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 8th CBD Meeting held on the 7th of November 2023

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 8th 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 7th of November 2023, online using Microsoft Teams.

Attendance

Committee Chair

Professor Alan Boobis - Chair of COT

Committee Members

Mrs Alison Austin - ACNFP

Dr Mac Provan - COT

Dr Stella Cochrane - COT

Professor Gunter Kuhnle - COT

Dr Cheryl Scudamore - COT

Prof. Gary Hutchinson - COT

Dr Lesley Stanley - ACNFP

Apologies

Dr Camilla Alexander-White - Chair of ACNFP

Dr James Coulson - COT

Professor Shirley Price - COT

Dr Simon Wilkinson - COT

Secretariat

Mr Ben Haynes - Lead Secretariat for Subgroup

Mrs Ruth Willis - Technical Secretary ACNFP

Dr Tahmina Khan - ACNFP Secretariat

Mrs Afielia Choudhry - ACNFP Secretariat

Mr. Will Smith - ACNFP Secretariat

Dr Olivia Osborne - COT Secretariat

Miss Victoria Balch - ACNFP and subgroup Administrative Secretariat

Miss Sophy Wells - 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 CBD and Hemp Derived Products met on the 7th November to further progress the review of wider cross cutting

questions raised by CBD. The meeting reviewed the further proprietary datasets available to the FSA for the group B CBD ingredients. A literature review on the toxicological effects of THC cannabinoids and how this can be applied to assessing THC as a contaminant in CBD products was also explored. Several areas were identified that need to be addressed in order to proceed with the safety assessment of CBD Novel Food applications containing a range of cannabinoids, and these will be explored further at the next meeting.

1. Apologies and Announcements

Apologies were received from Dr. Simon Wilkinson, Dr. Camilla Alexander-White, Dr. James Coulson and Prof. Shirley Price.

2. Welcome and introduction

The Chair welcomed the members, representatives from the FSA, the observers and the Secretariat team.

3. Minutes from the July meeting

CBD/07/MINS

The Chair reviewed the draft minutes from the July Minutes with the Subgroup. These were agreed as an accurate record subject to minor amendments and finalisation by Chairs action.

4. Item 1 – Group B CBD Ingredients Update Paper (Reserved Business)

CBD/08/01

Members reviewed in detail two further studies submitted to support group B ingredients. The first study (unique identifier FSACBD023) was with a 97% pure CBD preparation. Members considered the study had been appropriately conducted. It was noted that in interpreting the study, the test item NOAEL needed to be adjusted to take account of the CBD content. This resulted in a NOAEL for the novel food component of the test item that was consistent with the NOAELs of the studies used to establish the ADI for 98% pure CBD novel foods.

The Subgroup expressed the view that direct toxicological read across from the ADI for CBD to ingredients with compositions that were below 98% CBD was not possible, given the potential impact of other cannabinoids and non-cannabinoid constituents. However, in this case the toxicological evidence suggested this preparation has a similar toxicological profile to pure form CBD and so application of the ADI for CBD is appropriate. It was noted that variability introduced by the production process would need to be considered in evaluating the preparation as a novel food and that that the applicant's specification suggested the product is consistently 97% or greater CBD.

The second study (unique identifier FSACBD003) was for a preparation with 85% CBD. It was noted that to interpret the toxicological data, information on the other substances present would be important. Particularly in relation to any impurities present that may influence the toxicological profile of the novel food. Detailed consideration of the methodology was undertaken. Queries were raised on the study design and further information sought on the pathological examinations to ensure that the conclusions could be interpreted appropriately.

Action - Secretariat to seek further information from the applicant for study 2 to inform the novel food assessment.

Wider issues were raised including that the potential impact of growth conditions on the composition of the hemp starting material would need to be considered. For example, evidence from tobacco analysis indicates that the level of active substances can vary significantly as a result of growth and storage conditions. It was noted that this data was available in the novel food applications and could be reviewed further.

Members reiterated the need to review accurate compositional information for the novel ingredient to support interpretation of the data. This would be particularly important for group B novel foods. Both the analytical question and management of group B assessments will be considered again at the next Subgroup meeting in February 2024.

5. Item 2 – THC Literature Review (Reserved business)

CBD/08/02

The Subgroup reviewed data on the toxicity of tetrahydrocannabinol (THC) consumed orally, identified through a literature search performed by the FSA.

The Subgroup commented that the data set was limited and that a scientific opinion published by the European Food Safety Authority on THC as a contaminant of milk and foods of animal origin could serve as a core dataset to inform this question. Members advised that the approach used in the scientific opinion was a standard one and was suitable to identify a level of THC as a contaminant that would be sufficiently protective in the context of food safety.

The Subgroup agreed with the lowest observed adverse effect level (LOAEL) extracted from the literature of 1 µg/kg bw day. However, it was advised that further data would be needed to reach firm conclusions on the safety of THC after chronic exposure (through consumption of CBD novel foods). These included information on the use level of THC in edible forms of cannabis, information on the reproductive toxicity of THC and information on whether there was an impact on the absorption or action of either THC or CBD if co-consumed.

The recommendations of the ACMD for THC in CBD novel food products was also discussed. Further information was sought from the Secretariat on the potential levels of THC that could be permitted in CBD novel foods if the recommendation was enacted. This should also be compared to the LOAEL identified from the literature. The further data would inform discussion of whether the recommendation of the ACMD was likely to be sufficiently protective in terms of food safety. Members also sought tabulation of the key findings from the literature review to support further discussion at the next available Subgroup meeting.

Actions from this item – The Secretariat is requested further evaluation of the literature data and how the recommendations of the ACMD compare to the LOAEL derived from the review.

6. Date of the next meeting

The next meeting is scheduled for Thursday 1st February 2024. It will be held in person and online via Microsoft Teams as a hybrid meeting.