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Statement on the safety of cannabidiol as a novel food

Disclaimer

- This plain language summary (PLS) is a simplified communication of EFSA's *Statement on the safety of cannabidiol as a novel food: data gaps and uncertainties*.
- The purpose of this PLS is to enhance transparency and inform interested parties on EFSA's work on the topic using simplified language.
- Anyone interested in the more in-depth assessment and analysis should consult the full EFSA statement, which can be found here.

Cannabidiol – an overview

- Cannabidiol (CBD) is a substance which can be obtained from *Cannabis sativa* L. plants, and which can be synthesised chemically as well.
- CBD has been authorised as a drug to treat some epilepsies that do not respond to usual drug treatments.
- In a non-medical setting, the European Commission (EC) considers that CBD qualifies as a novel food (NF) under EU legislation.
- In the context of medical conditions, adverse effects of CBD are tolerated if the benefits outweigh any adverse effect. However, adverse effects are not acceptable in foods. They must be demonstrated to be safe for normal consumption.
- The EC asked the European Food Safety Authority (EFSA) to give its opinion on whether CBD is safe for humans as a NF.
- As of mid-March 2022, the EC has received more than 150 applications for CBD as NF and 19 of those are currently under assessment by EFSA.

What has EFSA asked the NDA Panel to do?

- As a self-mandate, EFSA asked its Panel on Nutrition, Novel Foods and Food Allergens (NDA) to evaluate the data that are available on the safety of CBD as a food ingredient and as a food supplement.
- In particular, EFSA asked the NDA Panel to identify any information gaps that exist concerning the use of CBD.

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How did EFSA carry out this work?

- The NDA Panel analysed the information available from both animal and human studies to identify any safety concerns for CBD usage as a NF. This included a systematic review of human CBD studies.
- The NDA Panel summarised the data and identified areas where data are considered to be either missing or inadequate in order to draw conclusions on the safety of CBD as a NF.

What are the main outcomes?

- By assessing the data submitted to EFSA and the scientific literature, the NDA Panel identified several data gaps and uncertainties that need to be addressed before any conclusion on the safety of CBD as a NF can be reached.
- The Panel identified several hazards related to CBD intake and pointed out deficiencies in both the experimental animal and human data.
- Data on the effect of CBD on liver, gastrointestinal tract, endocrine system, nervous system and on psychological function are insufficient and these gaps need to be addressed.
- Studies in animals show significant adverse effects especially in reproductive function. It is important to determine if these effects are also seen in humans.
- The Panel concludes that the safety of CBD as a NF cannot currently be established.

What were the limitations of the currently available data?

- The retrieved studies (animal studies) have been performed with non-chemically pure CBD, which could lead to confounding data (which may misrepresent or obscure the true effects of CBD).
- Several human studies were performed with patients that were, at the same time, treated with other medications and with high therapeutic doses that may have affected the data.
- Most of the human data referred to in the CBD applications are taken from studies that examined the efficacy of Epidyolex at therapeutic doses (i.e., the amount of the drug required to treat a disease) at which adverse effects were sometimes observed.
- A no observed adverse effect level (NOAEL) for CBD could not be identified from the reviewed studies.

Implications and recommendations for Public Health Authorities

- Several gaps in data and uncertainties (e.g., liver metabolism, drug interactions) have been identified which will need to be addressed by further studies.
- There is a need for data gaps to be filled as part of the safety assessment and authorisation process.
- It is the responsibility of the applicants seeking authorisation of CBD-based NFs to fill the data gaps.