Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 173rd Meeting held on the 24th and 25th September 2025

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 173rd meeting of the Advisory Committee on Novel Foods and Processes, held on the 24th and 25th of September at the Wesley Hotel & Conference Venue, Euston House, London, as a hybrid meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Professor George Bassel

Dr Mark Berry

Professor Dimitris Charalampopoulos

Dr Meera Cush

Dr Cathrina Edwards

Professor Susan Fairweather-Tait

Dr Sophie Foley

Professor Paul Fraser

Professor Gunter Kuhnle

Professor Paul Haggarty

Professor Wendy Harwood

Professor Huw D. Jones

Dr Ray Kemp

Dr Elizabeth Lund

Dr Lynn McIntyre

Professor Clare Mills

Dr Isabel Skypala

Professor Bruce Whitelaw

For the CBD items on the agenda

Rev. Professor Lesley Stanley - Co-opted Member–CBD subgroup

For items 8 and 9 on day 1

Professor Peter Gregory - Representative Science Council

Apologies

Dr Andy Greenfield

Prof Hans Verhagen

Professor Simon Pearson - Representative Science Council Member

Assessor

Ms Arvind Thandi - Head of Novel Foods Policy

Mr Adekunle Adeoye - Senior Policy Officer, Regulated Services

Mr Chris Stockdale - Head of CBD Policy, Regulated Services

Ms Melanie Harris - Head of Cell Cultivated Products Policy, Strategy

Observers FSA

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Mr David Kovacic - Senior Regulated Products Risk Assessor

Ms Erin Lewis - Senior Novel Food Policy Officer

Mr Max Tollitt - Senior Policy Advisor, Food Policy

Mr Shaun Jacobs - Senior Policy Advisor, Food Policy

Mr Solomon Okoruwa - Senior Policy Advisor, Food Policy

Ms Sophie Burder - Policy Advisor

Observers Devolved administration

Mr Jeremy Mills - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Mr Shazya Aslam - Policy, FSA Wales

Miss Katy Williams - Policy, FSA Wales

Ms Kaila Lee - Policy, FSA Wales

Mr Xosé Álvarez - Policy, FSA Wales

Dr Karen Pearson - Food Standards Scotland

Krystle Boss - Food Standards Scotland

Mr Lorcan Browne - Food Standards Scotland

Ms Siobhan Watt - Food Standards Scotland

Mr Niall Grieve - Policy, FSA, Northern Ireland

Ms Rachel Gilbert - Policy, FSA, Northern Ireland

Secretariat

Mrs Ruth Willis - Technical Secretary

Miss Jenny Rees - Science Secretariat & Acting ACNFP Lead Secretariat

Mr Ben Haynes - CBD Lead Secretariat

Dr Andrew Hartley - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Mr Will Smith - Science Secretariat

Dr Lucy Thursfield - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Dr Daniel Lloyd - Technical Secretary of the CCP subgroup

Mrs Jodie Towns - Science Secretariat

Dr Swati Arya - Science Secretariat

Dr Emily Davies - Science Secretariat

Mr Nathan Allen - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Apologies were received from Dr Andy Greenfield. Professor Hans Verhagen had intended to be present in person but was unable to attend due to new FSA policy relating to in-person attendance for members based overseas. Professor Verhagen provided comments after the meeting.

Apologies were received for the meeting day 1 (24th) from Professor George Bassel. Apologies were received for the meeting day 2 (25th) from Dr Mark Berry. Apologies were also received from Simon Pearson as Representative Science Council Member.

The Chair announced that it was Mrs Alison Austin's final meeting as a Member of the ACNFP. She was congratulated on her new appointment to the FSA board and was thanked for her contribution to the Committee's work since joining the Committee in 2021.

The Chair congratulated Professor Sophie Foley on her recent promotion to Professor.

The Chair announced that the former lead ACNFP Secretariat, Priscilla Wanjiru, has since been promoted to a new role in FSA Wales. She is thanked for her Secretariat support over the years.

The Chair reminded Members of the need to announce any potential conflicts of interests prior to the discussions of each item. Dr Anton Alldrick declared a potential conflict in relation to CBD applications RP47, RP46 and RP225 and would not be involved in the discussions on these applications.

2. Welcome

Chair welcomed the Members, representatives from the FSA, the observers from the devolved administrations and the Secretariat team. The Chair welcomed the delegated policy leads acting as FSA assessors for the CCP, GM and Novel Foods items on the agenda.

3. Meeting Minutes for the 172nd Meeting

ACNFP/172/MINS

The Committee agreed the 172nd meeting draft minutes for publication on the ACNFP website subject to minor amendments and Chair's action.

4. Matters Arising from the last meeting

ACNFP/172/MA

The Secretariat reported on actions from the 172nd meeting:

- *Fusarium* str. *flavolapis* RP1637 - The Committee had reviewed this application for the first time. Following Members' advice, the Secretariat sought further information from the applicant to address questions on identity, production process, composition, specifications, ADME, nutrition and toxicology. The response, once received, will be reviewed at the next available meeting.
- β-lactoglobulin RP1571 - The Committee had reviewed this application for the first time. Following Members' advice, further information from the applicant was sought to support the ongoing assessment in relation to identity, production process, composition, stability, specifications, nutrition and allergenicity. The Committee had agreed to conduct an in-depth review of the information on allergenicity separately. The outcome of the Members' review and the applicant response, once received, will both be discussed at the next available meeting.
- Fermotein RP1215 - Following Members' review of the applicant response, the Secretariat sought further information from the applicant to address questions on production process, composition, specifications, proposed uses, nutrition and ADME. The response, once received, will be reviewed at the next available meeting.
- Allulose RP1130 - Following Members' review of the applicant response, the Secretariat sought further information from the applicant to address questions on identity, production process, stability, proposed uses and intakes, ADME and toxicological information. The response, once received, will be reviewed at the next available meeting.
- Bambara Groundnut RP2272 – The Committee had reviewed this new traditional food notification in the April 2025 meeting to support FSA/FSS risk management decisions. A final summary was cleared by Chair's action and published on 31st July 2025.
- CCP tasting guidance – The Committee had provided comments on a proposed FSA owned document to update applicant guidance for conducting novel food tasting trials. The FSA guidance is being finalised for publication.
- February 2025 Cell Cultivated Products (CCP) Open Session Report - A final report was cleared by Chair's action and published on 24th September 2025.
- Allergenicity Workshop Report – Members had commented intersessionally on the draft report. The report is being finalised for publication.
- CBD THC statement – the statement was finalised and published on 1st July 2025
- Mung Bean Protein RP32 – the assessment was completed, and the Committee Advice Document (CAD) was published on 30th July 2025.

5. Urolithin A RP1777

ACNFP/173/02

An application for urolithin A, a compound for use in foods and food supplements by the adult population was reviewed for the first time. The Secretariat provided Members with a draft Committee Advice Document to support the Committee's review. The review identified several areas that required further information from the applicant to complete the assessment.

Members advised that further information on the reference material used to identify the novel food was needed. This was to verify if the substance produced chemically is the same as the substance that forms via actions of the gut microbiota in some people. In addition, further data on the solubility, the particle size distribution and the fraction of nanoparticles in the novel food was needed to characterise the novel food and support the review.

Regarding the production process, Members advised that further details on the reagents, the manufacturing steps and the process controls were needed from the applicant. Impurities were noted in the novel food and information on the identity of these substances was suggested to be sought.

Members advised that more recent batch data for the novel food's composition was needed as the analyses provided were not representative of the current production process. Queries were also raised on the variability in the reported values for certain parameters. Members advised further clarification regarding the selected parameters in the stability studies and the potential interaction of urolithin A with other components in foods was needed. Further compositional data would support refining the specification to manage all characterising parameters and potential hazards of concern.

It was noted that Urolithin A is formed from dietary sources by the gut microflora. However, exposure levels vary due to the inherent differences in the gut microflora within the population. Members advised that further details on the exposure levels for urolithin A in the background diet was needed with additional consideration for potential competitive uptake with other fat-soluble substances.

Members reviewed the safety studies provided. It was advised that clarification was needed on the digestibility of the novel food. Further information was also needed on the conducted human study and the outcomes reported to support interpretation of the data in the context of the safety assessment.

The Committee also advised further information on the relevance of the safety studies was needed with respect to the fraction of nanoparticles in the novel food in the test substances used.

Action: The Secretariat to seek further information from the applicant and update the draft Committee Advice Document.

6. CBD RP47 (reserved business)

ACNFP/173/03

The Committee reviewed application RP47 for isolated cannabidiol for the first time. The sub-chronic toxicology studies provided in support of the application had been reviewed by the CBD Subgroup. Further consideration by the Committee was required.

The Committee reviewed the sub-chronic toxicology study and noted concerns around the provenance and conformance with Good Laboratory Practice (GLP). Members advised that information was needed to confirm whether the sub-chronic study had been conducted according to GLP principles and that the subsequent quality assurance checks had been performed. This was needed to understand the reliability of the study data and therefore the contribution it could make to the assessment of the novel food.

Action: The Secretariat to seek further information from the applicant to further assessment of the novel food.

7. CBD RP46 (reserved business)

ACNFP/173/04

The Committee reviewed application RP46 for broad spectrum hemp extract for the first time. The sub-chronic toxicology studies provided in support of the application had been reviewed by the CBD Subgroup. Further consideration was required by the Committee. This was considered at this time as the questions raised on the provenance of the studies provided were similar to those considered in RP47.

The Committee reviewed the sub-chronic toxicology study and noted concerns around the provenance and conformance with GLP. Members advised that that information was needed to confirm whether the sub-chronic study has been

conducted according to GLP principles and that the subsequent quality assurance checks have been performed. This was needed to understand the reliability of the study data and therefore contribution it could make to the assessment of the novel food.

Action: The Secretariat to seek additional information from the applicant to further the assessment of the novel food.

8. Introduction to Group C CBD applications (reserved business)

ACNFP/173/05

The Committee was presented with a paper on Group C Cannabidiol (CBD) novel foods, which contain less than 80% CBD (hemp extracts). As part of the discussion, the Committee reviewed sets of compositional data for these products and discussed the minimum data requirements for risk assessment. It was noted that composition varies greatly amongst products within this grouping and, as a result, detailed compositional information would be critical in identifying any drivers of toxicity, other than CBD. The Committee advised on strategies for management of CBD novel food applications where compositional variability is unclear or data remains incomplete.

The Committee also discussed and provided advice on an approach for applying toxicology findings produced on another material to a novel food application. The importance of detailed compositional data was again raised by the Committee, and they advised on specific data that would be needed to assess whether data from a study was relevant to support the evaluation of safety for novel food(s) seeking to use it to support their assessment for authorisation.

The Secretariat provided an update to the Committee, detailing the approach the FSA will be taking on managing Group C CBD applications through the risk assessment process. An update was also provided on active work surrounding Tetrahydrocannabinol (THC) contamination in Group C products. The Committee noted that where consumption would allow for an intake of THC above the safe upper limit (SUL), these products would not be considered safe.

9. CBD RP225 (reserved business)

ACNFP/173/06

The Committee reviewed application RP225 for isolated cannabidiol for the first time. The sub-chronic toxicology studies provided in support of the application had been reviewed by the CBD Subgroup and were considered sufficient to support the safety of this novel food. Further consideration was required by the Committee.

The No Observed Adverse Effect Level (NOAEL) identified in the sub-chronic toxicology data to support this application was consistent with the evidence used to develop the provisional Acceptable Daily Intake (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 98% or above purity of 0.15 mg/kg bw/day, equivalent to 10mg CBD per day in a healthy 70 kg adult. The Committee Advice Document was agreed and will progress to publication.

Action: Secretariat to support publication of the CAD.

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.

11. Any other business

Members were introduced to the Innovation Research Programme being run by the FSA to support gathering knowledge on innovative novel foods.

12. Workshop on Cell Cultivated Products (CCP) (reserved business)

ACNFP/173/07

Members reviewed a draft FSA supplementary applicant guidance document that had been developed by the FSA Sandbox Team, with expert input from the ACNFP Subcommittee on Cell Cultivated Products. This was guidance focused on the nutrition and allergenicity assessments for these novel foods. The Committee provided feedback to the Secretariat and identified areas for further development.

Action: The Secretariat to update the guidance document and take the input from the workshop forward.

13. *Clostridium tyrobutyricum* 'Clostridium Protein' RP1920

ACNFP/173/08

An application for a microbial protein ingredient (dried and powdered biomass of heat-treated *Clostridium tyrobutyricum* strain ASM#19 cells) for use in a wide range of foods by the general population was reviewed for the first time.

It was noted that a pilot scale production process, in addition to a scaled-up process had been utilised for the analyses which had seen significant changes to the production method. Members advised that the Secretariat request full details on the final intended commercial scale method and updated information on the associated food safety management plans.

Concerns were raised by Members on the description of the novel food as containing non-viable cells of *Clostridium tyrobutyricum* strain ASM#19. The evidence provided had not confirmed that the cells are inactivated during the process. Queries on the efficacy of the heat inactivation steps of the cells were raised. Further details on these steps in the process in addition to evidence of their efficacy would be needed to support the assessment. The Secretariat was also advised to seek further information from the applicant on whether the nucleic acids present would degrade under the processing conditions, to understand the potential risks of uric acid formation.

Members agreed that a new set of compositional data was needed as representative of the commercial method. It was advised that clarification of the testing rationale is needed. More data on the microbial profile and updated information on the protein content with use of a more appropriate conversion factor based on the amino acid composition of the product was also advised. These data are needed to understand nutritional disadvantage and interpret wider data submitted in the application. These data would inform a revised specification with justification provided for the parameters selected in particular for the microbiological parameters.

Regarding stability, Members advised the Secretariat to request updated stability studies and for the applicant to measure the stability of the novel food in food matrices that reflect the properties of the proposed range of uses in foods.

The review of the proposed uses and anticipated intakes raised concerns on whether the evidence package supported the high use levels sought. It was noted that the wide category uses had implications for the exposure to younger population groups and that this would be an additional consideration.

Regarding ADME, data on the digestibility of the protein was insufficient and it was advised that the applicant use a Digestible Indispensable Amino Acid Score (DIAAS) method. It was advised that further information is sought on the sources of and variability in the levels of micronutrients to inform assessment of the potential for nutritional disadvantage.

While the applicant had provided data on the allergenicity of the novel food, further information was needed to interpret the relevance for food allergic consumers. A full protein profile assessment was suggested along with further clarification on the provided sequence homology analyses. These had identified sequency homology hits above the 37.4% cut off, without information on the significance of these alignments. The Committee recommended that the bioinformatics analysis should be updated utilising the protein profile of the novel food primarily and not just the genome sequence.

Action: The Secretariat to seek additional information from the applicant to further the assessment of the novel food.

14. Lyso-phosphatidylcholine (LPC)-rich oil from Antarctic krill (*Euphausia superba*) RP2181

ACNFP/173/09

An application for *lyso*-phosphatidylcholine (LPC)-rich oil from Antarctic krill (*Euphausia superba*) for use as a food supplement by the adult population, was reviewed for the first time. The Secretariat provided Members with a draft Committee Advice Document to support the Committee's review. The review identified several areas that required further information from the applicant to complete the assessment.

The novel food is manufactured by the enzymatic processing of an authorised krill oil novel food. The Committee advised that further information was needed to assess the impact of the production process on level of contaminants present in the final product. Comparison of the levels found in the novel food to that in the starting material would be beneficial. Clarification was also needed on the Hazard Analysis and Critical Control Points (HACCP) plan for the full-scale production process.

Members considered the proposed specifications for the novel food and advised that further parameters are needed to fully characterise the novel food based on the compositional data provided by the applicant.

The Committee reviewed the *in vivo* ADME study provided by the applicant. Further explanation was needed from the applicant concerning the relevance of the results with respect to the novel food seeking authorisation. This would inform interpretation of the toxicological data provided.

Action: The Secretariat to seek additional information from the applicant to further the assessment of the novel food.

15. GMB151 x DAS-44406-6 soybean RP2246 (reserved business)

ACNFP/173/10

An application for the authorisation of genetically modified GMB151 x DAS-44406-6 soybean had been reviewed by the ACNFP PGT sub-committee. The outcome was reviewed and collectively endorsed by the full ACNFP Committee.

Action: Secretariat to update the finalised Committee Advice Document in view of Members comments.

Date of next meeting

The next ACNFP meeting will be held as a hybrid meeting on the 19th of November 2025 in London and online.