Report

Joint ACNFP – COT Cannabidiol (CBD) Sub-group Phase 1 Summary Report

October 2025

Purpose of the sub-group

- CBD ingredients are classified by the FSA as novel foods, meaning any CBD-containing food or supplement must undergo FSA approval prior to legal sale in Great Britain.
- Companies selling CBD-containing foods must submit novel food applications assuring the safety of their products. As per an FSA call for data in February 2020, applicants had to submit their applications and data by 31 March 2021.
- New toxicology studies on CBD ingredients were received by the FSA, and these studies required expert technical review.
- Given the scale of the work anticipated (hundreds of CBD product applicants were expected), a new CBD Working Group was formed as a Sub-group under the ACNFP, to perform the new work and focus on the technical review of new data on CBD ingredients. This group included experts from both the ACNFP and Committee on Toxicity (COT) as below and hence was a Joint Working Group.

Members of the Joint ACNFP-COT CBD Working Group 2022-2025

The Co-Chairs for the duration of the group were the Chair of the ACNFP and toxicologist Dr Camilla Alexander-White, and Chair of the Committee on Toxicity and toxicologist Professor Alan Boobis.

Committee Co-Chairs

Dr Camilla Alexander-White - Chair of the ACNFP

Professor Alan Boobis - Chair of the COT

Committee Members

Ms Alison Austin - ACNFP

Dr Stella Cochrane - COT

Dr James Coulson - COT

Professor Gary Hutchison - COT

Professor Shirley Price - COT

Dr Mac Proven - COT

Dr Cheryl Scudamore - COT

Professor Lesley Stanley - ACNFP

Dr Simon Wilkinson - COT

Secretariat

Ben Haynes - Lead Secretariat for Subgroup

Cath Mulholland - Technical Secretary COT

Olivia Osbourne - COT Secretariat

Priscilla Wanjiru - ACNFP Secretariat

Ruth Willis - Technical Secretariat ACNFP

Tahmina Khan - ACNFP Secretariat

Afielia Choudhry - ACNFP Secretariat

Jenny Rees - ACNFP Secretariat

Victoria Balch - ACNFP and subgroup Administrative Secretariat

Dates of Meetings and Brief Purpose and Outcome of each meeting held

The Joint ACNFP-COT Working Group on CBD met 14 times in the period 2022-2025, on the dates shown in the table below. Final minutes of each meeting can be found at ACNFP and COT Joint Subgroup on CBD and Hemp Derived Products | Advisory Committee on Novel Foods and Processes.

1	27 July 2022	Introductory meeting to share background data and available toxicological evidence for CBD ingredients. *NB: It was identified early on in setting up the Working Group that there would be three types of CBD ingredient:* • *Pure ≥98% CBD (Group A),* • *CBD in mixtures of other cannabinoids (Group B),* • *CBD in hemp extracts (Group C).* *And there would be the issue of assessing the presence and safety of THC as a contaminant, given its status as an illegal drug in GB.*
2	28 September 2022	A first review was performed of new CBD toxicology data on Group A pure CBD isolates (which can be synthesised or extracted from plants) This was based on an initial high level review of the evidence received by the FSA from applicants, and in the knowledge of the COT position on CBD (2020) and an internal FSA CBD literature review performed by the FSA Science team.
3	30 November 2022	Data from the ACI Consortium on CBD was reviewed in detail – RESERVED BUSINESS.
4	17 January 2023 + extended to 13 February 2023	Data from the EIHA Consortium was reviewed in detail - – RESERVED BUSINESS. With continuation of meeting 4 in a 90-minute session in February – all available Group A CBD data were reviewed together in a technical meeting, with POD review and potential Acceptable Daily Intakes initially calculated. Three good quality studies for Pure form CBD were available.

5	8 March 2023	First Draft of a Position Paper for Group A CBD: outlining an approach to derive a provisional ADI for Group A CBD ≥98% pure. Review of literature data on other cannabinoids that could be in Group B mixtures. Data was very limited.
	March to July 2023	Completion of the Position Paper for Group A CBD was done by correspondence with the Sub-group. Joint position paper from ACNFP & COT on establishing provisional ADI for pure form CBD in foods | Advisory Committee on Novel Foods and Processes
6	3 May 2023	First review of available data for Group B CBD: including toxicology data, composition data and the possibility of new science on receptor-based activity that could be useful.
7	4 July 2023	Consideration of criteria for assessing Group B CBD in mixtures with other cannabinoids, based on the review of available data for Group B.
	October 2023	Key Milestone: FSA Published new Consumer Advice (Cannabidiol (CBD) | Food Standards Agency) for Group A CBD with a provisional Acceptable Daily Intake for CBD established at 10 mg CBD/day for a healthy 70kg adult. Given data gaps on reproductive and developmental toxicity and immunotoxicity, the sub-group stressed the importance of continuing the recommendation for labelling of CBD products to protect children, pregnant women, those try to conceive and immunocompromised individuals.
8	7 November 2023	• Continuation of the review of data for Group B CBD ingredients • Discussion of the FSA literature review on Tetrahydrocannibinol (THC) as a contaminant in CBD ingredients.

9	1 February 2024	A whole day in person/hybrid meeting in London: • Final discussions on Group B and how to handle these ingredients in novel foods, with a conclusion that they need to be treated case-by-case at the current time due to the wide variation in composition. • Presentation received from the FSA science team on the analytical issues for cannabinoids in food matrices and how this can affect compositional data. • Update provided on new data for THC.
10	22 May 2024	Review of new additional evidence on Group A CBD – check of the provisional ADI relevancy and status – all good. • Discussion on how best to apply the FSA ADI for CBD in the context of novel foods containing CBD at ≥98% pure and in the context of legal requirements for novel foods. • Mapping of the points of departure for Group B ingredients. • Review of the ADME section in the CBD template for novel foods Committee Advice Documents.
11	16 July 2024	• Review of new additional evidence on Group A CBD – check of the provisional ADI relevancy and status – all good. • First review of a Draft Statement on THC as a contaminant in foods and setting a safe upper limit value.
12	11 September 2024	• First review of the available datasets for Group C CBD ingredients with 70% CBD. General finding that these ingredients are not well characterised in terms of what other constituents are in the mixture. Toxicological review is challenging without this data. • Second review of a Draft Statement on THC as a contaminant in foods and setting a safe upper limit value.

13	6 November 2024	• Final review of a Draft Statement on THC as a contaminant in foods and setting a safe upper limit value. • Collate and review the FSA Evidence base for CBD: with special thanks to Prof Lesley Stanley for performing commissioned work to complete an excel data sheet with comprehensive detail on the toxicology data and an overview chart of the effects of CBD at critical points of departure. • Review of a key published literature review by Henderson et al 2023: confirm the Sub-group position on this review paper, based on a partial subset of data available to FSA.
14	22 January 2025	• Review of Group C data and provision of advice on how ACNFP should handle these ingredients, case-by-case. • Review of the FSA Evidence Base on CBD, with a view to handing this over to the FSA after this meeting. • Review of a published review by Lachenmeier et al., 2023, to explore the outcome of the review and the potential for using this peer review paper as a source of evidence in Group A CBD review.
	Q1 2025	Key Milestone: Completion of ‘Statement on a THC safe upper limit completed by correspondence. Joint position paper from the Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT) on establishing a Safe Upper Limit for delta-9-tetrahydrocannabinol (Δ^9-THC) and its precursor as contaminants of hemp-derived products including CBD novel foods.’ Harmonised with the work in UK by the Department of Health and Social Care on the misuse of drugs, and with the EFSA Opinion in the EU. Safe Upper Limit defined as 1 µg/kg bw/day based on scientific evidence.

Understanding the data on CBD

To provide an illustration of the data seen to date figure 1 summarises the sub chronic data submitted to support applications for 98% and above CBD novel foods. The figure identifies the doses at which effects were seen in the study reviewed. The x axis outlines the range of statistically significant effects seen for CBD and the doses at which these were observed.

As noted by the CBD Subgroup, CBD exerts a wide variety of affects and it is impossible to identify a single primary endpoint for use as a Point of Departure for risk assessment. This means that, rather than being driven by a single diagnostic endpoint, establishment of a NOAEL for any study on CBD requires a holistic assessment of all the effects observed. The CBD Subgroup based its advice on a constellation of effects, mainly those in the liver, thyroid, adrenal and kidney. The data indicates that the most sensitive effects are those on liver and thyroid and there is a gap between the effects seen and the provisional ADI to protect the population.

The data on the doses where effects were seen in the sub-chronic study are compared in figure 1 to the level established as the provisional ADI. This shows the margin between the lowest dose at which the effect was seen and the advice of the subgroup. This provides reassurance that consuming 98% purity and above CBD at 10mg a day is unlikely to lead to adverse effects.

Conclusions & Recommendations

The CBD Working Group has delivered the following:

a) A position paper – establishing a science based provisional ADI for Group A CBD ingredients ≥98% pure at 10 mg CBD/day for a healthy 70 kg adult, which has formed the basis of updated FSA Consumer Advice in October 2023. Important caveats remain about data gaps for reproductive toxicity and immunotoxicity leading to advisory statements about the protection of children, pregnant women, those trying to conceive a baby and immunocompromised individuals.

b) A position paper – deriving a safe upper limit of 1 µg/kg bw/day for the contaminant THC in CBD ingredients, based on the scientific evidence, which can be used in setting specifications and in novel foods safety assessment to ensure the safety of consumers from this illegal drug.

c) Clear advice that Group B and Group C CBD ingredients will need to be considered case-by-case by the ACNFP in novel foods applications.

d) An FSA Evidence base to underpin the justification for the Group A provisional ADI, with a useful graphic to explain how the ADI protects against all potential health effects of CBD.

Fig 1: FSA Evidence Base for Group A: A graphical representation of the data from Group A CBD ≥98% pure 90-day studies, including from the three pivotal studies that are used to establish a provisional ADI for Group A CBD ≥98% pure ingredients, Shows the provisional ADI is protective of all observed effects from CBD relevant to humans.