Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 169th Meeting held on the 20th of November 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 169th meeting of the Advisory Committee on Novel Foods and Processes, held on the 20th of November as a virtual Teams meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Professor George Bassel

Dr Mark Berry

Dr Meera Cush

Dr Cathrina Edwards

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw D. Jones

Dr Elizabeth Lund

Dr Lynn McIntyre

Professor Clare Mills

Dr Maureen Wakefield

Professor Bruce Whitelaw

Prof Hans Verhagen

Dr Lesley Stanley - Co-opted Member–CBD subgroup

Apologies

Professor Dimitris Charalampopoulos

Dr Sophie Foley

Dr Ray Kemp

Dr Isabel Skypala

Assessor

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

Observers FSA

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Mr Joshua Ravenhill - Head of Cell-Cultivated Product Sandbox Transition Team

Ms Sophie Burder - Policy Advisor

Ms Helen Kardos-Stowe - Stakeholder Engagement Manager

Mr Shaun Jacobs - Senior Policy Advisor

Ms Eleanor McCartney - Senior Policy Adviser

Ms Barbora Peck - Policy Adviser

Mr Max Tollitt - Senior Policy Adviser

Observers Devolved administration

Mr Xose Alvarez - Policy, FSA Wales

Ms Kaila Lee - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Mr Jeremy Mills - Policy, FSA Wales

Dr Karen Pearson - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Ms Jemma Foster - Policy, FSA NI

Observers (External)

Mr Simon Pearson - Science Council

Ms Ivy Wellman - Defra

Secretariat

Mrs Ruth Willis - Technical Secretary

Mrs Priscilla Wanjiru - ACNFP Lead Secretariat

Mr Ben Haynes - CBD Lead Secretariat

Dr Daniel Lloyd - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Ms Lucy Thursfield - Science Secretariat

Miss Jenny Rees - Science Secretariat

Ms Victoria Balch - Administrative Secretariat

Ms Carol Scott - Administrative Secretariat

1. Apologies and Announcements

Apologies were received from Professor Dimitris Charalampopoulos, Dr Ray Kemp, Dr Isabel Skypala and Dr Sophie Foley.

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

Dr Anton Alldrick declared a conflict of interest in relation to CBD and Professor Hans Verhagen in relation to Allulose. The Chair and Secretariat advised that these members would not be present for the discussion of these items.

The members were also informed of and congratulated Dr Lesley Stanley on her new title as Professor.

2. Welcome

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

3. Meeting Minutes for the 168th Meeting

ACNFP/168/MINS

The Committee agreed the 168th meeting draft minutes for publication on the ACNFP website subject to minor amendments.

4. Matters Arising from the last meeting

ACNFP/168/MA

The Secretariat reported on actions from the 168th meeting:

- GMO RP307 – The Committee Advice Document for this application was reviewed by the members. A revised version was finalised by Chair's action.
- Krill Protein RP1290 –The Secretariat amended the CAD in light of the comments from members, and this will be circulated for finalisation by correspondence.
- Dried Miracle Berry RP1351 –The Secretariat amended the CAD in light of comments from members, and this will be circulated for finalisation by correspondence.
- Esterified Propoxylated Glycerol RP1363 – The Committee identified data gaps on identity and toxicology for this novel food. Further information was sought from the applicant and the Secretariat are exploring a way forward for the dossier.
- Dry Cacaofruit Cascara RP1484 – Following review of this new application, the Secretariat sought further information as advised by the members on production process, composition and specification. The Members were informed that the applicant has since withdrawn this application.
- Proposal for a Cell Cultivated and Alternative Proteins Subcommittee – further details of the operation of the subcommittee and the potential to hold an open session of the ACNFP to develop the work plan for the group will be discussed under item 4.
- Cannabidiol (CBD) RP793 – Following advice from the members, the Secretariat updated the CAD and it has been cleared by Chair's action.
- Cannabidiol (CBD) applications from British Cannabis RP220, 245-256, 324-325 - Following advice from the members, the Secretariat updated the CAD and it has been cleared by Chair's action.
- Cannabidiol (CBD) RP349 – Following review of this new application, the CAD was updated by the Secretariat and has been cleared by Chair's action.
- Cannabidiol (CBD) RP176 – Following review of this new application, the Secretariat sought clarification from the CBD Subgroup on data related to toxicology studies. This application will be considered by Members again in due course.

5. Mung Bean Protein RP32

ACNFP/169/01

Mung Bean Protein is a novel food application that has previously been discussed at the 147th,149th, 150th, 152nd, and the 153rd ACNFP meetings. Members considered the applicant's response to the previous request for information. The Committee also made comments on the draft Committee Advice Document

(CAD).

The Committee had requested the next tier of allergenicity testing from the applicant to understand the likelihood of reactions in legume allergic consumers. The EFSA Guidance indicates the next tier is targeted serum screening. Although the applicant provided the FSA with a draft research proposal, this work was not commissioned. No further data was provided on the novel food. A paper providing limited new confirmational data on mung beans and food was provided for review but did not address the data gap.

Members were asked to conclude their assessment on the allergenicity of the novel food using the available information. The Committee concluded that mung bean protein presents an allergenic hazard of unknown severity. Members were unable determine the risk of the novel food to UK consumers with a clinically relevant allergy to peanuts and other legumes. The ACNFP also noted that risk managers may wish to consider risk management measures to inform consumers of the novel food who have clinically relevant legume allergies.

The Committee requested that the FSA further develop the allergenicity section of the CAD to reflect the discussions that led to their conclusion.

Action: The Secretariat to update the Committee Advice Document in light of the comments raised for clearance by the Committee via correspondence.

6. Allulose RP1130

ACNFP/169/02

A new application for Allulose was reviewed for the first time. The novel food is a monosaccharide low caloric sweetener produced into syrup and crystalline forms via enzyme-catalysed epimerisation of fructose. The production process uses a new food enzyme for GB, *D-tagatose 3-epimerase*. The applicant intends to use the novel food in a variety of conventional foods and beverages, including as a tabletop sweetener, as an alternative to table sugar.

Members noted that the identity of the novel food may include several allulose epimer structures and advised further information from the applicant is sought to understand this and the impact of any variability in form.

The production process raised several queries. Members advised that further information was needed on the purity, manufacture and uses of the food enzyme.

It was noted that a separate evaluation of the enzyme is required under the enzymes regulations, but as this is not in place additional consideration of this aspect as it relates to the safety of the novel food is needed.

Members raised that the description of the production process for allulose provided insufficient detail to understand whether key risks had been identified and effectively managed in the production scale process. Of particular interest was whether the potential for microbial contamination has been fully explored. The Secretariat were advised to seek further information from the applicant on these aspects and details of the corresponding control measures of the food safety management.

Members noted that the composition of the syrup had not been fully characterised and further information was required. Regarding stability, further information on the stability of Maillard Reaction Products (MRPs) in allulose syrup in the proposed uses, such as baked goods, was needed. Acrylamide is a type of MRP and it is important to assure that this potential contaminant is controlled. The Secretariat agreed to consult with FSA colleagues on how the current guidance on acrylamide would apply to products containing the novel food ingredient.

Members suggested that justification be sought for the specifications for both end products to ensure these were consistent with the analytical data and the known variability in the process.

Members advised that the Secretariat seek further information from the applicant on the proposed target population and exclusion to younger age groups. It was agreed that the exposure assessments would be reviewed separately in more detail and that FSA colleagues would be consulted where required.

Information gaps were raised in the absence of ADME data on allulose. Uncertainty was discussed with regards to long term exposure and effects on the gut microbiome and insulin response. If further data from the literature was not available, further testing to understand the potential for chronic effects may be needed.

It was noted that the Committee’s genotoxicity expert was not available to conduct the review of this data and as such the Secretariat committed to gaining a review on this part of the dossier from other relevant committee expertise.

The Secretariat had invited Members to review a draft Committee Advice Document. Members made comments on the draft and identified areas for the

Secretariat to amend.

Action: Secretariat to seek clarification from the applicant on the points raised.

Action: The Secretariat to seek review by genotoxicity experts and if necessary, seek further information from the applicant.

Action: The Secretariat to amend and update the draft Committee Advice Document.

7. Alternative and Cell Cultivated Proteins Subgroup

ACNFP/169/03

The Committee reviewed the refined proposal and terms of reference for establishing a Subgroup of the ACNFP to support the assessment of cell cultivated and alternative proteins. This Subgroup will focus on supporting the development of guidance to address cross-cutting issues and facilitate effective, timely risk assessment of these novel foods. This work will directly support the FSA's regulatory sandbox project for cell cultivated products (CCPs).

It was agreed that the Subgroup would consist of a core of ACNFP members to provide consistency and oversight across the programme of work. Following discussion, the Chair of the subgroup and the other two core members were identified as Professor Huw D. Jones, Alison Austin and Professor Hans Verhagen, respectively. Each meeting will focus on a specific area of uncertainty related to CCP risk assessment, with participation from relevant members of the ACNFP and non-Committee experts as needed to support the development of meaningful guidance.

After discussion, the Committee concluded that the Subgroup's scope should initially be limited to CCPs to effectively align its objectives with the FSA's CCP regulatory sandbox. It was agreed that the scope would be reviewed in 2027 to assess the regulatory landscape and ensure resources continue to be utilised effectively in supporting the safety of novel foods in the UK. The draft Terms of Reference were updated accordingly.

A discussion was held on the approach to an open session of the ACNFP to explore any hazards associated with CCPs. It was agreed to run this as part of the

February meeting, with the discussion informing the work programme of the subgroup for 2025/2026.

Action: Secretariat to finalise the terms of reference for the Subgroup.

Action: Secretariat to develop a proposal for an open session of the Committee to prioritise topics for the Subgroup to review.

8. Cannabidiol (CBD) RP354

ACNFP/169/04

The Committee reviewed application RP354 for isolated cannabidiol for the first time. The sub-chronic toxicology studies provided in support of the application were reviewed by the CBD subgroup 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. The Committee advised that the safe upper intake for the novel food was considered to be the provisional ADI for ≥98% pure CBD of 98% or above purity of 0.15 mg/kg bw/day, equivalent to 10mg CBD per day in a healthy 70 kg adult.

Members recommended clarification be sought on how the production process was effectively managed. It was also suggested that further detail be included on the methodology used to collate microbiological analysis data provided in the composition section.

Members also noted that this application had provided some studies on ADME. This highlighted that bioavailability remained an uncertainty for all novel foods when added to food matrices. However, for this application, no additional uncertainty factors needed to be considered within the risk assessment.

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 CAD was agreed subject to amendments for clearance by Chair’s action.

Action: Secretariat to send RFI to applicant and revise the CAD for clearance by Chair’s action.

9. Cannabidiol (CBD) RP521

ACNFP/169/05

The Committee reviewed a new application RP521 for Cannabidiol (CBD) Isolate for the first time. The sub-chronic toxicology studies provided in support of the application were reviewed by the CBD subgroup 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. The Committee advised that the safe upper intake for the novel food was considered to be the provisional ADI for ≥98% pure CBD of 98% or above purity of 0.15 mg/kg bw/day, equivalent to 10mg CBD per day in a healthy 70 kg adult.

Members recommended clarification be sought from the application on the methodologies used in the microbial analysis in the compositional section.

The Committee also discussed the potential for consumers exceeding the ADI of 10 mg/day through consumption of multiple types of CBD-containing food products in the same day. This is a general issue for CBD novel foods and should be considered by risk managers in terms of how to control against excessive CBD intakes. This concern will be reflected in the draft Committee Advice Document.

Action: The Secretariat to request for information from applicant to clarify methodology used in compositional analysis

Action: The Secretariat to update the Committee Advice Document in light of the applicant's response for clearance by the Chair via correspondence.

10. Items for Information

10.1 Novel Food Policy Update - Written

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

10.2 GM Policy Update - Written

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

10.3 SACS Update - Written

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

Date of next meeting

The next ACNFP meeting will be held hybrid on the 5th and 6th of February 2025