RISK ASSESSMENT OF CANNABIDIOL (CBD) AS A NOVEL FOOD

Webinar | 21 April 2026, 14:30 – 16:00 (CEST)

EUROPEAN FOOD SAFETY AUTHORITY

WELCOME AND INTRODUCTION

HOUSEKEEPING RULES

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One-way audio
(listen only mode)

The event is in **English**

This event is **being recorded** and the recording will be published on EFSA's website. Do not produce any recording or use AI tools to take notes or produce transcripts.

After the event, attendees will receive a **link to a survey** to evaluate the EFSA event

AGENDA

Welcome and introduction to the event

Ana Afonso, *Head of EFSA Nutrition & Food Innovation Unit*

Status of CBD assessment

Océane Albert, *EFSA Novel Food Safety Team Leader*

Updated statement on the safety of CBD as a novel food

Harry McArdle, *Chair and Expert, EFSA Working Group on Novel Foods*

Impact of the statement and future steps

Annamaria Rossi, *Chair of the EFSA Cannabidiol taskforce*

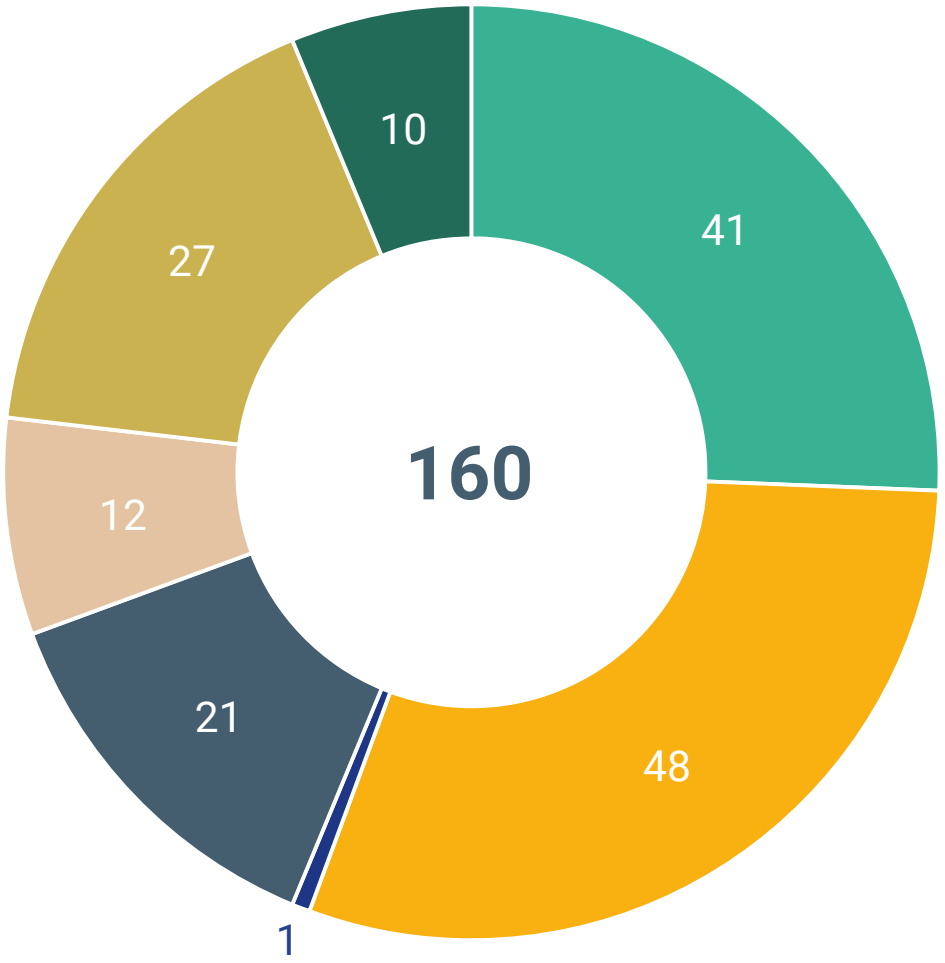
Q&A

Rafael Perez Berbejal, Océane Albert, Annamaria Rossi

Closing remarks

Ana Afonso

REGISTERED PARTICIPANTS



- Industry
- National authoritative/governmental bodies
- Non-governmental organization
- Regulatory consultancy providers/CROs
- Academia
- Private
- Others

GOAL OF THE WEBINAR

Present the updated statement on the safety of CBD as a novel food and provide insights on its impact on the risk assessment of applications.

STATUS OF CBD ASSESSMENT

CBD AUTHORISED IN THE EU FOR ORAL CONSUMPTION

Epidyolex®

- Approved by the European Medicines Agency (EMA)
- Active substance: CBD from the milled botanical raw material (*Cannabis sativa* L.)
- Indicated as adjunctive treatment for seizures associated with Lennox Gastaut syndrome, Dravet syndrome, tuberous sclerosis complex (intractable childhood epilepsy) for patients from 2 years of age

IN THE EUROPEAN UNION

EU **Court of Justice** (CJEU)C-663/18 ruling of November 2020: CBD cannot be regarded as a narcotic

*"Cannabidiol should not be considered as a drug within the meaning of the United Nation Convention Schedule IV of the 1961 Single Convention on Narcotic Drugs. This means that cannabidiol can be **qualified as food**"*

Cannabidiol qualifies as **novel food** (any food that was not used for human consumption to a significant degree within the EU before 15 May 1997). A pre-market authorisation is required.

According to Regulation (EC) No 178/2002 and Regulation (EU) 2015/2283, foods, including NFs, must be safe: EFSA shall conduct a risk assessment **based solely on health risks** and must conclude on that basis alone

OVERVIEW OF CBD AS NOVEL FOOD DOSSIERS

European Commission

efsa EUROPEAN FOOD SAFETY AUTHORITY

200+ dossiers

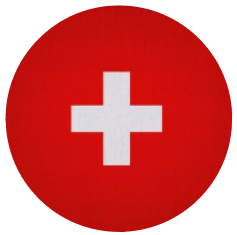
Suitability check
3 dossiers

Risk assessment
15 extracted
2 synthetic

Adopted
3 negative opinions

ASSESSMENTS FOR FOOD USES IN EUROPE OUTSIDE THE EU

- Provisional acceptable daily intake (ADI) of 10 mg/day for healthy adults based on hepatotoxicity (2023)
- Should not be consumed by vulnerable groups, including <18 - assessment only covers healthy adults
- Risk to certain groups (those on medication, pregnant women)



- Limit of 12 mg CBD/person (70 kg bw) per day based on hepatoxic effects in humans (2021)

OTHER ASSESSMENTS IN THE EU

ECHA
EUROPEAN CHEMICALS AGENCY

CLP classification: Category 1B toxicant for **reproduction and fertility, development** and Category Lact. H362 for **lactation**, applicable to **all exposure sources (including oral)**

European Commission
Scientific Committee on Consumer Safety

Considered safe when used at concentrations **up to 0.19% in dermal and oral cosmetic products** – whether used alone or together

UPDATED STATEMENT ON THE SAFETY OF CBD AS A NOVEL FOOD

EFSA STATEMENT 2022: SCOPE, OUTCOME, REQUESTS

SCOPE

- Identify the hazards of CBD
- Provide an overview of the uncertainties and data gaps that need to be addressed to assess the safety

DATA GAPS IDENTIFIED

- Liver, ADME, neurotoxicity and psychiatric/psychologic effect, hormonal levels, fertility and reproductive toxicity
- Presence of small particles and genotoxicity

OUTCOME

Additional data have been requested to the applicants

FOLLOW UP


Additional data requested in June 2022
No data have been submitted by the applicant to address the identified data gaps
In 2024 EFSA decided to update the Statement
5 weeks public consultation started on 9 September 2025
Adopted on 16 December 2025 - Published on 9 February 2026

SCOPE OF THE NEW STATEMENT

Provide an update on the uncertainties and data gaps identified for the safety assessment of CBD as a NF based on the assessment of the most recent published scientific literature

Identify a toxicological reference point and derive a provisional safe dose for CBD

Provide guidance on the applicability of the specific appraisal route based on octanol-water partition coefficient (K_{ow}) thresholds to assess if CBD is fully dissolved in oil or if nanoparticles are present in CBD-related NFs

ADME AND DRUG-DRUG INTERACTION

ADME

- The matrix used and food consumption have a marked effect on bioavailability
- CBD crosses the placenta
- Long-term effects of kinetic behaviour and accumulation in human have not been assessed

Drug interaction

- Many studies on interaction with antiepileptic drugs
- Clinical relevance is unclear
- Interactions can impact the kinetics of CBD
- Enzyme induction in humans remains a data gap

LIVER EFFECTS

- Dogs and cats may be more sensitive than rats
- Most robust data come from rat studies, where changes in liver weight and histopathology have been identified as sensitive endpoints

- Human clinical trials further support concerns for liver toxicity
- CBD could exacerbate hepatotoxicity when used with other medications
- Lowest dose with effects on liver enzymes in healthy persons not taking other drugs reported at 5 mg/kg bw per day (Florian et al., 2025)

NEUROLOGICAL, PSYCHIATRIC AND PSYCHOLOGIC EFFECTS

- Data gaps in the new literature on the neurological, psychiatric and psychologic effects of CBD, particularly regarding its safety profile in healthy individuals
- Most recent human studies have focused on evaluating the therapeutic efficacy of CBD in specific patient populations, rather than assessing its safety in the general population, and often only one dose was tested
- Still a lack of critical information on dose–response relationships and potential neurological or neuropsychiatric effects in healthy population
- Given CBD's interaction with multiple molecular targets involved in neurophysiological regulation, the absence of robust data on its long-term effects and dose-dependent outcomes in healthy individuals represents a substantial data gap

REPRODUCTIVE SYSTEM

- Integrity of reproductive organs affected
- *In utero*/lactational exposure produce similar effects in offspring

Oestrous cyclicity may be affected

Effects on sperm chromatin integrity, spermiation and overall sperm quality

High doses of CBD during pregnancy may trigger severe maternal toxicity and alter pregnancy outcomes

DEVELOPMENTAL TOXICITY AND NEUROTOXICITY

Studies suggest that prenatal CBD exposure can result in adverse, long-lasting and sex-specific neurodevelopmental outcomes

Intraperitoneal studies suggest that CBD exposure during pregnancy or adolescence may affect liver function, liver metabolism and possibly cardiac cells and function

OTHER ENDPOINTS

Gastro-intestinal system (assessed in studies as secondary outcome): no effect at lower doses, diarrhoea and vomiting at higher doses

Immune system: interaction with immune pathways warrants caution, but lack of studies

Genotoxicity: formulation (*e.g.*, nanoformulation) and production process may introduce genotoxic hazards

Presence of nanoparticles: needs to be investigated in powder and viscous extract formulations

CRITICAL EFFECTS IN 90-DAY STUDIES SUBMITTED BY APPLICANTS

Recurrent effects

- Organ weight changes: notable, often dose-dependent increases in organ weights have been recorded in animals of both sexes, including liver, adrenal glands and kidneys. **Elevated liver weight was frequently associated with histopathological findings indicative of liver hypertrophy.**
- Thyroidal and hormonal alterations: changes in thyroid weight and fluctuations in hormonal levels have also been observed, suggesting potential endocrine-related effects.

Critical effects

Liver was identified as the most sensitive and consistently affected organ, and liver weight-to-body weight ratio was determined as the most critical parameter for further analysis.

SUMMARY OF NEW STATEMENT

There are still many data gaps, which make it very difficult to derive safe levels

However, it may be feasible to derive a toxicological reference point, which will help inform on the way forward

EFSA has calculated a BMDL from the most robust data available

CALCULATION OF BMD

$BMDL_{10}$ = 11.1 mg/kg

BODY WEIGHT PER DAY

Purity ≥ 98%

According to GLP and OECD 408

Endpoint liver weight relative to body weight

Critical effect size 10%

Females

UNCERTAINTY FACTORS

Inter- & intraspecies variability:

100

- **Evidence from human studies not sufficient** to deviate from the default value for interspecies differences.
- **Interaction of CBD with liver enzymes**: potential impact of CYP-polymorphisms and drug-drug interactions.

Subchronic to chronic exposure:

2

Additional uncertainties:

2

- Due to **uncertainties linked to adverse effects** that could occur at lower doses in tissue or organ systems other than liver.

Total UF:

400

BMDL10:

11 mg/kg bw per day

Provisional safe dose:

0.0275 mg/kg bw per day

2 mg/day for a 70-kg adult

CONCLUSIONS OF THE STATEMENT

New literature not sufficient to address data gaps and uncertainties previously identified. Limitations: single dose testing, high drop-out rates, unclear adherence to protocol.

Remaining uncertainties on effects of long-term consumption of CBD on liver, reproductive and immune systems, neurological function and development and kinetic behaviour. Concern for potential interactions with medicinal drugs.

Provisional safe dose: **2 mg/day in adults** (0.0275 mg/kg body weight per day) for CBD formulations with purity ≥ 98%, consumed as food supplements, without small/nano particles, and for which genotoxicity has been ruled out

Safety of CBD in individuals under 25, pregnant or lactating women, and those on concurrent medications cannot be established

IMPACT OF THE STATEMENT AND FUTURE STEPS

NEXT STEPS

EFSA assessment will perform an **independent RA**:

- Assessment is **NOT based on risk-benefit**
- EFSA target **general population**, not patients

Evaluation of CBD will follow the approach from the **EFSA NDA Guidance on novel foods**

Safety above the use levels of 2 mg/day cannot be established at the moment

WHEN DOES THE PROVISIONAL SAFE DOSE APPLY?

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PURITY

≥98% for CBD extracted and synthetised

USES

Only as food supplement NOT as food ingredient

PRODUCTION PROCESS

Assessed for all CBD extracted and synthetised

SMALL AND NANO PARTICLES

Absence should be confirmed on the bases of the final formulation

GENOTOXICITY

Need to be ruled out

QUESTIONS & ANSWERS

ADMINISTRATION

Where can we find information on the status of applications?

Why did EFSA derive a provisional safe dose even though this was not included in its mandate?

What is EFSA’s view on timelines and the regulatory pathway for pending applications?

How possible divergent agency conclusions will be handled (e.g. reprotoxicity between the SCCS and RAC)?

RISK MANAGEMENT

- Is it possible to use CBD as food?
- Why is CBD freely available on the market also as food ingredient?
- Is there an interest in reaching a harmonised EU approach to address illegal CBD (or other cannabinoid-containing) products?
- How will the EC proceed to remove unauthorised CBD products from the market?
- How will the 2 mg/day be taken into consideration by the Commission?
- What are the implications of CBD classification under CLP for food and feed law?

RISK ASSESSMENT

- Is a positive assessment of CBD likely?
- Can NAMs for genotoxicity, oral toxicity and hepatotoxicity be used as supplemental data?
- Is the proposed 2 mg/day definitive, or could applicant data justify higher use levels?
- What are EFSA’s current priorities for addressing the main data gaps (long-term toxicity, liver effects, reproductive toxicity)?
- Are there guidance updates planned to support applicants?
- Hemp-derived products not classified as novel foods have similar properties and long histories of use. How was history of safe use considered?
- How does EFSA justify the request for additional studies despite widespread market presence since 2014?

CLOSING REMARKS