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 10th CBD Meeting held on the 22nd of May 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 10th 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 May, 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 Mac Provan - COT

Professor Gunter Kuhnle - COT

Dr Cheryl Scudamore - COT

Prof. Gary Hutchinson - COT

Dr Lesley Stanley - ACNFP

Dr Simon Wilkinson - COT

Dr James Coulson - COT

Professor Shirley Price - COT

Apologies

Dr Stella Cochrane - 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

Dr. Cath Mulholland - Technical Secretary COT

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 22nd May to further progress the review of wider cross

cutting questions on CBD safety. In the meeting, the subgroup reviewed updated group A (98% purity or above CBD) datasets to move forward the assessment of these applications with the ACNFP.

Possible further actions for management of the group B CBD novel foods with a range of cannabinoids present were explored in light of a mapping exercise to visualise the dataset. A decision was reached to manage applications with a range of cannabinoids present on a case-by-case basis due to limitations in the available data.

1. Apologies and Announcements

The Chair noted apologies of absence had been received from Dr Stella Cochrane.

2. Welcome and introduction

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

3. Minutes from the February meeting

CBD/09/MINS

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

4. Item 1 – Group A novel food applications where a new dataset has been provided (Reserved Business)

CBD/10/01

The Subgroup were requested to review new datasets provided for a pair of applications and their associated partners. The Subgroup had previously advised that the original datasets supplied could not support the toxicological evaluation of the novel food. This was raised with the applicants in January 2024 and new datasets had been provided to support these applications.

The Subgroup was asked whether the new datasets were now of a suitable quality and on appropriate test materials to allow a conclusion on the toxicological safety of the novel food to be reached for each application. Once a decision was reached on whether the new dataset could support the safety of one of the applications which had associated partners, members were also asked whether the dataset could be used to support the partner applications for CBD novel foods of 98% or greater purity, seeking to use it.

Review of the application with associated partners (unique identifier FSACBD006)

Following the review, members raised concerns that specific laboratory information had been redacted. This was information that is used to understand if good laboratory practice has been followed and the quality assurance that has been applied to the study. It is common practice for experts to review confidential information when it is necessary for the assessment.

The Subgroup did note that there was no new evidence that warranted any toxicological concern regarding the administration of CBD. The Subgroup concluded a No Adverse Effect Level (NOAEL) from the study as a Point of Departure (POD) for this CBD novel food of 80 mg/kg bw/day. The point of departure was comparable with the range of points of departure identified in development of the provisional ADI. When the safety factors identified for the ADI were applied to the POD, i.e. 80 mg/kg bw/day /(10x10x3), this led to an upper intake level of 0.27 mg/kg bw or 18.7 mg/person/ day for a healthy adult. The Subgroup considered it appropriate for the provisional ADI for 98% or above CBD to be applied as it was consistent with the toxicological profile of CBD seen in the data to date.

Further discussions were held regarding the available data for the associated partners and their products and concluded that conclusions would ultimately be based upon the matrices in which the data had been generated and each novel food applied for. However, in principle the toxicological data presented would be relevant for the other 98% CBD applications it is intended to support, so long as the other 2% composition did not highlight areas of concern.

Review of the applications with no associated partners (Unique identifier FSACBD005)

The Subgroup reviewed the new study which was in the form of published literature. Limitations in the data presented were identified which reflected that it

was not a full 90-day study report. These included a lack of information on the composition of the test item to allow interpretation of relevance to the novel food seeking authorisation.

Members also noted the suggestion that the 98% CBD item tested did not have adverse effects at the doses administered and agreed the NOAEL identified in the study of 50 mg/kg/bw/day was appropriate. However, the highest dose tested was lower than the lowest point of departure used to generate the provisional ADI. As such, it was concluded that the study did not contribute to the dataset as there is no information on the level at which adverse effects would be found and is outside the current range of data. To include the data set would only lower the provisional ADI, and the evidence presented did not suggest new risks not already taken into account by the current level.

On this basis of the discussion, the Subgroup considered the substance safe, primarily based on the provisional ADI. However, alone the data is not of sufficient quality to contribute to the dataset of 98% and above CBD and support the positive assessment of the novel food. The data presented was consistent with the toxicological profile of the novel food and could be considered safe if the wider dataset was taken into account.

A general point was raised that scientifically it would be appropriate to assess applications on the basis of compositional data and the provisional ADI if above 98% purity and the remaining 2% composition did not raise concerns. The additional studies to date have not indicated new effects or areas of concern that would deviate from the toxicological profile of CBD that has been generated from the data from CBD novel foods. As stated in the statement on the provisional ADI the Subgroup continued to view additional 90-day studies being generated on 98% CBD products as not a good use of resources to further the understanding of CBD and cannabinoids consumed as foods in such products. However, the Secretariat noted that the provisions of data sharing under the regulations may impact on to what extent this could alter the approach applied by the FSA in assessing the applications.

Actions from this item – The Secretariat to gather further information from the applicant of the dossier with multiple partners to ensure the study meets quality assurance standards.

Secretariat to consider the options available how to take forward the dossiers for review at ACNFP.

Secretariat to consider the implications for assessment of the advice of the subgroup on where additional data would support the ongoing assessment of 98% purity or above CBD novel foods.

5. Item 2 – Consideration of further information to support the review of the toxicology of four RPs as novel foods (Reserved Business)

CBD/10/02

In January, the applicants for using studies FSACBD002, FSACBD012, FSACBD013, FSACBD015 were asked further questions about their studies to inform a view on the datasets and whether they demonstrate the products are safe. Members were asked to advise on whether the four 98% CBD or greater applications where clarifications had been provided following the original review of the dataset were of a suitable quality to support safety of novel foods seeking authorisation.

Each response and the impact of the response on the dataset previously reviewed was discussed. A POD for each study was decided upon by members of the Subgroup based on the effects seen and NOAEL identified. The applications were concluded to be of sufficient quality to support the toxicological safety of the respective novel foods.

The points of departure were compared to those used to generate the provisional ADI for CBD novel foods of 98% or above purity. It was noted that the points of departure were in line with those used in the development of the provisional ADI both in terms of the effects seen and the doses. As such the provisional ADI could be scientifically justified to apply to the applications. These dossiers can now move to ACNFP for review of the other aspects of the dossiers.

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.

6. Item 3 – Characterisation and NOAEL data mapping and roundtable decision making on future assessment options to support the review of CBD novel food ingredients for Group

B (applications with a range of cannabinoids present) (Reserved business)

CBD/10/03

At the previous discussion of group B applications with a range of cannabinoids present Members had requested the Secretariat map the NOAEL data for each end point for this group of applications to better visualise patterns in the data. It was noted that while there was some variation, the greater the purity, the greater consistency in the doses and the adverse effects that influenced the NOAEL identification. Uncertainty remains as more of the mixture consists of other cannabinoids or impurities as there is not a volume of published data to support the interpretation of the impact of the other cannabinoids on the toxicological profile.

It was noted that while similarity is seen in the data for group B applications there are greater uncertainties including the absence of human data for group B. The safety evaluation of other cannabinoids in Group B products would largely rely on in vivo toxicology data available in the public domain or submitted by applicants. The presence of a range of different cannabinoids in different novel foods made interpreting the study results from mixtures more difficult, especially in the context of the lack of data on effects individually for other common cannabinoids present in the mix. Overall, while study to study variability was high, members agreed that the pattern of liver effects for high level CBD (e.g. 60-98% w/w) in Groups B products were similar to those seen for Group A studies, with liver effects occurring at similar doses once the data was corrected for CBD content.

Based on the visualisation of the data from the novel food applications three possible approaches for managing the assessment of group B CBD ingredient applications were explored.

The Subgroup discussed the potential to build on the provisional ADI of 10 mg per day for CBD applying an additional uncertainty factor to the provisional ADI for the missing human data for group B cannabinoids and the unknown effects of the other cannabinoids. To take such an approach of applying an extra assessment factor would be invoking the precautionary principle in the absence of scientific evidence. It was considered that there was insufficient data on both the characterisation of the novel foods and of the effect of individual cannabinoids to identify an appropriate safety factor at this time.

Members also explored the potential for an innovative assessment approach, new for use in food assessment but used elsewhere that could be applied, where all the data from the novel food applications could be used in an ‘interpolation approach’. This would allow a view on the safety of any CBD novel food based on a specification of cannabinoids and other impurities compared to similar data for the material used to generate the toxicological dataset. As such the safety of a novel food would be based on the data provided by others.

To apply this approach high quality data would be needed on the analytical composition of the test substances used to generate the data and the novel foods seeking to use it. At this stage the Subgroup does not consider that they have that data. Therefore, the interpolation approach cannot be deployed but remains available for the future.

This meant that the approach adopted was to consider the group B applications on an individual basis. Applicants’ toxicology studies that related directly to a Group B product can be used to determine a point of departure on a case-by-case basis, if data quality allows. Reading across from one Group B product to another, without characterisation data on the different products, was not considered possible. As such, at present it was not possible to identify for the consortium that the data presented could support the other applications it was intended to support.

Actions from this item – The Secretariat is requested to continue to explore further development of the interpolation approach to be published in the form of a statement.

Secretariat to manage the review of the group B applications where data on the novel food has been submitted for review by ACNFP.

Secretariat to explore a way forward for consortium applications where a number of novel foods with different compositions are seeking to use a single dataset.

7. Date of the next meeting

The next meeting is scheduled for Tuesday 16th July 2024. It will be held online via Microsoft Teams as a virtual meeting.