Meeting

Advisory Committee on Novel Foods and Process. Minutes of the 171st Meeting held on the 24th of April 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 171st meeting of the Advisory Committee on Novel Foods and Processes, held on the 24th of April 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

Professor Dimitris Charalampopoulos

Dr Meera Cush

Professor Susan Fairweather-Tait

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw D. Jones

Dr Ray Kemp

Professor Gunter Kuhnle

Dr Elizabeth Lund

Dr Lynn McIntyre

Professor Clare Mills

Prof Hans Verhagen

Dr Maureen Wakefield

Professor Bruce Whitelaw

Dr Lesley Stanley - Co-opted Member–CBD subgroup

Apologies

Dr Cathrina Edwards

Professor Paul Fraser

Dr Isabel Skypala

Dr Sophie Foley

Assessor

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

Observers FSA

Professor Robin May - Chief Scientific Adviser

Mr Shaun Jacobs - Senior Policy Advisor

Mr Liam Burke - Policy Adviser

Dr Eleanor McCartney - Policy Adviser

Mr Max Tollitt - Policy Adviser

Ms Sophie Burder - Policy Adviser

Ms Helen Arrowsmith - Risk Assessor (Allergens)

Ms Helen Kardos-Stowe - Stakeholder Engagement Manager

Observers Devolved administration

Ms Shazya Aslam - Policy, FSA Wales

Ms Kaila Lee - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Ms Krystle Boss - Food Standards Scotland

Dr Aileen Livingstone - Food Standards Scotland

Observers (External)

Ms Ivy Wellman - Defra

Secretariat

Mrs Ruth Willis - Technical Secretary ACNFP

Ms Priscilla Wanjiru - Lead Secretariat

Dr Karin Heurlier - PGT Lead Secretariat

Mr Ben Haynes - CBD Lead Science Secretariat

Mr Matt Hall - Science Secretariat

Mr Will Smith - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Ms Lucy Thursfield - Science Secretariat

Miss Jenny Rees - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Apologies were received from Professor Paul Fraser, Dr Christina Edwards, Dr Isabel Skypala and Dr Sophie Foley. The Chair announced that three new members were joining the Committee following the last recruitment round, Dr Alastair Macrae, Professor Paul Haggerty and Professor Gunter Kuhnle. Prof Kuhnle was able to attend the meeting. It was explained the other new members will be attending from June.

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 SLCP. 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 170th Meeting

ACNFP/170/MINS

The Committee agreed the 170th meeting draft minutes for publication on the ACNFP website subject to minor amendments.

4. Matters Arising from the last meeting

ACNFP/170/MA

The Secretariat reported on actions from the 170th meeting:

- CBD RP 340 (reserved business) – The Committee Advice Document for this application was reviewed by the members. A revised version was finalised by Chair’s action and published in April.

- CBD RP176 (reserved business) –The Committee Advice Document for this application was reviewed by the members. A revised version was finalised by Chair’s action and published in April.
- CBD RP294 (reserved business) –The Committee Advice Document for this application was reviewed by the members. A revised version was finalised by Chair’s action and published in April.
- Open session on Cell Cultivated Products – The output from the discussion on the key hazards for this group of applications is being prepared and a further update is expected in June.
- Fermotein RP1215 – Following review of this new application, the Secretariat sought further information as advised by the members on production process, composition and specification, nutrition and toxicology. Following response from the applicant, this application will be reviewed at a future meeting.
- Solein RP1326 – Following review of this new application, the Secretariat sought further information as advised by the members on production process, composition and specification, nutrition and toxicology. Following response from the applicant, this application will be reviewed at a future meeting.
- MS11 × RF3 × MON 88302 BRASSICA NAPUS (OILSEED RAPE), RP2029 – The Committee reviewed this GM application that had previously been reviewed by the PGT Subgroup. The final CAD was agreed with minor suggested edits and is being finalised for publication.
- Bt11 × MIR162 × MIR604 × MON 89034 × 5307 × GA21 MAIZE, RP2044 - The Committee reviewed this GM application that had previously been reviewed by the PGT Subgroup. The final CAD was agreed with minor suggested edits and is being finalised for publication.
- EPA+DHA BRASSICA NAPUS L. (OILSEED RAPE), RP2065 – The Committee reviewed this GM application that had previously been reviewed by the PGT Subgroup. The final CAD was agreed with minor suggested edits and is being finalised for publication.

5. Cannabidiol (CBD) isolate (RP343, RP345 and RP346)

ACNFP/171/01

The Committee reviewed three applications RP343, RP345 and RP346 for isolated cannabidiol for the first time. The sub-chronic toxicology studies provided in

support of the applications 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 these applications 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 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 and will progress to publication.

Action: Secretariat to support publication of the CAD.

6. EPG RP1363

ACNFP/171/02

This novel food application for esterified propoxylated glycerol was first reviewed in September 2024. Following a discussion by the Committee, additional information was requested from the applicant in relation to identity, production process, composition, proposed use, ADME, and toxicology. The applicant's response was considered by Members who identified areas where further information is required to complete the assessment.

Information provided by the applicant on the identity of the novel food was discussed. It was recommended that further analytical data be sought to clarify the structures of the modified triglycerides present in each form of EPG. Members also noted that the physicochemical properties of the hard and soft forms of EPG showed marginal variability despite significant differences in the relative proportions of different fatty acids. Further information to be requested on the relationship between the fatty acid content and the type of fatty acids in EPG with respect to the physicochemical properties.

The applicant provided updated specifications for each form of EPG. Members noted that the specified limits for certain fatty acids were very broad, and this appeared to be due to the inclusion of analytical data from older batches of the novel food. Further refinement of the specifications for each form of EPG was needed, using more recent compositional information. It was also suggested that further information on the production process be sought to further understand sources of variation and to what extent these are controlled within the process.

The combined exposure assessment for both forms of the novel food was updated using data from the UK National Diet and Nutrition Survey. However, Members noted that the number of proposed food categories had been significantly increased compared to the original novel food application. This resulted in a concomitant increase in the combined anticipated intake for EPG. Separate exposure assessments for each form of EPG, covering the anticipated exposure in each population group and the contribution from each food category to the estimated intake levels, were recommended to be sought from the applicant. This would allow the impact on different population groups from the uses proposed to be clarified.

The applicant provided a report for an *in vivo* study to assess the impact of EPG consumption on radio-labelled vitamin D3 levels. The relevance of the results from this study for human uptake of vitamins when consuming EPG were unclear given that only one dose of EPG was administered, and follow up in rats, who have known differences in their fat metabolism to humans, was for a limited time – 48 hours.

The Committee discussed whether the toxicological data supported the safety of EPG given that these studies were conducted using previous OECD test guidelines on similar compounds. Whilst the point of departure for the novel food could not be determined, the results from these *in vivo* EPG feeding studies reported similar outcomes. Commissioning further animal studies was not considered feasible or relevant because the EPG doses in the current in vivo studies are already high and there are known human and rat differences in fat metabolism.

There is an expectation that applicants use the current OECD guidelines for their toxicity testing and where older study procedures are used an explanation is needed to address all the endpoints not considered in the older version of the guidance. Members indicated that an additional *in vitro* study and a human trial may be needed to complete the assessment. A request for these studies will be considered following a review of the applicant’s response to the queries raised.
tat Any new data generated should be tailored to address the specific points of interest.

7. Bambara groundnut (*Vigna subterranea* (L.) verdc.) RP2272 (Traditional Food)

ACNFP/171/03

The Committee reviewed a new traditional food notification for Bambara groundnut (*Vigna subterranea* (L.) verdc.) to provide advice to inform risk management decisions. The applicant sought two forms of use: dried whole seeds and flour made from the dried seeds.

Queries were raised on the evidence of safe use in a third country and the consistency of the product that is consumed in parts of Africa. The implications this had for food safety had not been explored by the applicant nor was it reflected in choice of samples for analysis.

Members raised a variety of concerns with the production process and the food safety management. In particular, how management for growth of microbes and moulds with the concomitant potential for production of mycotoxins, was managed throughout the process. The effectiveness of the controls was not appropriately addressed to provide reassurance that quality assurance measures were in place for the entire process. It was noted that the product can be stored for significant periods of time and the impact this had on the product and the variability between batches was unclear.

It was noted that the compositional data had not explained the provenance of the samples in terms of geographic origin and harvest year, limiting understanding of the variability of the product. An added challenge for review was that separate batches had been analysed for individual parameters rather than a complete analysis per batch.

It was noted that a known risk for legumes is the presence of undesirable phytotoxins and antinutrients in the whole food and this was raised by the Committee. Queries were raised on whether this risk was effectively managed by the cooking process for the production of the flour product.

Members noted the information on the potential for allergenicity and based on data identified from the literature were able to reach a view that Bambara was a low risk of clinically relevant reactions in individuals with allergies to other legumes, such as peanuts. However, the risk of *de novo* sensitisation was not excluded and the extent of use and forms of use for GB consumers were factors not well defined in the dossier.

Action: Secretariat to prepare a summary of the outcome of the Committee’s review and invite public views on the summary through a 10-day public consultation.

Action: Secretariat to provide advice of ACNFP to Risk managers to inform FSA/FSS decisions for whether reasoned safety objections are raised for this notification.

8. Solid lipid curcumin particle (SLCP) RP1776

ACNFP/171/04

An application for solid lipid curcumin particle (SLCP) as a food supplement was reviewed for the first time. The discussion of the application identified areas where further information is required to complete the assessment.

While the identity of the novel food was appropriately characterised, clarification on the particle size distribution reported in independent batches of the novel food was needed to understand the impact on the bioavailability of the novel food. Members also noted that the potential for agglomeration of particles in the novel food was not assessed in the compositional analysis or the stability study. Further information on the composition and on stability is recommended.

The Committee reviewed the novel food production process. Clarification was sought on the HACCP plan. Queries were also raised on the control and variability of the particle size, and the risk of inhomogeneity with respect to the dose distribution of curcuminoids. It was recommended that the role of silicon dioxide in the novel food should also be clarified.

A review of the novel food specification noted that the other ingredients used to manufacture the SLCP were not listed; therefore, the specification should be updated to reflect the characterising components in the novel food.

The Committee noted that data provided by the applicant indicated that the curcuminoids in the novel food are more bioavailable compared to those in curcumin. Further qualitative and quantitative information was r needed relating to the ADME and/or bioavailability of the curcuminoids from SLCP.

Members reviewed the toxicological information for the novel food. Based on the Committee on Toxicity statement concerning the potential risk to human health of turmeric and curcumin supplements, the acceptable daily intake for curcumin was not considered appropriate given the enhanced bioavailability of the curcuminoids from SLCP. Further review of the data on the novel food was needed and clarification on the test substance used in the toxicology studies recommended to support this.

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

9. Annual Report

ACNFP/171/05

This item was not discussed in the meeting due to time constraints.

Members input on the report had been sought prior to the meeting by the Secretariat. It was agreed that the Secretariat would provide an additional two-week commenting period by correspondence before seeking final sign off by the Chair.

Action: Secretariat to finalise the report with members via correspondence.

Action: Secretariat to seek sign off by the Chair for publication shortly.

10. Allergenicity Workshop

ACNFP/171/06

Members were updated on the outcome of the allergenicity workshop held in February 2024. The workshop sought to explore the latest thinking on assessing allergenicity in food. This was in response to growing trends in protein-based foods in applications to the novel foods service. It also recognised the differences in prevalence of food allergy in the UK and other countries in Europe.

Members held an introductory discussion on the output of the event. It was agreed to provide a 2-week commentary period to capture any further comments or amendments before clearance by Chair’s action.

The discussion then focused on how the output from the workshop and the insights it provides can support on going novel food assessments. Particularly in supporting applicants to tailor the data gathered to support the review of allergenicity. It was agreed to consider further the flow diagram developed in the workshop and new resources that have been published since. This will be explored further with the Committee at a later date.

Action: Secretariat to seek comments from members on the draft output of the allergenicity workshop for clearance by Chair’s action.

Action: Secretariat to explore with members use of the flow diagram for allergenicity assessment and how this can support advice for applicants.

11. Items for Information

11.1 Novel Food Policy Update - Written

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

11.2 GM Policy Update - Written

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

11.3 SACS Update - Written

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

12. Any other business

The Secretariat thanked members for their support in progressing novel food and GM applications through the system. They were updated on the achievements in the 2024/2025 financial year. There were 26 Novel Food outcomes and 11 CBD outcomes (with 3 more due for publication at the start of 2025/2026 financial year). These also included withdrawals from the service but reflect the work of all involved to move the applications forward while maintaining safety for consumers. Similarly on GM, the work of the Committee has supported the review of 10 applications.

Date of next meeting

The next ACNFP meeting will be held online on 24th June 2025.