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 13th CBD Meeting held on the 6th of November 2024

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 13th 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 6th November 2024, held online using Microsoft Teams.

Attendance

Committee Chair

Dr Camilla Alexander-White - Chair of ACNFP

Committee Members

Mrs Alison Austin - ACNFP

Dr Stella Cochrane - COT

Dr James Coulson - COT

Prof. Gary Hutchinson - COT

Professor Gunter Kuhnle - COT

Dr Mac Provan - COT

Professor Shirley Price - COT

Dr Lesley Stanley - ACNFP

Dr Simon Wilkinson - COT

Apologies

Professor Alan Boobis - Chair of COT

Dr Cheryl Scudamore - 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. Cath Mulholland - Technical Secretariat COT

Dr Olivia Osborne - COT Secretariat

Miss Victoria Balch - ACNFP and subgroup Administrative Secretariat

Executive summary

At the 13th CBD subgroup meeting, members reviewed an amended draft of a statement on THC as a contaminant in CBD and hemp derived products. This will be finalised by correspondence before seeking the agreement from the Advisory Committee on Novel Foods and Processes (ACNFP) and Committee on Toxicity (COT).

The subgroup discussed development of a database of the data supplied to support novel food applications for CBD. This will support formation of a database in the next few months.

Henderson et al 2023(footnote), which is a published paper outlining an alternative approach to identifying an ADI for CBD, and work by Lachenmeier et al 2023 more 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

" href="#">(footnote), were reviewed. Comparison was made to the approach in the joint ACNFP and COT statement. It was agreed to add these papers to the wider dataset on highly purified CBD.

1. Apologies and Announcements

The Chair noted apologies of absence had been received from Prof. Alan R Boobis and Dr. Cheryl Scudamore.

2. Welcome and introduction

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

3. Minutes from the July and September meetings

CBD/11/12/MINS

The Chair reviewed draft minutes for the July and September 2024 meetings with the Subgroup. The July minutes were further reviewed to allow members not present in September to comment. 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. The minutes were agreed subject to minor amendments for clearance by Chair’s action.

The minutes of the September meeting were reviewed. Suggestions were made to capture some of the detail provided elsewhere to make the minutes more focused. It was suggested that the key issue, the need for the novel foods to be fully characterised, should be brought out. The minutes will be reviewed by correspondence and finalised by Chair’s action.

4. Item 1 – Draft statement on the safety of tetrahydrocannabinol (THC) as a contaminant of foods (Reserved business)

CBD/13/01

To support the assessment of CBD and other in novel foods and hemp derived ingredients, the Subgroup had previously considered the potential to set a safe upper intake level for Δ 9 tetrahydrocannabinol (THC) as a contaminant in food. Members reviewed a revised draft of the statement which had been updated to capture more fully the available evidence underpinning the conclusions reached previously.

The group provided detailed comments on the draft. These were primarily to ensure the consistent use of terminology and clarity on scope of the work. Amendments were made to ensure the nature of the evidence considered was appropriately explained, along with the role of evidence generated by other regulators. Detailed consideration was given to the weighting of data from human studies when collected from vulnerable or limited populations and whether this could be applied to the general population. It was agreed that the explanation of the uncertainties identified should be strengthened but that no changes to uncertainty factors were needed.

Members agreed to review the cleaned draft by correspondence. Once agreed by the Subgroup, agreement would be sought from the Committee on Toxicity (COT) and the Advisory Committee on Novel Foods and Processes (ACNFP) before publication.

Actions from this item –Secretariat to work with members on refining the uncertainties section of the statement.

The Secretariat to update the draft and seek final agreement to text by correspondence.

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

CBD/13/02

The Subgroup had previously considered the potential to create a database for the data that has been reviewed on CBD ingredients. At their meeting in September the ACNFP requested that the advice of the Subgroup on the studies submitted to support CBD novel foods be summarised to support the application review process. It was noted that this would provide robust governance of the information generated by the Subgroup and used by the ACNFP.

The structure and function of the database was discussed it was noted that the data base could address three needs:

1: As a means of capturing the subgroups advice on each of the studies reviewed to support novel food applications – the RP database.

2: Capturing the wider data that underpins the provisional ADI and how this dataset has evolved with new data –ADI evidence database.

3 – The compositional information on the test items/ novel foods.

Members agreed there were benefits in considering all three aspects as time and resources allowed. A phased approach was suggested for the work. Of particular importance to the FSA was the advice on each study support applications. Members also highlighted the importance of cataloguing the evolving data available to support the provisional ADI. A volunteer from the group was sought and identified to gather the information for this purpose.

Members provided some comments on some of the information on each study that it was useful to include. This included information on the key endpoints that supported the NOAEL identified and quality measures. Best practice that could provide a framework for the database were also considered.

The subgroups views were also sought for two applications, using studies FSACBD 008 and FSACBD0016, the specifications for which had a lower range of CBD of 97% CBD, but which had tested 98% or higher materials in the toxicological studies. The individual studies had been reviewed but confirmation was sought on whether it was appropriate to apply the provisional ADI to these applications. It was agreed this was scientifically appropriate based on the data presented and would be consistent with management of applications in a similar situation.

Actions from this item – Secretariat to commission the RP database as a first phase of the work, for Subgroup review in January.

Action: Secretariat to support database work by providing the relevant background information.

Action: Secretariat to bring outputs for applications using studies FSA CBD008 and FSACBD016 for review at ACNFP.

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

CBD/13/03

As part of the discussions at September meeting ACNFP it was requested that the Subgroup review Henderson *et al.,2023a*.(footnote) It was noted the paper outlines an alternative approach to calculating an Acceptable Daily intake (ADI) as well as including further references of interest in evaluating the safety of CBD.

Members commented that the data had been previously considered as part of the wider evidence base. A detailed review of the paper and comparison of the approach of Henderson et al to that used in the Joint ACNFP COT statement was needed. It was recognised that both papers sought to use the dataset that was available to them at the time to identify an ADI or other safe intake level for CBD of 98% or above purity. The same endpoints – in particular impact on liver enzymes - was identified as important from both datasets. Similar patterns were identified in other references considering the same data, in particular *Lachenmeier et al., 2023*. The underpinning data was considered consistent to that underpinning the ACNFP and COT provisional ADI.

It was noted that while the data gathering was similar, Henderson *et al* 2023 uses a more limited data set than is available to the FSA, and applied different uncertainty factors to calculate their ADI of 30mg per day for a 70kg adult. The approach proposed in the paper then seeks to exclude vulnerable groups through use of labelling and calculate revised safe intake levels resulting in higher exposure. Due to the applications of codex principles of risk analysis the use of risk management measures cannot be taken into account in assessments. It would not be appropriate for a regulator whose primary function is to ensure consumer safety to take the approach proposed.

The paper was considered as important by the Subgroup in identifying references that may be useful to consider in maintaining a review of the provisional ADI. A

paper by Lachenmeier et al., 2023 had been identified in the Henderson et al review, and its references were highlighted as potential studies to review. It was suggested that Lachenmeier et al should be considered further at the next meeting.

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

Action: Secretariat to bring Lachenmeier et al 2023, and relevant references for Subgroup consideration at the next meeting to further develop the database of published literature.

7. AOB

The Secretariat informed members that the next meeting of the Subgroup would be the last meeting in this phase and the next steps for the work with the ACNFP.

8. Date of the next meeting

The next meeting is scheduled for Wednesday 22nd January 2025. It will be held online via Microsoft Teams as a virtual meeting.

1. 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.’â?¯Regul Toxicol Pharmacol. 2023;144:105482. doi:10.1016/j.yrtph.2023.105482

2. 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.â?¯Psychoactives. 2023; 2(1):66-75. https://doi.org/10.3390/psychoactives2010005

3. 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

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16. 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.’â?¯Regul Toxicol Pharmacol. 2023;144:105482. doi:10.1016/j.yrtph.2023.105482

17. 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.â?¯Psychoactives. 2023; 2(1):66-75. https://doi.org/10.3390/psychoactives2010005

18. 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