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 5th CBD Meeting held on the 8th of March 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 5th 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 8th of March 2023, online using Microsoft Teams.

Attendance

Committee Chair

Dr Camilla Alexander-White - Chair of ACNFP

Committee Members

Professor Alan Boobis - Chair of COT

Mrs Alison Austin - ACNFP

Dr Cheryl Scudamore - COT

Dr Stella Cochrane - COT

Dr Lesley Stanley - ACNFP

Dr Mac Provan - COT

Professor Shirley Price - COT

Dr Simon Wilkinson - COT

Professor Gunter Kuhnle - COT

Prof. Gary Hutchinson - COT

Apologies

Dr James Coulson - COT

Dr Cath Mulholland - Technical Secretary COT

Dr Olivia Osborne - COT Secretariat

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

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 CBD and Hemp Derived Products has considered a final draft of the updated position paper for pure form CBD products

and a cannabinoid literature review during their meeting on 8th March 2022. They identified several aspects that need to be revised and updated in order to finalise the Subgroup's position on CBD ingredients with greater than 98% CBD.

1. Apologies and Announcements

Apologies were received from Dr. James Coulson, Dr. Cath Mulholland and Dr. Olivia Osborne.

2. Minutes from the 4th meeting

The Chair welcomed the members, representatives from the FSA, the observers and the Secretariat team. The Chair noted that the status of minutes from the previous Subgroup meetings was to be addressed by the lead Secretariat.

Minutes

The lead Secretariat thanked the members for their continued patience whilst awaiting the package containing the minutes from 17th January 2023 which had yet to be reviewed by FSA staff. The Secretariat explained that the minutes should be made available to subcommittee members for further commentary in the coming weeks.

3. Pure form CBD position paper (Reserved Business)

CBD/05

The Subgroup were provided with an updated draft of the pure form CBD position paper, which summarises the decisions and advice concluded thus far by the Subgroup on pure form CBD products. The position paper will incorporate the package of evidence and reasonings for the Subgroup's decision to update the consumer advice on CBD administration and the updated evidence that is required of the applicants.

The identification of the provisional ADI for pure form CBD products by the Subgroup during their previous meetings allowed the group to make some initial conclusions and build upon the advice already provided to consumers on consuming CBD in foodstuffs. For this meeting, the FSA provided the final draft which collated all of the necessary conclusions into one document. The FSA also

requested that the Subgroup provide an indication as to whether the draft position paper in its current form could be cleared by the parent committees or whether further refinement was required.

Members reviewed the draft and considered the narrative and overall message that would ultimately be presented to applicants to ensure they are updated accordingly with the new advice. Additionally, the Subgroup considered the toxicological parameters and whether the whole body of evidence would provide further support for the previously derived toxicological point of departure, for which toxicological effects/endpoints and whether there were any outstanding evidence gaps. Considerations were made by the Subcommittee on the draft as follows:

Members recommended a number of areas where the wording could be tightened to more clearly explain the considerations of the Subgroup. This included being more precise on the use of toxicological terms such as provisional ADI so these were being used correctly and consistently.

Members also emphasised the need to restrict comments in the paper to the oral exposure route. It was noted that consumers were exposed to CBD from a number of routes but that the regulatory scope for the paper was food consumption.

Members agreed that the summary and conclusions sections should clearly outline both the aims and objectives of the Subgroup and follow with a statement that clearly expresses the updated advice in clear, layman’s terms. It was decided that the summary should not include an account of the history of CBD validation, it should only emphasise the new advice, the conclusions made by the Subgroup and pure form CBD products of ≥98% purity. This was to give clarity to users of the statement and in particular the general public.

The Subgroup suggested the statement should clearly explain that the data for the current position paper and review was driven by applicants wanting to market CBD products. This new data was being generated to support applications and was integral to having a basis for review. It was also suggested that the statement should explain the original work done by COT and COM and how this formed the foundation for the new work following further data being requested and provided by applicants.

Members recommended that there should be emphasis in the statement on the impacts of the review for potentially vulnerable groups. This was part of a wider

call to be clearer on the sources of scientific uncertainty in the assessment and the impacts this has on the conclusions that can be reached. This would form the basis for explaining the nature of the uncertainty factor selected.

The uncertainty section was linked to the commentary on the outstanding data gaps and how these could be addressed by further studies. The Subgroup was keen to emphasise that they no longer required further animal studies for their work. In their view the focus going forward will be on the human study evidence that is presented to the Subgroup.

Overall, the Subgroup concluded that the Secretariat needed to revise the draft position paper further before seeking clearance. The Secretariat agreed to provide a revised draft to members by the following week for comment via correspondence.

Action: Secretariat to revise position paper in line with comments received from Members for further input by correspondence.

4. Item 2: Cannabinoid literature review

The Secretariat introduced item two on the agenda; the Cannabigerol (CBG) cannabinoid literature review paper skeleton which collates the results of a scoping search of literature that might be used to determine an ADI and observe the availability of literature on other cannabinoids. The main focus was CBG, as early observations are depicting CBG and THC as the most prevalent cannabinoids.

The Secretariat sought the views of members on whether the data identified was sufficient to support their review of CBD ingredients with significant levels of other cannabinoids. Of particular interest was the impact of the data on the review of Group B and C ingredients where other cannabinoids are present alongside CBD.

The Subgroup discussed the literature articles on CBG in the context of using the data to determine an acceptable daily intake (ADI) for CBG alone. It was advised that setting an ADI from the literature provided would not currently be possible, due to the lack of data identified.

The Subgroup advised that setting an ADI for each individual cannabinoid would not necessarily provide an adequate basis for a safety assessment of broad-spectrum CBD products which contain a range of cannabinoids. Members

explored the data that would be needed. It was suggested that studies comparing the effects of cannabidiol and cannabigerol, as well as other cannabinoids, may be useful in determining their potency when consumed alone and in combination contributing to the weight of evidence for these ingredients.

An approach to gathering the information required for a safety assessment of contaminant cannabinoids in broad spectrum CBD products was discussed by the Subgroup. The Subgroup advised on the kind of information and data to draw from the available literature; helping to inform decisions on safe levels of consumption. It was suggested that literature surrounding cannabinoid-receptor targets, activity, and mechanism of action, would provide a useful basis for future decisions on what further information is required to inform safety assessments of broad-spectrum CBD products. This information would also provide a basis to understanding the interactions and potential synergies between various cannabinoids.

The Subgroup also suggested that further data on the cannabinoid composition of broad-spectrum CBD products would help provide direction to what information is required to assess the safety of contaminant cannabinoids when consumed as part of a CBD product.

Action: Secretariat to collate composition information on the cannabinoid content of applications received for ingredients containing other cannabinoids for Subgroup review.

The Subgroup discussed how to approach the current gaps in the data on composition of cannabinoids in CBD products. It was concluded that there is not currently enough information about both the composition and the potency of the minor cannabinoids to provide advice on the levels of contaminants that would be a safety concern. However, the application of uncertainty factors was suggested to be a possible approach to mitigating the unknown risks associated with the presence of other, minor cannabinoids. The gathering of human evidence data by industry was determined to be beneficial to the Subgroup as they could then utilise post market monitoring data and New Approach Methodologies (NAMs).

Given the data gaps members suggested that a review of studies may need to be on an individual basis. It was concluded that the Subgroup could not extrapolate an ADI based on one individual cannabinoid to another cannabinoid in CBD products and would therefore be observing each application on a case by case, product by product basis.

5. Date of the next meeting

The next meeting is scheduled for Wednesday 3rd May 2023. It will be held online via Microsoft Teams.