Adopted: 29 September 2025

DOI: 10.2903/j.efsa.2025.9708

efsa JOURNAL

SCIENTIFIC OPINION

Safety of synthetic cannabidiol as a Novel food pursuant to Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) | Dominique Turck | Torsten Bohn | Montaña Cámara | Jacqueline Castenmiller | Stefaan De Henauw | Ángeles Jos | Alexandre Maciuk | Inge Mangelsdorf | Breige McNulty | Androniki Naska | Kristina Pentieva | Alfonso Siani | Frank Thies | Margarita Aguilera-Gómez | Francesco Cubadda | Rosangela Marchelli | Harry J. McArdle | Peter Moldeus | Monika Neuhäuser-Berthold | Josef Rudolf Schlatter | Alexandros Siskos | Viviana Trezza | Océane Albert | Elisa Beneventi | Areti Favata | George E. N. Kass | Marcello Laganaro | Maura Magani | Irene Nuin Garciarena | Anna Maria Pieger | Annamaria Rossi | Karen Ildico Hirsch-Ernst

Correspondence: nif@efsa.europa.eu

The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on synthetic cannabidiol as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF which is subject of the application is the (–)-cannabidiol (CBD) produced by chemical synthesis and proposed to be used in food supplements at a maximum use level of 150 mg/day. The target population is the general population above 6 years of age, excluding pregnant and lactating women. During the risk assessment, the Panel identified a number of data gaps, which needed to be addressed by the applicant. EFSA's request for additional information was sent to the applicant. The requested data concerned the identity, the production process, the compositional data, the specifications, the genotoxicity, the reproductive and developmental toxicity and the human data of the NF. The applicant did not reply or provide sufficient information on the identity (small particles and/or nanoparticles), stability, genotoxicity, reproductive and developmental toxicity and the human data for the NF. The applicant did not reply to the latest EFSA's request (in June 2022) for additional data. Based on the available data, the Panel concludes that the safety of the NF cannot be established.

KEYWORDS

CBD, example: Novel foods, food supplement, safety, synthetic cannabidiol

CONTENTS

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the requestor

On 26 November 2019, the companies "Cibdol AG" and "Labocan BV" submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283[1] to authorise placing on the market of synthetic cannabidiol as novel food.

The application requests to authorise the use of synthetic cannabidiol in food supplements, the target population being children above 6 years of age and the adult population excluding pregnant and lactating women.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the safety of synthetic cannabidiol as a novel food.

In addition, the European Food Safety Authority is requested to include in its scientific opinion a statement as to if, and if so to what extent, the proprietary data for which the applicant is requesting data protection was used in elaborating the opinion in line with the requirements of Article 26(2)© of Regulation (EU) 2015/2283.

1.2 | Additional information

Cannabidiol (CBD) is the active substance of Epidyolex®, a medicine approved by the European Medicines Agency (EMA). Epidyolex® contains nearly 100% pure CBD and it is used as an adjuvant to treat patients suffering from Lennox–Gastaut syndrome, Dravet syndrome or tuberous sclerosis complex in patients from 2 years of age and above.[2]

On 26 April 2022, the NDA Panel adopted a statement on the safety of CBD as a novel food (NF), which outlined data gaps and uncertainties in the risk assessment. The Panel concluded that the safety of CBD as an NF cannot be established until gaps in both the experimental animal and human data are addressed (EFSA NDA Panel, 2022).

2 | DATA AND METHODOLOGIES

2.1 | Data

The safety assessment of this NF is based on data supplied in the application and information submitted by the applicant following EFSA requests for supplementary information.[3] In June 2022, EFSA issued a further request for additional data. However, the applicant did not reply to the additional information requested by the Panel.

Administrative and scientific requirements for NF applications referred in Article 10 of Regulation (EU) 2015/2283 are listed in Commission Implementing Regulation (EU) 2017/2469.[4]

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (including both data in favour and not in favour) that are pertinent to the safety of the NF.

This NF application includes a request for protection of proprietary data in accordance with Article 26 of Regulation (EU) 2015/2283. The data requested by the applicant to be protected comprise: production process, compositional data, ADME, toxicological data. Despite the applicant did not provide studies for ADME and toxicological data, they claimed the performed public literature search as confidential and proprietary.

2.2 | Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of Commission Implementing Regulation (EU) 2017/2469.

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any claimed benefit.

[1]Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJL 327, 11.12.2015, p. 1.

[2]https://www.ema.europa.eu/en/medicines/human/EPAR/epidyolex.

[3]https://open.efsa.europa.eu/question/EFSA-Q-2020-00084.

[4]Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

3 | ASSESSMENT

3.1 | Introduction

The NF that is the subject of the application is synthetic (–)-cannabidiol (CBD).

According to Article 3 of Regulation (EU) 2015/2283, the NF falls under Article 3(2)(a)(i) 'food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997'.

The NF is a crystalline powder produced by chemical synthesis consisting of CBD with a purity of ≥ 98%. It is proposed by the applicant to be used in food supplements at the maximum dose of 150 mg/day. The proposed target population is the general population above 6 years of age, except for pregnant and breastfeeding woman.

3.2 | Identity of the NF

The NF is (–)-cannabidiol (CBD). Table 1 lists the main chemical identifiers of CBD while Figure 1 shows its chemical structure.

TABLE 1 Chemical identity of synthetic CBD (i.e. the NF).

Chemical substance	
Chemical (IUPAC) name	-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol
Common name	(–) *trans*-cannabidiol or cannabidiol
Other names: Synonyms, trade names, abbreviations	CBD, Cannabidiol, (–)-*trans*-cannabidiol, *trans*-cannabidiol, (–)-Cannabidiol
CAS Number:	13956-29-1
Molecular formula:	$C_{21}H_{30}O_2$
Molecular weight	314.46 g/mol

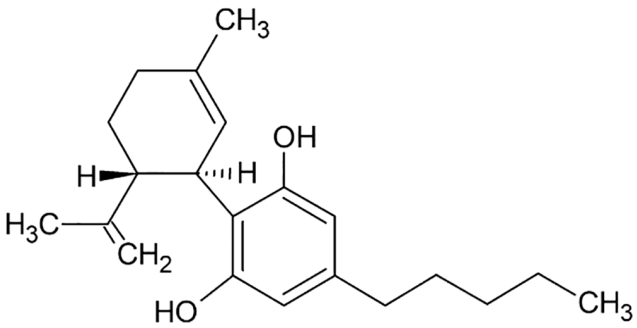

FIGURE 1 Chemical structure of CBD (i.e. the NF).

The identity of the NF has been demonstrated through a combination of spectroscopic techniques, including proton (^{1}H) and carbon-13 (^{13}C) nuclear magnetic resonance (NMR), attached proton test (ATP), two-dimensional heteronuclear single quantum correlation (HSQC) spectroscopy, as well as correlated spectroscopy (COSY) with corresponding NMR assignments, UV–Vis spectroscopy, infrared spectroscopy (IR), gas chromatography–mass spectroscopy (GC–MS) and further confirmed by the consistency with literature values.

Additional data were requested to evaluate the presence of small particles and/or nanoparticles in the novel food, following the relevant EFSA guidance documents (EFSA Scientific Committee, 2021). The applicant submitted analyses using scanning electron microscopy (SEM). However, several issues were identified, resulting in a potential bias towards measuring larger particles: the magnification levels were inadequate for proper particle characterisation, the number of images used for analysis was insufficient, the sample was not adequately dispersed and agglomeration issues were present. The data provided referred generically to the measurement of 'size' without clearly specifying the type of measurement considered, nor justifying it in relation to particle morphology. Notably, the data suggested the presence of non-equiaxial particles, which would have required the selective measurement of the smallest external dimension. Remarkably, all particle size data were derived from a single sample from one batch, failing to account for potential batch-to-batch variations in particle size and homogeneity.

The applicant provided quantitative data from analytical centrifugation, which indicated that over 99% of the particles in the NF (mass based) are smaller than 500 nm, with modes between 80 and 140 nm, suggesting that most particles (number based) are smaller than 250 nm. This was supported by the quantitative SEM imaging, which, despite its deficiencies, confirmed that 76% of particles smaller than 1 μm (number based) had a minimum Feret diameter under 100 nm, based on expected sedimentation of larger particles.

Overall, the Panel considered that the evidence provided on small particles or nanoparticles, although insufficient, is suggestive of their presence in the NF.

The Panel considers that, although the chemical identity of the NF has been sufficiently demonstrated, the evidence provided on small particles and/or nanoparticles is insufficient.

3.3 | Production process

According to the information provided, the NF is produced in line with good manufacturing practice (GMP) and hazard analysis critical control points (HACCP) principles.

The NF is synthesised through a stereospecific condensation reaction, starting from *p*-mentha-2,8-dien-1-ol and 5-pentyl-1,3-benzenediol (olivetol) coupled with Lewis-acid catalysed alkylation while heating. Following a sequence of solvent–solvent extractions, the final product is obtained through subsequent dual crystallisation, filtering, washing and drying steps.

The Panel considers that the production process is sufficiently described.

3.4 | Compositional data

The NF consists of CBD in powder form with a purity of ≥ 98%.

In order to confirm that the manufacturing process is reproducible and adequate for producing a product with the required characteristics on a commercial scale, the applicant provided analytical information for four independently produced batches of the NF.

According to the data submitted by the applicant, the CBD content was assessed using an in-house method based on high-performance liquid chromatography–ultraviolet (HPLC-UV) and all the results were between 98.6% and 100% with a water content up to 0.054%.

Processing-related substances (i.e. CBD regioisomer, olivetol, Δ^8- and Δ^9-tetrahydrocannabinol isomers, Δ^8- and Δ^9-THC) were analysed using an in-house method based on high-performance liquid chromatography with a diode array detector (HPLC-DAD) operated on a single wavelength of 220 nm. 5-pentyl-1,3-benzenediol was analysed using an in-house gas chromatography–mass spectroscopy (GC–MS) method. While residual starting materials (i.e. olivetol and 5-pentyl-1,3-benzenediol) and unspecified impurities were below their respective limits of detection (LODs), the abnormal CBD regioisomer was present at levels up to 0.0018%, Δ^8- and Δ^9-THC up to 0.0054% and 0.0075%, respectively.

Residual solvents analysed through an in-house headspace gas chromatography (HS-GC) method were below their respective LODs for acetonitrile and heptane and detected up to 390 ppm for hexane.

Heavy metals such as cadmium, lead, arsenic and mercury were determined using inductively coupled plasma mass spectrometry (ICP-MS) and were below the respective LODs as well as in compliance with the Regulation (EC) 2023/925 when applicable.

Microbiological parameters were also conducted according to the validated procedures of the European Pharmacopoeia. The results showed that total aerobe counts and total yeast and mould counts were both below 10 CFU/g, while *Escherichia coli* and Salmonella were not detected in 1 and 25 g, respectively.

Incomplete information was provided on the accreditation of the laboratories that conducted the analyses presented in the application.

3.4.1 | Stability

The applicant performed stability tests with three batches of the NF. The tests were carried out at storage conditions and temperatures ranging from 15°C to 20°C, with different humidity conditions, light–dark cycles and frequent opening and closing of the container, and at accelerated conditions at 40 ± 2°C and at 75 ± 5% relative humidity. Both studies lasted 12 months. These batches were analysed for CBD content, Δ^8- and Δ^9-THC, and unspecified total impurities.

Only the certificates of analysis for the initial 3 months tested were provided. No certificate of analysis was provided for microbial stability analysis.

Due to the absence of the complete certificate of analysis covering the entire duration of the stability studies, the Panel could not conclude on the stability of the NF based on the submitted data.

3.5 | Specifications

The applicant proposed specifications for the NF. However, due to the limitations concerning the identity and the compositional data, the Panel considered that the specifications for the NF cannot be established.

3.6 | History of use of the NF and/or of its source

3.6.1 | History of use of the source

CBD (synthetically produced or plant-derived) has no history of consumption as food in the EU.

CBD is a naturally occurring compound produced in the trichomes, which are primarily located on the flowering tops and leaves of the *Cannabis sativa L*. plant. Traces of CBD can also be found on the surface of the seeds. In hemp used for fibre production, the concentration of CBD typically ranges between 0.5% and 2.0%.

Traces of CBD in hempseed oil can be detected at levels of 10–200 mg/kg. Cleaning of hempseed is not sufficient to eliminate CBD from hempseed oil.

3.6.2 | History of use of the NF

As reported above (see Section 1.2), Epidyolex® is the only CBD containing product authorised for oral consumption in EU as a medicinal product.

3.7 | Proposed uses and use levels and anticipated intake

The NF is intended to be used in food supplements.

3.7.1 | Target population

The target population proposed by the applicant is the general population above 6 years of age, excluding pregnant and lactating women.

3.7.2 | Proposed uses and use levels

The applicant intends to market the NF for use in food supplements, at a maximum dose of 150 mg per day irrespective of the age group.

3.8 | Absorption, distribution, metabolism and excretion (ADME)

The applicant presented information from a literature search for the assessment of ADME.

3.9 | Toxicological information

The Panel notes that no toxicological studies with the NF were provided in the original submission. Instead, the applicant presented information from a literature search for toxicity studies. Upon EFSA's request, the applicant provided the studies listed in Table 2.

TABLE 2 List of toxicological studies performed with the NF.

Reference	Type of study	Test system	Dose
Study No. B-03261 (Unpublished, 2021a)	Bacterial reverse mutation test (GLP, OECD TG 471)	*S.* typhimurium TA98, TA100, TA1535 and TA1537 and *E. coli WP2 (pKM101)*	Up to 5 mg/plate (absence and presence of S9 mix)
MIC-PH-21/0522 (Unpublished, 2021b)	In vitro mammalian cell micronucleus test (GLP, OECD TG 487)	Chinese hamster ovary (CHO) cells	Short term: 0.92–51.2 mg/mL (absence and presence of S9 mix) Long term: 0.37–20.48 mg/mL (absence of S9 mix)

Abbreviations: GLP, Good Laboratory Practice; OECD TG, Organisation for Economic Co-Operation and Development Test Guideline.

Owing to the lack of a correct characterisation of the fraction of small particles, including nanoparticles, in the NF (EFSA Scientific Committee, 2021), the Panel cannot confirm whether the toxicological testing strategy proposed by the applicant is appropriate to assess its safety.

3.9.1 | Genotoxicity

A bacterial reverse mutation test was performed with the NF in *S*. typhimurium strains TA1535, TA1537, TA98, TA100 and *Escherichia coli* WP2(pKM101) (Unpublished, 2021a) in the presence and absence of metabolic activation applying the plate incorporation and pre-incubation method. Two independent experiments were conducted according to the OECD Test Guideline 471 (OECD, 1997), in a study claimed to be compliant with the principles of good laboratory practice (GLP). The NF was dissolved in ethanol and tested in a preliminary cytotoxicity test to select five concentrations (range: 0.06–5 mg/plate) to be used in the main experiment. Cytotoxicity was not observed at any concentration tested. The NF was visibly soluble in culture medium up to 5 mg/plate, where precipitate was observed.

S. typhimurium strains TA98, TA1535 and TA1537 showed a non-dose-dependent increase in the mean number of revertant colonies compared to the vehicle control (ethanol) at the highest concentration following the direct incorporation method without metabolic incubation (2.5-fold increase in TA98), pre-incubation method without metabolic activation (7.5-fold increase in TA1535) and with metabolic activation (17.9-fold increase in TA1537) and above the historical background data for the solvent. The applicant claimed that the positive results were due to precipitation without providing any evidence. A confirmatory test was carried out on *S*. typhimurium TA98, TA1535 and TA1537 at 5 mg/plate followed by a 1/3 dilution series, following both the direct incorporation and pre-incubation methods in the presence and absence of metabolic activation. None of the concentrations analysed led to an increase in the mean number of revertant colonies compared to the vehicle control in any of the strains tested.

The Panel notes that the Ames test is not appropriate to cover for genotoxic effects of nanoparticles (EFSA Scientific Committee, 2021).

The NF was also evaluated for its potential to induce micronuclei (MN) in Chinese Hamster Ovary (CHO) cells in a study in compliance with the OECD Principles of GLP and with OECD TG 487 (OECD, 2016) (Unpublished, 2021b). Two experiments were performed in duplicate with concentrations selected based on a preliminary cytotoxicity test. The cells were incubated with the NF at concentrations from 0.92 to 51.2 μg/mL for 4 h treatment in the presence and absence of S9, further incubated for 1.5–2 normal cell cycle lengths after the beginning of the treatment (short-term treatment). The cells were incubated with the NF at concentrations from 0.37 to 20.48 μg/mL for 1.5–2 normal cell cycle lengths in the absence of S9 (long-term treatment).

Precipitation was not observed at any concentration tested. Short-term treatment with 8.19 μg/mL of the NF in the absence of S9 induced 51% cytotoxicity, and the MN were scored for the samples at concentrations of 8.19, 5.73 and 3.28 μg/mL. Short-term treatment with 8.19 μg/mL of the NF in the presence of S9 induced 57% cytotoxicity and the MN were scored for the samples at concentrations of 8.19, 5.73, 3.28 μg/mL. Long-term treatment with 3.28 μg/mL of the NF induced 57% cytotoxicity and the MN were scored for the samples at concentrations of 3.28, 2.29 and 1.31 μg/mL.

No statistically significant differences were observed between the frequency of micronucleated binucleated cells in treated and vehicle control cultures in all of the experimental conditions applied and at all the concentrations tested.

The Panel notes that, for the MN test, technical adaptations to cover for small particles and nanoparticles were not considered (EFSA Scientific Committee, 2021).

3.9.2 | Subchronic toxicity

The applicant presented information from a literature search for subchronic toxicity studies on CBD in general. No studies on the NF were provided.

Considering a risk assessment conducted by the NDA Panel based on the body of evidence provided in other CBD dossiers and the data gaps identified in the Statement on safety of cannabidiol as a novel food (EFSA NDA Panel, 2022), the applicant was requested to provide reproductive and developmental toxicity studies and human data on consumption of CBD (see Sections 3.9.3 and 3.9.4).

3.9.3 | Reproductive and developmental toxicity

The applicant presented information from a literature search for reproductive and developmental toxicity studies on CBD in general. No studies on the NF were provided.

As reported above, to fill the data gaps identified in the Statement on safety of cannabidiol as a novel food (EFSA NDA Panel, 2022), the applicant was also requested to provide reproductive and developmental toxicity studies on 07/06/2022.

The applicant did not reply to this data request. EFSA contacted the applicant on three separate occasions, namely on 24/3/2025, 7/4/2025 and 24/4/25 without receiving any reply.

3.9.4 | Human data

The applicant presented information from a literature search for human data on CBD in general. No studies on the NF were provided.

As reported above, to fill the data gaps identified in the Statement on safety of cannabidiol as a novel food (EFSA NDA Panel, 2022), the applicant was also requested to provide a human study on consumption of CBD on 07/06/2022.

The applicant did not reply to this data request. EFSA contacted the applicant on three separate occasions without receiving any reply.

3.10 | Allergenicity

The Panel considers that, owing to the nature of the NF and the absence of proteins, it is unlikely that the NF will trigger allergic reactions in the target population under the proposed conditions of use.

4 | DISCUSSION

The NF which is the subject of the application is synthetic CBD.

The NF is intended to be used in food supplement for the general population above 6 years of age, excluding pregnant and lactating women.

During the risk assessment, the Panel identified data gaps that needed to be addressed by the applicant.

After the data submission in May 2022, the applicant did not reply to any subsequent request sent by EFSA for additional data regarding identity, reproductive and developmental toxicity and human data.

5 | CONCLUSIONS

Based on the available data, the Panel concludes that the safety of the NF synthetic CBD cannot be established.

ABBREVIATIONS

ADME	Absorption, distribution, metabolism and excretion
ATP	Attached Proton Test
CAS	Chemical Abstracts Service
CBD	*trans*-Cannabidiol
CFU	Colony Forming Units
CHO	Chinese hamster ovary
COSY	Correlated Spectroscopy
EMA	European Medicines Agency
GC-MS	Gas Chromatography-Mass Spectroscopy
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Points
HPLC-DAD	High-Performance Liquid Chromatography with a Diode Array Detector
HPLC-UV	High-Performance Liquid Chromatography–ultraviolet spectroscopy
HS-GC	Headspace Gas Chromatography
HSQC	Heteronuclear Single Quantum Correlation
ICP-MS	Inductively Coupled Plasma Mass Spectrometry
IR	infrared spectroscopy
IUPAC	International Union of Pure and Applied Chemistry
LOD	Limit of Detection
MN	Micronuclei
NDA	Panel on Nutrition, Novel Foods and Food Allergens
NF	Novel Food
NMR	Nuclear Magnetic Resonance
OECD	Organisation for Economic Co-Operation and Development
TG	Test Guideline
THC	Tetrahydrocannabinol
UV-Vis	Ultraviolet-Visible
SEM	Scanning Electron Microscopy

REQUESTOR
European Commission

QUESTION NUMBER
EFSA-Q-2020-00084

PANEL MEMBERS
Dominique Turck, Torsten Bohn, Montaña Cámara, Jacqueline Castenmiller, Stefaan de Henauw, Karen-Ildico Hirsch-Ernst, Ángeles Jos, Alexandre Maciuk, Inge Mangelsdorf, Breige McNulty, Androniki Naska, Kristina Pentieva, Alfonso Siani and Frank Thies.

REFERENCES
EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2016). Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. *EFSA Journal*, *14*(11), 4594. https://doi.org/10.2903/j.efsa.2016.4594

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens). (2022). Statement on safety of cannabidiol as a novel food: data gaps and uncertainties. *EFSA Journal*, *20*(6), 7322. https://doi.org/10.2903/j.efsa.2022.7322

EFSA Scientific Committee. (2021). Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. *EFSA Journal*, *19*(8), 6769. https://doi.org/10.2903/j.efsa.2021.6769

OECD (Organisation for Economic Co-Operation and Development). (1997). Test no. 471: Bacterial reverse mutation test. OECD Guidelines for the Testing of Chemicals, Section 4, OECD Publishing, Paris, 11. https://doi.org/10.1787/9789264071247-en

OECD (Organisation for Economic Co-Operation and Development). (2016). Test no. 487: In vitro mammalian cell micronucleus test. OECD Guidelines for the Testing of Chemicals, Section 4, OECD Publishing, Paris, 23. https://doi.org/10.1787/9789264264861-en (Corrected 2023).

Unpublished. (2021a). Bacterial reverse mutation test (GLP, OECD TG 471). Study No. B-03261.

Unpublished. (2021b). *In vitro* mammalian cells micronucleus test (GLP, OECD TG 487). Study no. MIC-PH-21/0522.

How to cite this article: EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck, D., Bohn, T., Cámara, M., Castenmiller, J., De Henauw, S., Jos, Á., Maciuk, A., Mangelsdorf, I., McNulty, B., Naska, A., Pentieva, K., Siani, A., Thies, F., Aguilera-Gómez, M., Cubadda, F., Marchelli, R., McArdle, H. J., Moldeus, P., … Hirsch-Ernst, K. I. (2025). Safety of synthetic cannabidiol as a Novel food pursuant to Regulation (EU) 2015/2283. *EFSA Journal*, *23*(11), e9708. https://doi.org/10.2903/j.efsa.2025.9708