Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 167th Meeting held on the 12th of June 2024

These minutes are subject to confirmation by the Committee.

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 167th meeting of the Advisory Committee on Novel Foods and Processes, held on the 12th of June as a hybrid meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Dr Meera Cush

Dr Sophie Foley

Professor Paul Fraser

Dr Hamid Ghoddusi

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw D. Jones

Dr Elizabeth Lund

Professor Dimitris Charalampopoulos

Mrs Rebecca McKenzie

Professor Clare Mills

Dr Lesley Stanley

Dr Ray Kemp

Prof Hans Verhagen

Professor Bruce Whitelaw

Dr Cathrina Edwards

Professor George Bassel

Dr Lynn McIntyre

Dr Isabel Skypala

Associate Members

Dr Christine Bosch

Dr Kimon-Andreas Karatzas

Dr Antonio Peña-Fernández

Apologies

Dr Maureen Wakefield

Professor Harry McArdle

Professor Susan Fairweather-Tait

Dr Mark Berry

Assessor

Mr Paul Tossell - Head of Radiological, GM, Novel Foods & Radiological Protection

Observers FSA

Dr Lindsay Holden - Team Leader, Regulated Products

Ms Chun-Han Chan - Head of Regulatory Innovation and Engagement

Mr Shaun Jacobs - Senior Policy Advisor

Ms Annabel Rice - Senior Policy Advisor

Ms Jessica Dewhurst - Policy Advisor

Ms Sophie Burder - Policy Advisor

Observers (External)

Ivy Wellman - Defra

Observers Devolved administration

Mr Jeremy Mills - Policy, FSA Wales

Mr Xose Alvarez - Policy, FSA Wales

Ms Lucy Smythe - Food Standards Scotland

Ms Aileen Livingstone - Food Standards Scotland

Evangelos Katsoulis - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA Northern Ireland

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary PGT subcommittee

Dr Karin Heurlier - Lead Secretariat PGT subcommittee

Dr Tahmina Khan - Science Secretariat

Dr Daniel Lloyd - Science Secretariat

Dr Rhys William - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Mr Will Smith - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Professor Harry McArdle, Professor Susan Fairweather-Tait, Dr Mark Berry and Dr Maureen Wakefield sent their apologies for non-attendance. Mrs Priscilla Wanjiru the lead Secretariat also sent her apologies for non-attendance.

This was Dr Hamid Ghoddusi and Mrs Rebecca McKenzie’s last meeting as they have reached the maximum term serving on the Committee.

Dr Lesley Stanley will also be coming off the main ACNFP committee, as she has also completed the maximum term of office but has kindly agreed to continue as a co-opted member on the CBD Subgroup and will support the transfer of this work back to the main committee for as long as the CBD sub-group is in place. The Chair thanked the 3 outgoing Members for their hard work and dedication during a period of great change for the Committee.

The Chair reminded Members of the need to announce any potential conflicts of interests prior to the discussions on each item.

Dr Anton Alldrick previously declared interests in relation to CBD. The Chair and Secretariat advised that these members would not be present for the discussion of these items.

2. Welcome

Chair welcomed the Members, representatives from the FSA, the observers from the devolved administrations and the Secretariat team.

3. Meeting Minutes for the 165th and 166th Meeting

ACNFP/165 & 166/MINS

The Committee agreed the 165th and 166th meeting draft minutes for publication on the ACNFP website as an accurate record, pending some minor amendments to fully capture the discussions, to be cleared by Chair's action.

4. Matters Arising from the last meeting

ACNFP/167/MA

The Secretariat reported on actions from the 165th and 166th meetings:

- CBD (RP427 and RP793) - Requests for further information, for these two applications, were sent to the same applicant. The Committee Advice Documents were updated in light of the comments by members and will be cleared by Chair's action.
- 2'-Fucosyllactose (2'FL), 3'-Syllactose (3'SL) and 6'-Syllactose (6'SL) - Members agreed the Committee Advice Documents subject to amendments. These will be cleared by Chair's action and will be published in the next batch of publications.
- Olive Fruit Extract standardised in Hydroxytyrosol – The Secretariat sent a request for further information to the applicant in relation to the toxicological information. The Secretariat are exploring the next steps for this application.
- Vitamin D2 mushroom powder - The Secretariat sought further information from the applicant on composition to make a conclusion on the safety of this application. The response once received is expected to be reviewed at the next available meeting.
- GM dossier (RP1962) - The Committee Advice Document for this application was amended and cleared by Chair's action. This will be published in the next publications.
- GM Dossier (RP1869) – since consideration by the Committee at ACNFP165, the applicant withdrew their application.

Update from the PBO (166th ACNFP) workshop:

- Draft Precision Bred Organisms (PBO) Technical Guidance for applicants seeking authorisation of PBOs for marketing for food and feed use was

reviewed. The ACNFP Chair ensured that the technical advice received both in the ACNFP 166th meeting, by correspondence subsequently, and in the ACNFP-PGT 14th Subcommittee meeting was correctly used to amend the draft.

Other Updates:

- Publication of UK Safety assessments for 3 novel foods – Calcidiol, and the first two CBD applications (RP07 and RP350).

5. Genetically Modified Organism application RP1962 (reserved business)

ACNFP/167/01

The Committee reviewed the Committee Advice Document which had been prepared by the secretariat following review of the application by the ACNFP-PGT Subcommittee.

The Committee reviewed the 28-day toxicology study as there were some anomalous observations that required more detailed review. Members agreed that there were no treatment related findings. The No Observed Adverse Effect Level (NOAEL) was verified as accurate in the draft CAD.

The Committee Advice Document was agreed subject to amendments to be finalised by Chair’s action. Once finalised the outcome will move forward to publication.

Action: The Secretariat to update the Committee Advice Document to conclude the assessment.

6. Baru nut (Dipteryx Alata Vogel) RP2176

ACNFP/167/02

The Committee reviewed a new traditional food application for Baru nut (Dipteryx Alata Vogel), to inform risk management advice from the FSA/ FSS to Ministers.

Data gaps were identified in the production process, composition, nutrition, allergenicity, history of use and the proposed use that did not allow a risk assessment to be completed.

Members raised a variety of concerns with the description of the production process, including the roasting temperatures and the potential issues that could be associated with acrylamide generation during roasting, the storage temperatures, process contaminants, and the sampling plan. The compositional analysis was largely insufficiently explained, with significant variations making it difficult to form a conclusion on the traditional food with the information provided.

Nutritional analysis especially on carbohydrates was deemed necessary both for the peeled and unpeeled nut to understand which part of the nut was contributing to the high fibre levels. The members also noted the potential for allergenicity risks with other legumes. However, the suggestion that the food was likely to elicit reactions in peanut allergic consumers as a result of cross reactivity was not supported with evidence. The history of use information was also limited, which made it difficult to predict the safety impact on a larger population of consumers in the UK.

Action: Secretariat to prepare summary of discussion and seek public views through a 10-day public consultation.

Action: Risk managers to review Committee Advice as a basis for whether reasoned safety objections should be raised.

7. Corn protein RP1238

ACNFP/167/03

The Committee first reviewed the application in February 2023. At the 164th ACNFP meeting, further questions were raised on the production process, specification and ADME.

Mycotoxin reduction factors are utilised by the applicant in the novel food production process to assess the suitability of maize raw material. Members discussed this approach and were unconvinced this would be a reliable method for estimating the level of mycotoxins present in the final novel food. This could only be achieved by direct measurement of the mycotoxins present in the corn protein.

Further details were provided by the applicant concerning the steps used to control microbial growth in the novel food production process. Members felt that the information provided to date did not provide reassurance that cross-contamination would not be an issue downstream in the production process.

The Committee requested that data on the water activity of the novel food should be provided to understand whether this suggested the potential for the novel food to support microbial growth. The applicant conducted further testing on five batches of the novel food and reported that the water activity did not exceed 0.25. The applicant has proposed a specification limit for water activity of 0.6. Members noted that this level could support mould growth and that the source of the variability in the data was not explained.

Confirmation that the applicant's *in vitro* digestibility methodology had been validated was requested. The applicant stated that their test was comparable to the standardised INFOGEST method; however, Members did not agree that these approaches were comparable given key differences in their methodologies particularly in the enzymes used. The Committee also noted that the "DIAAS" value for corn protein was not derived using the internationally recognised FAO methodology. Members indicated that this data could be misinterpreted in future by researchers. As the method had neither been validated nor comparison made to other accepted methods the reliability and applicability of the results remained uncertain.

Separately, the Secretariat sought expert support from FSA colleagues to review the applicant's intake assessment. Significant differences between the applicant's data and the FSA assessment of the expected corn protein consumption levels were noted. Under the current intended uses and maximum use levels, the Committee considered the novel food to be nutritionally disadvantageous for some population groups.

Action: The Secretariat to highlight the concerns with the proposed uses in light of the data presented and explore the way forward for this application.

8. Akkermansia muciniphila RP1468

ACNFP/167/04

An application for pasteurised *Akkermansia muciniphila* was discussed for the third time by the ACNFP at the 167th meeting. A number of requests for information and corresponding responses from the applicant were reviewed. Members also made comments on the draft Committee Advice Document.

In considering the Committee Advice Document, Committee members advised on a revision of the terminology used when describing the results of the bioinformatic analysis. They highlighted the importance of explaining what the

sequence homology results mean for any risks from the novel food.

The Committee advised the need for consistency and accuracy on the description of the number of cells present and whether they were viable cells, living cells or dead cells. It was recommended that further information be sought from the applicant to allow accurate reporting and interpretation. This led to a discussion on whether the number of viable cells in the specification of 500 would be safe for the range of users proposed. Applicant's arguments for setting the level at 500 were not accepted and as such it was recommended further justification be sought from the applicant.

Further clarification was sought on the proposed uses and particularly how the novel food would be used in food categories such as Food with Special Medical Purposes. This would allow assessors to understand if there are risks for specific population groups. Following discussion on the potential risks for younger users in the target population and the known impact of the gut microbiome on organ development, further elaboration and justification on the chosen target population was considered to be needed.

Members noted that in this case the toxicological evidence from animal studies is not the driver of the safety evaluation. There was exploration of the human evidence on safety and tolerability and the Committee noted the association between higher levels of this microbe in the gut and certain neurological conditions (EFSA, 2020). However, it was considered this may be a marker of a disregulated gut for people with these conditions.

While the organism is considered unlikely to be allergenic given its presence naturally in the human gut, further consideration was given to any carryover of media to the final product. The information provided suggested that the level of carryover was low, but in the range where if food allergens from Annex II of 1169/2011 EU were present, they could elicit food allergic reactions in sensitive people. Further information was sought on whether any of the major allergens were present.

The Committee agreed that subject to responses by the applicant, the novel food pasteurised *Akkermansia muciniphila* would be expected to be safe under the proposed conditions of use.

Action: Secretariat to seek clarification based on the points raised by the Committee on identity, specification, proposed use and allergenicity.

Action: Secretariat to update the Committee Advice Document in light of the points raised and the applicant’s responses for clearance by the Committee.

9. Cannabidiol RP11 (Reserved Business)

ACNFP/167/05

The Committee reviewed a new application for Cannabidiol (CBD) isolate as outlined in application RP11 for the first time. The novel ingredient is proposed by the applicant for use in food supplements.

The Committee were also asked to review a draft Committee Advice Document for this application.

In relation to the Committee Advice Document, members commented on the information regarding the starting material and clarification was required on the growth and harvesting information provided.

The toxicology studies provided in support of the application were reviewed and were considered sufficient to support the safety of this novel food. The NOAEL identified in the sub-chronic toxicology data to support this application was consistent with the evidence used to develop the provisional ADI and the wider evidence seen on CBD. As such it would be scientifically appropriate to apply the ADI as per Government advice. The Committee advised that the safe upper intake for the novel food was considered to be the provisional ADI for ≥98% pure CBD of 10mg CBD per day, equivalent to approximately 0.15 mg/kg bw/day in a healthy 70 kg adult.

The proposed uses of the novel food were discussed, and it was noted that there was ongoing discussion with the applicant to update the uses to reflect the provisional Acceptable Daily Intake (ADI) of 10 mg CBD/day, with the applicant's permission.

Members also identified areas for the Secretariat to amend in the draft Committee Advice Document to accurately reflect the assessment that had been done. The document was agreed subject to amendments, if the proposed uses could be modified to be consistent with Government advice on consuming CBD.

Action: The Secretariat to update the Committee Advice Document to conclude the assessment.

10. Cannabidiol RP340 (Reserved Business)

ACNFP/167/06

The Committee reviewed application RP340 for isolated cannabidiol for the first time. The toxicology studies provided in support of the application were reviewed and were considered sufficient to support the safety of this novel food. The NOAEL identified in the sub-chronic toxicology data to support this application was consistent with the evidence used to develop the provisional ADI and the wider evidence seen on CBD. As such it would be scientifically appropriate to apply the provisional ADI as per Government advice. The Committee advised that the safe upper intake for the novel food was considered to be the provisional ADI for ≥98% pure CBD of 10mg CBD per day, equivalent to approximately 0.15 mg/kg bw/day in a healthy 70 kg adult.

The proposed uses of the novel food were discussed, and it was noted that there was ongoing discussion with the applicant to update the uses to reflect the provisional Acceptable Daily Intake (ADI) of 10 mg CBD/day, with the applicant's permission.

Members also identified areas for the Secretariat to amend in the draft Committee Advice Document to accurately reflect the assessment that had been done. The document was agreed subject to amendments, if the proposed uses were modified to be consistent with Government advice on consuming CBD. The agreement was also contingent on a review of the genotoxicity information. Further information was subsequently sought from the applicant regarding genotoxicity of the CBD isolate which would require review by the ACNFP before the assessment is finalised

Action: The Secretariat to coordinate a review of the genotoxicity data.

Action: The Secretariat to update the Committee Advice Document in light of the amendments proposed.

11. Cannabidiol RP349

ACNFP/167/07

Item was postponed to allow further checking of the analytical and compositional data.

12. Annual report

ACNFP/167/08

The Secretariat invited the Committee to review a draft of the 2023 annual report outlining the work of the Committee and its' subgroups for 2023, seeking their feedback and agreement ahead of publication. The Committee made suggestions for a few changes that could be beneficial to consider for this and future reports. Members encouraged the Secretariat to explore the possibility of an open meeting or alternative event with external stakeholders and interested organisations. This would raise awareness of the Committee's work, and the standard needed from application dossiers for review by the Committee.

It was agreed that the draft with the amendments addressed would be cleared by Chair's action.

Action: The Secretariat to publish the 2023 ACNFP Annual Report following clearance by Chair's action.

13. Items for Information

13.1 Novel Food Policy Update - Written

The Committee was provided with a written update on the issues under consideration regarding novel foods.

13.2 GM Policy Update - Written

The Committee was provided with an written update on the issues under consideration regarding GM.

13.3 SACS Update - Written

The Committee was provided with a written update on the activities of the different SACs.

Date of next meeting

The next full ACNFP meeting will be held in-person and online on 17th and 18th September 2024.

References

EFSA Panel on Biological Hazards (BIOHAZ), 2020. Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 12: suitability of taxonomic units notified to EFSA until March 2020. EFSA Journal 2020, 18(7): 6174. **https://doi.org/10.2903/j.efsa.2020.6174**