Minutes

Joint Subgroup of the Advisory Committee on Novel Foods and Processes (ACNFP) and Committee on Toxicity (COT) on CBD and Hemp Derived Products. Minutes of the 14th CBD Meeting held on the 22nd of January 2025

These minutes are subject to confirmation by the Subcommittee.

Members are required to declare any personal interest in matters under discussion; where Members have a particularly close association with any item, the Chairman will limit their involvement in the discussion. In cases where an item is to be discussed in their absence, a Member may make a statement before leaving.

Minutes of the 14th meeting of the Joint Subgroup of the Advisory Committee on Novel Foods and Processes (ACNFP) and Committee on Toxicity (COT) on CBD and Hemp Derived Products, held on 22nd of January 2025, online using Microsoft Teams.

Attendance

Committee Chair

Dr Camilla Alexander-White - Chair of ACNFP

Committee Members

Mrs Alison Austin - ACNFP

Prof. Gary Hutchinson - COT

Professor Gunter Kuhnle - COT

Professor Shirley Price - COT

Dr Mac Provan - COT

Dr Cheryl Scudamore - COT

Dr Lesley Stanley - ACNFP

Dr Simon Wilkinson - COT

Apologies

Professor Alan Boobis - Chair of COT

Dr Stella Cochrane - COT

Dr James Coulson - COT

Secretariat

Mr Ben Haynes - Lead Secretariat for Subgroup

Mrs Ruth Willis - Technical Secretary ACNFP

Mrs Afielia Choudhry - ACNFP Secretariat

Mr. Will Smith - ACNFP Secretariat

Dr Olivia Osborne - COT Secretariat

Miss Victoria Balch - ACNFP and subgroup Administrative Secretariat

Executive summary

At the 14th CBD subgroup meeting, members reviewed the further analysis of the toxicological profiling of hemp CBD extracts. The next steps for the Group C ingredients were confirmed and the data needed to support review by Advisory Committee on Novel Foods and Processes (ACNFP) identified.

The Subgroup discussed development of a database of the data supplied to support novel food applications and its future management and maintenance that

would be needed in the FSA, as data evolves.

Members reviewed Lachenmeier *et al* 2023CBD) in Food Supplements Pose a Serious Health Risk? Consequences of the European Food Safety Authority (EFSA) Clock Stop Regarding Novel Food Authorisation. Psychoactives. 2023; 2(1):66-75. https://doi.org/10.3390/psychoactives2010005

" href="#">(footnote), which is a published paper outlining an alternative approach to identifying an ADI for CBD. It was agreed to add the paper to the wider dataset on highly purified CBD. This formed the basis for a discussion on how published literature can be used to support review of novel food applications and minimise the use of animal studies.

1. Apologies and Announcements

The Chair noted apologies of absence had been received from Prof. Alan R Boobis and Dr. Stella Cochrane and Dr. James Coulson.

2. Welcome and introduction

The Chair welcomed the members and representatives from the FSA Secretariat.

3. Minutes from the November meeting

CBD/13/MINS

The Chair reviewed draft minutes for the November 2024 meeting with the Subgroup. Minor amendments were made to ensure the nature of the review of the studies undertaken and whether these were new to the Subgroup were clear. Referencing of papers was explored to support providing a clear basis for the discussions held. The minutes were agreed subject to minor amendments for clearance by Chair’s action.

Suggestions were made to review the minutes of the meetings in the second half of 2024 to ensure accuracy in recording the Subgroup’s views. These focused on level of detail included and the need to ensure the discussions of the hemp CBD extract dossiers clearly reflected the need for the novel foods to be fully characterised. Some points of clarification were raised to accurately capture the conclusions reached by the Subgroup.

It was noted that the thinking of the Subgroup on CBD has developed over time. It was agreed the Chair would review the body of minutes before publication to ensure they remain accurate in the context of the wider conclusions reached by the Subgroup. The minutes will be reviewed by and finalised by Chair's action, before being submitted to the FSA Publication system, and a brief report prepared to summarise the work of the Subgroup will be prepared in 2025, as this meeting in January 2025 was the final formal meeting of this CBD subgroup in this phase of the work.

4. Matters Arising

While not a formal agenda item, members were updated on action that had occurred since the previous meeting on the areas they had been discussing.

The analytical guidance on testing of cannabinoids had been updated in light of the comments received. The finalised guidance will be shared with applicants where further compositional data is needed to ensure that the data generated is robust and applicable to the novel food assessment.

Comments on the draft statement on THC as a contaminant in food had been received and the statement amended. This will now proceed for review at ACNFP and COT before publication. The use of the term safe upper limit in the statement was explored. It was noted that there was not a directly applicable term and that it was the most appropriate available and so it was agreed as the term for the statement.

Members also received an update on the CBD applications with a range of cannabinoids present. Work was ongoing with applicants to assess the relevance of the test material used in the subchronic studies to the novel foods seeking authorisation. Once complete the dossiers will move to ACNFP for further assessment.

5. Item 1 – Investigating the source of variation in the toxicological profile of group C CBD novel foods (hemp extracts) compared to the CBD content (Reserved business)

CBD/14/01

In the Subgroup meeting in September 2024 initial review of the subchronic studies submitted to support novel food applications for hemp extracts containing a range of cannabinoids, had indicated that the toxicological profile seen for these applications was not fully explained by differences the CBD content. This prompted the need for further review. A subgroup member had reviewed the data and presented to the group the findings in order to support identification of a way forward for these applications.

Following discussion, the Subgroup concluded that it was not possible to reach conclusions on subchronic studies for Group C. This included identifications of a point of departure for each of the studies.

Further information was identified as being needed on the composition of both the test items used to generate the data, and the novel food to support interpretation of the toxicological studies. This should allow understanding of the CBD content and the presence of any contaminants such as but not limited to terpenes, solvent residues, controlled cannabinoids such as THC and waxes. This would allow understanding of the role of contaminants on the effects seen.

It was noted that these substances were more complex than other CBD extracts and that fat was a significant proportion of the substance. Mixture effects could not be ruled out. In addition, the impact of the carrier for the test item and its contribution to the composition of the test substance was also an unknown.

It was reiterated that each application should be assessed on an individual basis and brought to the ACNFP for further consideration and review. Prior to the ACNFP reviews, members emphasised the need for appropriate information on composition and characterisation of the substance in order to provide a basis for interpretation of the subchronic toxicology data.

Actions from this item – The Secretariat is to go back to the applicants and request more information on the 100% constitutional profile, including relevant cannabinoids and contaminants.

The Secretariat is to bring each hemp extract CBD application to the ACNFP for further review.

6. Item 2 – Review of draft summary of FSA evidence base for CBD (Reserved business)

CBD/14/02

The Subgroup had previously considered plans to collate the evidence reviewed for novel food applications for pure >98% CBD ingredients to catalogue the body of evidence. A Subgroup member had undertaken this work, and the result was presented to the Subgroup. Members input was sought on whether the conclusions for each study had been accurately captured and considerations for the future maintenance of the data set had been identified.

Members thanked the Subgroup task lead, Prof Lesley Stanley, for collating the information and agreed the data was accurate. The conclusions for study FSACBD 023 were rediscussed and the results confirmed to ensure the basis of the NOAEL identified had been captured fully. Once the databased had been discussed and agreed, it was considered up to date to this time point and would be locked and archived by the FSA, at the end of the Sub-group's work.

A separate live version of the database would be used to capture emerging evidence. Members also highlighted the importance of cataloguing the evolving data available to support the provisional ADI. The Chair pressed the need for the FSA to seek a toxicology specialised volunteer to gather the future information, maintain and update the database, accordingly, for the mid to long term.

Actions from this item – The Secretariat discuss with Chair and appropriate members of the Subgroup the approach and way forward for a narrative report of the Subgroup' work to date.

Action: Secretariat is to determine how and who will manage the database for the future.

Action: Develop outputs for the application using study FSACBD023 for publication post confirmation of the conclusions.

7. Item 3 – Review of the Lachenmeier *et al*, 2023 and the approach used to develop an ADI for CBD (Reserved business)

CBD/14/03

At the last meeting it was noted that there is an emerging set of evidence in the public domain. Consideration is needed to understand how this could support the assessment of novel foods particularly where subchronic studies are not available.

Currently there are three sets of evidence for the safety of 98% or greater purity have been actively shared with the subgroup:

- The body of evidence used to support the novel food applications submitted to FSA and FSS.
- Henderson et al *2023a*.(footnote), - published paper of a subchronic study on 98% CBD to formulate an ADI.
- Lachenmeier *et al* 2023CBD) in Food Supplements Pose a Serious Health Risk? Consequences of the European Food Safety Authority (EFSA) Clock Stop Regarding Novel Food Authorisation. Psychoactives. 2023; 2(1):66-75. https://doi.org/10.3390/psychoactives2010005 " href="#">(footnote) - A BMD approach for deriving and ADI includes a number of references of relevance

The Subgroup's view was sought on additional references identified from Henderson *et al.,2023a*.(footnote); namely Lachenmeier *et al.,* 2023. Members commented that the data from Lachenmeier *et al* conclusions of a safe dose of 10mg/day produced using alternative methodology BMD, provides further confirmatory evidence that the provisional ADI in the UK of 10 mg CBD/day for a healthy 70kg adult is appropriate to assure consumer safety. It was recognised that the underpinning data to Lachenmeier *et al* shows similar patterns of effects to that seen in the CBD datasets reviewed by the Subgroup.

The role of this and other published data in supporting novel food applications was explored. Much of the data reviewed by the Subgroup is protected under the novel food regulation and could not be used by others without prior consent. Equally, as stated in the statement on the provisional ADI, further subchronic studies would not further benefit the understanding of CBD as a substance. Wider data to address data gaps, understanding of the impact of CBD metabolites and to explore mechanisms of action would be more beneficial.

It was noted that emerging publications on CBD, such as Henderson et al 2023a., and the sources in Lachenmeier et al., 2023 are not owned by other applicants. It was agreed that literature could provide a basis for a body of evidence approach. However, the quality assurance on literature was less than is applied to an SRO report on the testing of a substance. As such literature evidence should summarise all available papers in order to understand which had relevance to the novel food.

The question of ownership of the data was noted. Members concluded that if applicants provide a package of good quality papers and a good quality data set it will be reviewed on a case-by-case basis. It would be based on the quality of data

that is being provided and its relevance to the novel food. a good justification for why the evidence presented supports the safety of the novel food would be needed.

It was recommended that a clear set of guidance documents that relates to what the FSA would be looking for and what literature is owned by others and how they use the available literature can support novel food applications, would be helpful for applicants and minimise animal use.

The scientific validity of applying a substantial equivalence approach between new substances seeking authorisation and existing datasets was explored. This was considered scientifically valid as a means of minimising animal use. It was noted that while this was provided for under the old novel food regulation this is not available in assimilated regulation 2015/2258 EU.

Action: The Secretariat to add Lachenmeier et al 2023 and associated references to the growing evidence base of published literature on 98% pure CBD.

Action: Secretariat to consider guidance for applicants to be able to provide a valid wider body of evidence to support the assessment of 98% pure or greater CBD novel foods.

8. AOB

The Secretariat and Chair thanked members for their work on the Subgroup over the past 3 years. While there is not intended to be further meetings at this stage, the Secretariat made members aware that they would be approached if significant new pieces of evidence emerge in order to ensure the impact on the body of evidence is reviewed.

In terms of further work that may be need on CBD it was agreed that a short narrative report outlining the work completed by the Subgroup, would be useful for transparency. This could explain the evolution of the Subgroup’s views and summarise the work to date.

Members discussed that a graphical representation/depiction of the toxicology data for CBD would be quite useful for this narrative report and aid external communications relating to the ADI for CBD. This could provide an overview of the body of evidence without disclosing information data protected under the novel food regulation.

Actions from this item – The Secretariat discuss with Chair and appropriate members of the Subgroup for the approach and way forward for a narrative report of the Subgroup's work.

1. Lachenmeier DW, Sproll C, Walch SG. Does Cannabidiol (CBD) in Food Supplements Pose a Serious Health Risk? Consequences of the European Food Safety Authority (EFSA) Clock Stop Regarding Novel Food Authorisation. Psychoactives. 2023; 2(1):66-75. https://doi.org/10.3390/psychoactives2010005

2. Henderson, RG., Vincent, M., Rivera, BN., Bonn-Miller, MO and Doepker C. 'Cannabidiol safety considerations: Development of a potential acceptable daily intake value and recommended upper intake limits for dietary supplement use.' Regul Toxicol Pharmacol. 2023;144:105482. doi:10.1016/j.yrtph.2023.105482

3. Lachenmeier DW, Sproll C, Walch SG. Does Cannabidiol (CBD) in Food Supplements Pose a Serious Health Risk? Consequences of the European Food Safety Authority (EFSA) Clock Stop Regarding Novel Food Authorisation. Psychoactives. 2023; 2(1):66-75. https://doi.org/10.3390/psychoactives2010005

4. Henderson, RG., Lefever, T., Heintz, M., Trexler, K., Borghoff, S., Bonn-Miller, M. Oral toxicity evaluation of cannabidiol. Food and Chemical Toxicology, Volume 176, 2023,113778,ISSN 0278-6915. Doi:10.1016/j.fct.2023.113778.

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