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 12th CBD Meeting held on the 11th of September 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 12th 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 11th September 2024, 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

Prof. Gary Hutchinson - COT

Dr James Coulson - COT

Professor Gunter Kuhnle - COT

Dr Mac Provan - COT

Dr Cheryl Scudamore - COT

Dr Simon Wilkinson - COT

Apologies

Dr Stella Cochrane - COT

Dr Lesley Stanley - ACNFP

Professor Shirley Price - COT

Secretariat

Mr Ben Haynes - Lead Secretariat for Subgroup

Mrs Ruth Willis - Technical 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 cannabidiol (CBD) and Hemp Derived Products met on the 11th September 2024. The subgroup reviewed the dataset submitted for Group C CBD ingredients that contained a range of other cannabinoids and lower than 70% CBD, for the first time. Advice was provided on the quality of the evidence and whether there were trends in the data that should be considered in the novel food assessment. Members also reviewed a draft of a statement on THC as a contaminant in CBD and hemp derived products. Following

revision based on member comments, this will be considered again in the November meeting.

1. Apologies and Announcements

The Chair noted apologies of absence had been received from Dr. Stella Cochrane, Dr Lesley Stanley and Prof. Shirley Price.

2. Welcome and introduction

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

3. Minutes from the July meeting

CBD/11/MINS

The Chair reviewed the draft minutes with the Subgroup. These were agreed to be an accurate record of the meeting subject to a check on the recorded ‘six new studies’ statement in Section 5. As LS was not present and knew the detail, this point would need to be checked following the meeting and appropriate amendments made to the minutes to assure technical accuracy in Section 5. Once amended the minutes would be cleared by Chair’s action.

4. Introduction to the subchronic datasets for CBD novel foods with a range of cannabinoids present and CBD below 70% (Reserved Business)

CBD/12/01

The Subgroup were provided with an introduction to the datasets for CBD novel foods with less than 70% CBD present together with a range of other cannabinoids, also known as broad spectrum CBD, for the first time. The introductory paper introduced six sub-chronic studies (unique identifiers FSACBD 010, FSACBD011, FSACBD018, FSACBD021 and FSACBD025).

It had previously been agreed with the subgroup that these CBD novel foods have a range of compositions and as such a single safe upper intake level for this type

of CBD novel food was unlikely to be identified from the data. This view was reiterated following the review of the studies. It was noted that the factors that will influence the toxicology and the safety of these CBD novel foods were similar to other plant extracts that have been previously reviewed by the ACNFP.

Members were asked to advise on whether the 90-day study data for the six applications were of a suitable quality to provide scientific evidence on the safety of CBD ingredient with less CBD present but a range of other cannabinoids. The subgroup was also asked:

- whether there were any new observations in any study in this group which had not been seen in previous CBD datasets.
- whether the toxicological profiles were consistent with the data reviewed previously and
- whether there were patterns in the data that suggested new considerations when these are reviewed by ACNFP.

Detailed discussion of the six studies submitted to support CBD novel foods with a range of cannabinoids and lower levels of CBD.

Each study was reviewed and discussed individually. The Point of Departure (POD) for each study was reviewed by members of the Subgroup based on the effects seen and POD identified by the applicants, if the data provided allowed quantification. Members explored whether standard methodology had been used, if information on quality assurance and GLP had been provided and whether the conclusions reached by the applicant were consistent with the data.

It was noted that across the studies the level of detail in the compositional analysis of the test material was not sufficient, impacting on the ability to interpret the data without further information on the characterisation of the novel food. The need to consider all the data provided in the studies and critically evaluate the characterisation of the ingredient and the toxicology information provided was noted. An area of particular focus was the specification and compositional characterisation reports provided for the novel foods. It was highlighted that characterisation of the substances present to account for 100% composition, and any precursor or breakdown products of key cannabinoids, is likely to be needed to fully interpret the toxicological data provided.

From the information provided in the Certificate of Analysis it appeared in the majority of cases that CBD was the majority cannabinoid with very low levels of other cannabinoids present. As a result of the cannabinoid profile in this batch of

ingredients, there were no new significant toxicological effects observed in the studies provided that would give rise for special concern.

Members commented that most of the toxicological findings from the subchronic studies were consistent with the effects seen for pure CBD as a substance, once corrected for CBD content and taking into account the other reported constituents in the ingredient. Observations on body and organ weights are seen and further assessment will need to be undertaken to better understand the constituents (cannabinoid or otherwise) within the extract influencing the toxicological profile. It was discussed whether the high fat content of the hemp derived constituents affected general metabolism in the rat for example.

It was agreed that product-specific issue evaluation re bioavailability was best done as part of the ACNFP review but further checks on the detail of each study would be done by the sub-group to check on the body and organ weight changes and what may be the causes of these observations.

If more detailed information from applicants on 100% composition of the ingredients can be obtained, this will facilitate such a review.

Actions from this item – The Secretariat is requested to obtain compositional analysis of the novel food with the applicants for all applications in this group to ensure they are appropriately characterised to 100% composition of the ingredient. Clarity on the composition of the novel food should be sought where necessary, before further review by the sub-group ACNFP.

Subgroup to revisit studies in light of the BW/Target organ observations and conclude on these before the Subgroup finishes.

5. Item 2 – Draft statement on the safety of tetrahydrocannabinol (THC) as a contaminant of foods (Reserved business)

CBD/12/02

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 in food. While reviewed in the context of the CBD novel food applications, THC contamination is

a generic issue for food derived from hemp. A draft statement had been prepared to capture the available evidence and conclusions that could be reached on what would represent a safe level for THC as a contaminant in food.

The group commented that the second draft of the THC statement was much improved from the first draft. Members comments were sought on the revised version to ensure the points raised previously had been addressed and to refine the text. Once agreed by the Subgroup, sign off by the Committee on Toxicity (COT) and the Advisory Committee on Novel Foods and Processes (ACNFP) would be sought with the aim of publishing the statement as soon as possible.

Members feedback that the structure of the statement better explained the process followed in reviewing the evidence. The importance of consistency in the terms used to aid clarity was highlighted. This was important where utilising information from published works from other regulatory bodies, e.g. the UK the Advisory Council on the Misuse of Drug (ACMD), and in Europe (European Food Safety Authority (EFSA)) and in other countries such as Canada. This would ensure the scope and use of evidence in the UK was clear.

Members also reviewed in more detail the work of the ACMD on THC in consumer products, to ensure that this information and its application to food use had been appropriately explored. A particular focus was the data used to underpin their conclusions and whether this was reflective of the general population.

It was noted that the ACMD work had considered experimental psychopharmacology studies in humans that have found that acute administration of Δ9-THC can produce psychoactive effects at single oral doses as low as 2.5 – 5 mg. However, it was unclear whether these studies used healthy populations or were based on medical community/population data. It was agreed to consider the five studies as a group to inform refinement of the statement draft.

Members noted that the current statement makes use of the work undertaken by EFSA using the available evidence at the time. EFSA had chosen to base their assessment on Ballard & Witt (2011), as a single pivotal study but it was not fully clear why. It was proposed this study could have been for a general population relevant to foods exposure. This should be checked. As this was completed in 2015, and the FSA literature review had been completed in 2023, it was considered prudent to ensure any emerging literature in this active field of study was considered. It was agreed to do this alongside further development of the statement.

Actions from this item – The Secretariat to provide references from the EFSA paper (Ballard and Witt., 2011) to the subgroup to support their discussions on the Final statement draft.

The Secretariat to provide literature used in support of the ACMD statement on CBD in consumer products (Haney, 2007), (Ballard & Wit, 2011), (Chesher, Bird, Jackson, Perrignon, & Starmer, 1990), (Beal, et al., 1995), (Beal, et al., 1997) to complete the evidence base for review of the Final statement.

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

6. AOB

The Secretariat informed members that the ACNFP is looking to recruit a toxicologist. Members were asked to utilise their networks accordingly to flag the recruitment.

7. Date of the next meeting

The next meeting is scheduled for Wednesday 6th November 2024. It will be held online via Microsoft Teams as a virtual meeting.