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 6th CBD Meeting held on the 3rd of May 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 6th 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 3rd of May 2023, online using Microsoft Teams.

Attendance

Committee Chair

Professor Alan Boobis - Chair of COT

Committee Members

Dr Camilla Alexander-White - Chair of ACNFP

Mrs Alison Austin - ACNFP

Dr Stella Cochrane - COT

Dr Lesley Stanley - ACNFP

Dr Mac Provan - COT

Professor Shirley Price - COT

Professor Gunter Kuhnle - COT

Prof. Gary Hutchinson - COT

Apologies

Dr Cheryl Scudamore - COT

Dr James Coulson - 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 Cath Mulholland - Technical Secretary COT

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 has considered the introductory datasets available to the FSA for the group B CBD ingredients during their meeting on 3rd May 2023. They identified several issues that need to be addressed in order to proceed with the safety assessment of CBD Novel Food applications containing a range of cannabinoids.

1. Apologies and Announcements

Apologies were received from Dr. Simon Wilkinson, Dr. Cheryl Scudamore and Dr. James Coulson.

2. Welcome and introduction

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

3. Minutes from the January and March meetings

CBD/04/05/MINS

1. The Chair noted that the status of minutes from the previous Subgroup meetings was to be addressed by the lead Secretariat.

The lead Secretariat thanked the members for their continued patience whilst awaiting the package containing the minutes which had been reviewed by FSA staff. The Secretariat explained that the package was to be circulated to the Chair in the coming week and would therefore become available to subcommittee members as early as possible to allow further commentary, in time for comments by the next meeting date.

4. Item 1 – CBD Group B introductory paper

CBD/06/01

2. The Subgroup were provided with an introduction to the range of datasets to expect from the Group B focused meetings. The introductory paper incorporated the results of three detailed studies, in order to provide a reliable depiction of the

range of compositions and results that Group B will bring compared to the previous Group A discussions.

3. The need to consider all the data provided in the studies and critically evaluate the conclusions was noted. An area of particular focus was the clinical pathology reports in order to verify if the conclusions reached by the study teams were robust.

4. Within the studies presented a range of compositions were seen with differing levels of the non-CBD cannabinoids. It was proposed by the Chair that it would be useful to check if there is a standard analysis that applicants and the laboratory companies are using to determine cannabinoid levels and other product constituents e.g., terpenes. In order to have a clear basis for considering products with a range of cannabinoids. It was recognised that currently while there was some consistency in the cannabinoids analysed this was yet to be standardised and limited data was available on the quality of the analysis in the challenging matrices of foodstuffs. This was recognised as an uncertainty in analysing the composition of cannabinoid food ingredients.

5. Members also discussed the potential for stability issues in this group of CBD ingredients, with emphasis on the ability for CBD to undergo conversion to THC/CBN being of particular concern. The Chair also raised the consequences of not analysing any long-term stability results on batches being kept long term and whether stability of other components is being accurately considered by the applicants. It was explained this data is submitted as part of the application and could be shared with members.

Action: Secretariat to provide a summary of the stability data for the group B applications to inform Subgroup discussions.

Members continued with a review of the studies. Members declared that the three 90-day studies provided were consistent with previous views expressed for highly purified CBD ingredients, including the conclusions made for Group A products despite the compositional differences. It was noted that the group B ingredients had some unknown / other cannabinoid content. The Chair proposed that there is a need to define how much of an unknown can be allowed in these products and the conclusions on CBD as a substance still apply. The observed levels of unknowns which range from 15-20% could potentially require their own 90-day study. This will become one of the initial outputs from the Subgroup for Group B ingredients.

7. Members raised the question of whether terpenes are a concern in the Group B application. It was suggested that terpenes are a normal constituent of the diet, so the Subgroup should not be worried about these being present in compositional analyses.

8. It was concluded that the Subgroup should be able to use the 10mg/day CBD allowance for Group B studies, for products where CBD is the main constituent and other cannabinoids and constituents are at low levels. This would be confirmed by review of the 90-day study to ensure that the toxicological data was consistent with the effects seen for CBD as a substance.

9. The idea that the Subgroup should have specifications, that if the product matches, was proposed and was agreed to be a sufficient method of analysing the differing compositions of each application. Levels would need to be set for total other cannabinoids and CBG as a more prevalent cannabinoid in the ingredients. However, members would need to consider bioavailability and further bridging studies to demonstrate comparability.

10. Members considered how the data gaps for ingredients with a range of cannabinoids and a relatively high amount of CBD could be managed. It was noted that additional data on individual cannabinoids could be helpful. Taking CBG as an example, given its prevalence in the data, one high quality 90-day study was considered sufficient to be used as a read across study for CBG, as a minor constituent in an ingredient. This was on the basis that CBD would always contribute the most to any effects seen due to a higher level of the cannabinoid being present in the compositional analyses. As such if the data was to be generated a consortium approach would be beneficial.

5. Item 2 – Cannabinoid composition and receptor activity paper

CBD/06/02

11. A paper was presented with two sets of information. The first dataset was a summary of the cannabinoid composition of all of the Group B CBD ingredient applications. This had been used to inform a search of the available literature to identify the available knowledge cannabinoid receptor activity for those cannabinoids identified as being present in Group B ingredients. These data were presented to members for comment and further discussion.

12. The discussion, by approaching this paper via a pharmacology point of view, highlighted the fact that the paper was missing essential pharmacology data on the potency of the cannabinoids on the receptors. The Secretariat agreed to collate information on the KDI values for these receptors for consideration at the next meeting on this topic. It was concluded that if the potency was in the range of 0.1-1%, there would be no concern as the exposure to these cannabinoids would be trivial compared to exposure to CBD from the ingredient.

13. Members discussed the concept of entourage effects, where the suggestion is that there are other components that may not directly affect the receptors, but they may have an allosteric effect, alter metabolism and initiate secondary receptor pathways with the potential to alter the effects seen in the studies. The effects of cannabinoids in a mixture form were also identified as an area of uncertainty. It was proposed that it would be useful to collate the data available on entourage effects, due to the topic becoming an emerging issue amongst cannabinoid studies.

14. The potential for the above issues to affect the discussions of Group B was deemed relatively low risk. Members agreed that it would be beneficial to start relating any of the observations in relative potency measures between cannabinoids that also relate back to the mechanisms of toxicity that are being observed.

15. Members also discussed the possible synergistic effects between cannabinoid receptor activity and the type of product i.e., vaping products and the harshness of nicotine effects when administered in this form.

Actions from this item – The Secretariat is to gather more quantitative information and separate these into direct or indirect effects. Particular emphasis was given to species differences, the potency of the doses in the form of KDI values.

6. Date of the next meeting

The next meeting is scheduled for Tuesday 4th July 2023. It will be held online via Microsoft Teams.