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 11th CBD Meeting held on the 16th of July 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 11th 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 16th July, held online using Microsoft Teams.

Attendance

Committee Chair

Dr Camilla Alexander-White - Chair of ACNFP

Professor Alan Boobis - Chair of COT

Committee Members

Mrs Alison Austin - ACNFP

Dr Stella Cochrane - COT

Dr James Coulson - 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

Prof. Gary Hutchinson - COT

Secretariat

Mr Ben Haynes - Lead Secretariat for Subgroup

Dr Tahmina Khan - ACNFP Secretariat

Mrs Afielia Choudhry - ACNFP Secretariat

Dr Olivia Osborne - COT Secretariat

Miss Victoria Balch - ACNFP and subgroup Administrative Secretariat

Executive summary

The Joint Subgroup of the Advisory Committee on Novel Foods and Processes (ACNFP) and Committee on Toxicity (COT) on cannabidiol (CBD) and Hemp Derived Products met on the 16th July 2024 to further progress the review of wider cross cutting questions on CBD safety. In the meeting, the subgroup reviewed updated group A (>98% pure CBD) datasets to review the quality of the evidence and check that new evidence did not impact on the published provisional ADI for >98% pure CBD of 10 mg CBD/day.

Further actions for the draft statement on the safety of tetrahydrocannabinol (THC) as a contaminant of foods was discussed and reviewed, with particular emphasis on the importance of document structure and consistency with referenced materials.

1. Apologies and Announcements

The Chair noted apologies of absence had been received from Prof. Gary Hutchinson.

It was explained that from the Secretariat neither Mrs Ruth Willis or Mr Will Smith were able to attend and any queries for them to address would be managed outside the meeting.

2. Welcome and introduction

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

3. Minutes from the February meeting

CBD/10/MINS

The Chair reviewed the draft minutes with the Subgroup. These were agreed as an accurate record subject to minor amendments.

4. Group A novel food applications – new datasets for review (Reserved Business)

CBD/11/02

Post publication of the provisional ADI in October 2023, 4 applicants have each since submitted a 90-day subchronic study dataset as part of their novel food applications since the intial review of the dataset (studies FSACBD004, FSACBD 008, FSACBD009, FSACBD022). The toxicology studies from each of these applications had not been previously considered as part of the development of the provisional ADI in 2023. Members were asked to advise on whether the 90-day study data for the four applications were of a suitable quality to provide scientific evidence on the safety of >98% pure CBD. In particular, whether there were any new observations in any study, or whether the observations were as

expected and consistent with the FSA knowledgebase of CBD toxicity.

Each study was reviewed and discussed individually and in detail. A Point of Departure (POD) for each study was decided upon by members of the Subgroup based on the effects seen and NOAEL identified. The study data for FSACBD004 and FSACBD022 were considered to be of sufficient quality to derive a POD for >98% pure CBD as tested in the studies. For two studies, FSACBD008 and FSA CBD009 , there were queries on the quality of the protocol applied for example, how the studies had been written up, the quality assurance measures in place and the selection of the doses the test animals received. As there was little-to-no elaboration and discussion of the implications of the results for both studies, this meant a POD could not be derived with confidence from these studies. It was recommended further information be sought from the applicant to review the studies further.

The POD for the FSACBD004 and FSACBD022, were compared to those used to generate the provisional ADI for >98% pure CBD in novel foods. It was noted that the PODs were considered reliable and, were in concordance with those studies and POD used in the development of the provisional ADI both in terms of the doses identified as No Adverse Effect Levels (NOAELs) and type of effects seen. As such, the provisional ADI could be scientifically justified to apply to these applications based on the composition of the novel food and the pattern of effects seen in the supporting 90-day studies.

The next step for these applications would be for the ACNFP to review the other aspects of the applicant’s dossiers to advise on the safety of CBD use as an ingredient in the specific novel food products in each application.

Actions from this item – The Secretariat is requested to continue the further assessment of these applications by taking the applications to ACNFP Committee for review of the wider dossier.

5. Review of the provisional ADI in light of new datasets on novel ingredients of 98% or greater purity CBD (Reserved Business)

CBD/11/02

The FSA has committed to keeping the provisional ADI for >98% pure CBD under review as new data emerges. Following the review of the new datasets for >98%

pure CBD novel foods at both the previous meeting (CBD10/2024/01, in the previous item (CBD11/2024/01) and in light of six published studies that have been provided since the original ADI's development, it was timely to consider whether the new data has an impact on the provisional ADI. Particularly whether any of the new data has addressed the uncertainties highlighted in the original assessment. Upon review, the Subgroup concluded that of the six provided studies, three had already been seen and written up within the public domain.

The Subgroup was asked to advise on whether the six published works provide any further evidence for consideration in reviewing the provisional ADI and whether the published data suggested any alterations of the provisional ADI is needed in light of this evidence. Following the review, members agreed that none of the new datasets or extra published works refined any of the uncertainties that were set when the provisional ADI was created. The studies did not alter the applied safety factors. The views expressed by members suggested the findings were consistent with the wider body of evidence considered.

The Subgroup continued to be of the view that there is now a sufficient body of evidence on the subchronic toxicology of >98% pure CBD as an ingredient that is orally consumed. The Subgroup remains confident that the provisional ADI is scientifically justifiable to apply on the basis of the evidence of liver toxicity and somnolence, and use of appropriate uncertainty factors to account for knowledge gaps, and that no further 90-day studies or indeed any further in vivo toxicology data are needed scientifically for this form of >98% pure CBD to support the provisional ADI.

It was commented that there were outstanding scientific questions and uncertainties on the differences in toxicological responses between sexes, no data on the potential for impacts to the developing child, equivocal observations relating to effects on the thyroid and data gaps on the potential impacts on cholesterol levels in the blood from consuming >98% pure CBD. However, it was noted that from the limited data available on non-hepatic effects in 90-day studies, other effects are expected to be less sensitive to CBD than the impacts on liver and somnolence in humans. As such it is expected the provisional ADI of 10 mg/day will be protective for a healthy 70kg adult consumer but there remain caveats to sensitive sub-populations such as pregnant and breastfeeding women, children and people on medications.

As outlined in the joint ACNFP and COT statement outlining the provisional ADI, if further work is to be conducted this would be better to focus on human studies particularly in relation to bioavailability studies of CBD in different food matrices

to enable more evidence based kinetic factors to be considered.

It was the Subgroup’s view that the provisional ADI remain subject to the existing advice to consumers that pregnant and breastfeeding women and people taking any prescription medication should avoid the consumption of CBD if possible. Consumers on regular medications should seek advice from a medical professional before using any type of CBD food product. In addition, children, prospective parents trying for a baby and those who are immunosuppressed are advised against consumption of CBD due to remaining data gaps and residual uncertainties concerning the safety of CBD for these groups of consumers.

6. Item 3 – Draft statement on the safety of tetrahydrocannabinol (THC) as a contaminant of foods (Reserved business)

CBD/11/03

To support the assessment of CBD and other cannabinoids as ingredients in novel foods, the Subgroup had previously considered the potential to set a safe upper intake level for tetrahydrocannabinol (THC) as a contaminant of food as carried over with the CBD/cannabinoid ingredient. At present the ACNFP are including a section in Committee Advice Documents (CADs) relating to the THC contaminant levels. THC contamination is a generic issue for food where cannabinoids are present and as such it is considered appropriate to develop a generic statement on safe levels of THC that can then be applied to all novel foods dossiers where cannabinoids are used as ingredients.

A general safety evaluation for THC in food was drafted by the FSA. Members comments were sought to refine the text with a view to seeking agreement to a joint statement of with the Committee on Toxicity (COT) and the Advisory Committee on Novel Foods and Processes (ACNFP) to be published later this year.

It was noted that the draft would benefit from refinement to ensure the narrative and the evidence used to support the conclusions reached were clearly explained. Most of the scientific points were there, but the drivers and logic for the development of the statement could be improved in this first draft. Members highlighted the importance of a list of abbreviations and consistency in the terms used to aid clarity.

It was noted that further work was needed to refine the statement. In particular, to be clear on the purpose of the need for this statement from the FSA, and in the context of work on THC by other regulators, both in the UK the Advisory Council on the Misuse of Drug (ACMD), in Europe (European Food Safety Authority (EFSA)) and in other countries such as Canada. There are known chemical isomers of THC, but in terms of the cannabinoid substance to be considered here, it was agreed the statement would focus wholly on Δ9-THC as this is where the evidence is currently available. Members also emphasised the importance that the evidence for THC, based mainly on acute psychoactive effects, enabled an Acute Reference Dose (ARfD) to be defined and not an Acceptable Daily Intake (ADI).

Members also considered to what extent the statement should be consistent with the work of the ACMD on THC in consumer products. It was noted that the ACMD work had considered THC as a contaminant in CBD-containing consumer products and members were keen not to duplicate or be inconsistent with the work that had been done, for example if a different evidence base was being used- this should be checked. It was agreed to consider the ACMD statement on CBD-containing consumer products offline with the potential for further discussion on this as a group as needed.

Members noted that the current statement makes use of the work undertaken by EFSA using the available evidence at the time. As this was completed in 2015, it was considered prudent to double check if the literature review that had been undertaken to support the earlier subgroup discussion had adequately addressed the emerging literature in this active field of study. It was agreed to do this alongside further development of the statement.

Actions from this item – The Secretariat is requested to provide the Subgroup with a copy of the ACMD recommendations and continue discussions as needed.

Secretariat to further development of the THC as a contaminant draft statement, in light of the points raised.

7. Date of the next meeting

The next meeting is scheduled for Wednesday 11th September 2024. It will be held online via Microsoft Teams as a virtual meeting.