevant?

Epidyolex® is an orphan medicine with CBD as the active substance and is used in the treatment of rare types of epilepsy. EFSA's NDA Panel considered the public assessment report of Epidyolex® published by the European Medicines Agency as well as peer-reviewed human studies conducted with similar preparations for its Statement on the safety of cannabidiol as a novel food: data gaps and uncertainties. While these studies inform on potential risks associated with CBD, they cannot be used to derive a safe level for CBD as NF, since they were carried out in patients treated with other medications, at high therapeutic doses, and/or designed to determine the efficacy of Epidyolex® rather than the safety of CBD. Adverse effects are tolerated for drugs for which remedial benefits outweigh the risks while a food must be safe in the healthy general population under the uses and use levels proposed by the applicants.

Will data from other international agencies be considered?

All data will be considered in the safety assessment of CBD when made publicly available.

Can EFSA advise on the studies needed to address the data gaps identified?

EFSA cannot give direct advice on study design. However, applicants with dossiers that are under risk assessment can request a teleconference with EFSA to clarify protocols and other aspects related to their individual application.

More information can be found in EFSA's catalogue of support initiatives for regulated products at this link.

Why has the UK Food Standards Agency (FSA) proposed a human adult upper limit of 70 mg CBD per day for foods, and why does EFSA not use this value?

The UK Food Standards Agency recommended that healthy adults should consume no more than 70 mg of CBD per day based on a position paper from the Committee on Toxicity (COT). However, the COT position paper acknowledges that the data available are insufficient to undertake a provisional

risk assessment as it was not possible to determine a reliable point of departure. EFSA was mandated by the EC to carry out risk assessments for each application for CBD novel food products. So far a safe intake level cannot be derived from the data available.

When will EFSA's literature review of human studies on CBD be available?

EFSA plans to publish its systematic review of CBD human studies by the end of 2022.

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