Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 163rd Meeting held on the 15th of November 2023

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 163rd meeting of the Advisory Committee on Novel Foods and Processes, held on the 15th of November as a virtual meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Dr Mark Berry

Professor Dimitris Charalampopoulos

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Hamid Ghoddusi

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw Jones

Dr Ray Kemp

Dr Elizabeth Lund

Professor Harry McArdle

Mrs Rebecca McKenzie

Professor Clare Mills

Dr Lesley Stanley

Prof Hans Verhagen

Dr Maureen Wakefield

Professor Bruce Whitelaw

Dr Cathrina Edwards

Professor George Bassel

Associate Members

Dr Kimon-Andreas Karatzas

Dr Christine Bosch

Dr Antonio Peña-Fernández

Assessor

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

Observers FSA

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Mr Shaun Jacobs - Senior Policy Advisor

Mr Wecktone Munyai - Senior Policy Advisor

Mr Henry Jones - Senior Policy Advisor

Mr Jamie Luck - Senior Policy Manager

Mr Hoa Chang - Policy Advisor, Genetic Technology

Ms Sophie Burder - Policy Advisor, Novel Foods

Ms Sharon Thompson - Policy Advisor, Novel Foods

Dr Daniel Lloyd - Senior Regulated Products Risk Assessor

Observers (External)

Professor Simon Pearson - Science Council

Ms Ivy Wellman - Defra Representative

Dr Martin Cannell - Defra Representative (GM)

Observers Devolved administration

Mr Jeremy Mills - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Mr Joshua Evans - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Ms Aileen Livingstone - Food Standards Scotland

Mr 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

Mrs Priscilla Wanjiru - Lead Secretariat

Dr Karin Heurlier - Lead Secretariat

Mr Ben Haynes - Science Secretariat

Dr Andrew Hartley - Science Secretariat

Dr Tahmina Khan - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Miss Jenny Rees - Science Secretariat

Miss Lucy Thursfield - Science Secretariat

Mr Liam Blacklock - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

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

Professor Hans Verhagen declared an interest in relation to Dried Miracle Berry. Similarly, Dr Anton Alldrick and Professor Harry McArdle declared interests in relation to CBD. The Chair and Secretariat advised that they would not be present for the discussion of these respective items.

2. Meeting Minutes for the 162nd Meeting

ACNFP/162/MINS

The Committee agreed the 162nd meeting draft minutes for publication on the ACNFP website as an accurate record, pending a minor amendment.

3. Matters Arising from the last meeting

ACNFP/163/MA

The Secretariat informed the panel that the public consultation on proposals for a new framework in England for the regulation of PBOs used for food and feed had gone live on the FSA website. Volunteers from the ACNFP who would like to be involved in developing technical guidance for PBOs would be welcomed and should contact the Secretariat to express interest.

The members were also updated on the ongoing work in progressing the Committee Advice Documents (CAD) being developed by the secretariat, and the plans around how these will be presented consistently whilst capturing the technical information at an appropriate level of detail to allow transparency and readability.

The Secretariat also reported on actions from the previous two day 162nd meeting:

- The Committee reviewed further information supplied by the applicant for *Schizochytrium sp*. Oil rich in DHA and EPA. A Draft Committee Advice Document was discussed and will be finalised by Chair's action.
- Members also reviewed further information for Cellobiose where similarly, a Draft Committee Advice Document was discussed and will be finalised by Chair's action.
- The Committee reviewed further information supplied by the applicant for Corn Protein and advised the Secretariat to seek further information on the production process and composition.
- Following the Secretariat's request for further information, the applicant's response on 'Olive fruit dry extract standardised in hydroxytyrosol' was reviewed and considered sufficient. A Draft Committee Advice Document was requested to be drafted by the Secretariat. This CAD will be reviewed under item 7 of the 163rd meeting.
- Similarly, the response for the request for further information for Magnesium-L-threonate was reviewed and considered sufficient. The Secretariat was requested to draft a Committee Advice Document and this will be reviewed under item 5 of the 163rd meeting.
- The Committee reviewed a new application for Vitamin D2 Mushroom Powder. Areas where further information was needed were identified and this has been requested from the applicant.
- Three new Human Milk Oligosaccharide (HMO) applications had been received from the same applicant in separate dossiers.
  2'-Fucosyllactose (2'-FL)
  3'-Sialyllactose sodium salt (3'-SL)

6’-Sialyllactose sodium salt (6’-SL)
Each dossier was reviewed by the ACNFP, and in all three cases further information was needed. This has been requested from the applicant in each case.

- The Committee reviewed a new application for *Clostridium butyricum*. A number of data gaps were identified, and consideration is being given to how the applicant can be best supported by the FSA to address these.
- The Secretariat provided Members with an update of the work of the joint COT and ACNFP sub-committee on cannabidiol (CBD) and hemp derived products. To note, the sub-committee had completed its work on the Group A pure form >98% pure CBD in 2023 and revised FSA consumer advice was published on the FSA website on 12th October. 2023.
- The Committee reviewed RP07 which is the first of the CBD novel food applications to be reviewed by the ACNFP following the publication of the FSA’s consumer advice. This will be the first of CBD Draft Committee Advice Documents presented to the Committee on a CBD novel food product and will be discussed under item 11 of the 163rd meeting.
- The Committee agreed that the 2022 ACNFP Annual Report is accurate, pending minor adjustments and clearance by Chair’s action. This was published and can be found on the ACNFP website.

4. Dried Miracle Berry - RP1351

ACNFP/163/01

The Committee first reviewed this application at the 159th meeting in April 2023. This resulted in further information being sought from the applicant on the identity, production process, composition, nutrition, Absorption Distribution Metabolism and Excretion (ADME) and toxicology sections.

Members reviewed the applicant’s responses and agreed that the information did not sufficiently inform on safety of the product in certain areas. The Secretariat was advised to seek further information from the applicant on the production process, particularly on discrepancies arising from the HACCP process including the company’s quality assurance process with its suppliers for raw materials. To ensure the novel food was appropriately characterised in relation to the polyphenols and proteins present in the final specification of the novel food, further information on composition was also requested.

Action: The Secretariat to request further information from the applicant.

5. Magnesium-L-threonate - RP956

ACNFP/163/02

The Committee reviewed this application for the first time in September 2022 with further reviews at the November 2022, April 2023 and September 2023 meetings to review further information provided on each occasion by the applicant. Members reviewed a draft Committee Advice Document and provided comments to ensure clarity in the reporting of the assessment undertaken. Recommendations were made by Members to include a statement in all ACNFP Committee Advice Documents to explain that the Committee does not assess potential health claims or nutritional benefits as this is the responsibility of the Department of Health and Social Care. The document was agreed subject to amendments for agreement by Chair's action.

Action: The Secretariat to amend the draft summary opinion and send to Chair for clearance.

6. Isomalto-Oligosaccharides - RP1033

ACNFP/163/03

The Committee reviewed this application in the June 2023 meeting. Members requested clarification from the applicant on the intended uses and anticipated intake.

Members noted that the proposed use of Isomalto-Oligosaccharides (IMOs) in food supplements was amended. A revised assessment of the estimated intake levels of IMOs using data from the UK National Dietary and Nutrition Survey (NDNS) was conducted by the applicant. The Committee considered the implications of this data for UK consumers of the novel food. It was recommended that further advice be sought from the FSA's experts on exposure.

Subject to the additional analysis of the exposure data not raising additional issues that the Committee should be aware of, the Committee Advice Document was agreed subject to amendments to be cleared by Chair's action.

Action: The Secretariat to seek further advice from Exposure Assessment Team on the revised estimated intake levels of IMOs by consumers.

The Secretariat to amend the Committee Advice Document for agreement by Chair's action.

7. Olive fruit dry extract standardised in hydroxytyrosol - RP1074

ACNFP/163/04

The Committee first reviewed the application in the 159th meeting in April 2023. The novel food is an extract of the *Olea europea* L. fruit and standardised in either 10% or 20% hydroxytyrosol for use in food supplements. Members had advised the Secretariat to produce a draft Committee Advice Document for review at the next meeting.

Whilst drafting the document, some areas were identified requiring further time for assessment to better inform on safety. The Secretariat requested the Committee to review and comment on the composition, specification, genotoxicity and toxicology.

The Committee reiterated their queries in relation to the polyphenol content in order to understand how the exposure from the novel ingredient compared to other sources of polyphenols in the diet such as olives. The interpretation of both the toxicological and genotoxicity data was discussed. The Committee recommended that further information was required from the applicant to inform on these areas. Further information will be sought from the applicant to address the data gaps identified and further develop the assessment output.

Action: The Secretariat to request further information from the applican t.

8. Proposed approach for a workshop on the assessment of allergenicity of new protein sources

ACNFP/163/05

The Committee were asked to provide comments on the proposed agenda for an allergenicity workshop, to be held provisionally in February 2024, which will consider the current approach for assessing the potential allergenicity of novel foods.

Members were asked to consider whether they wished to participate in the workshop and also identify possible invitees with relevant expertise in allergenicity.

The Committee agreed that a Core Working Group (CWG) drawn from members of ACNFP should define the terms of reference of the agenda prior to the workshop to ensure a focused and deliverable work programme. Members suggested that the workshop should focus on the current state of the art and avoid replicating but building upon the work already conducted by EFSA. Members noted that preparation would be key to the success of the workshop.

Action: The Secretariat to meet with CWG to finalise agenda and identify participants for the allergenicity workshop.

9. Update paper on the applications to be considered for novel food safety assessment

ACNFP/163/06

The Committee were provided with a written update by the Secretariat on the workload of applications under the novel food and genetic technologies regimes that have been received to the regulated products service. This provided an indication of volume and the range of novel foods application and genetic traits seeking authorisation.

Members were asked to comment on how the current process could be modified to make best use of committee time and resources whilst maintaining risk assessment standards.

Members were in favour of the Secretariat taking additional steps to increase the general quality of dossiers reaching the Committee for review. This included suggesting that the Secretariat should take a tougher stance on applicants that fail to provide meaningful responses to requests for information, as well as considering the potential benefits and drawbacks of introducing an application fee to dissuade the submission of incomplete dossiers and communications going back and forth to obtain data.

Action: Secretariat to note views as part of the development of the regulated products service ways of working.

10. Committee Advice Documents from the PGT Subcommittee on GM applications

ACNFP/163/07

The Committee reviewed three Committee Advice Documents for GM applications, as reviewed by PGT Subcommittee. ACNFP as the main committee was asked to provide governance and assurance, which was completed in all three applications.

There was a discussion on the level of assessment expected for allergenicity of stacked events where the included events have been assessed and authorised individually. An approach was agreed and reflected in the documents discussed.

Action: Secretariat to agree final text of the Committee Advice Documents by Chair's action.

11. CBD RP07

ACNFP/163/08

The focus of the item was to review the updated text for a Committee Advice Document for this synthetic CBD novel food. Detailed comments had been provided by correspondence with the applicant and would be addressed alongside the feedback received in item discussion.

It was flagged that when referring to the recent FSA statement on consumer advice for pure form >98% pure CBD in the CAD, this should reflect the wording of the statement and be reproduced consistently. Solvent residues and reporting on the implications for safety were explored. It was suggested that the level of residues in the novel food should be compared to relevant limits in other sectors such as the REACH regulatory framework to put them in context, if such data exists. Some suggestions of other regulators who may have assessed the toxicological profile of the substances of interest were discussed.

Action: Secretariat to amend the Committee Advice Document's text for agreement by Chair's action.

12. Items for Information

12.1 Novel Food Policy Update - Written

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

12.2 GM Policy Update - Written

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

12.3 SACS Update - Written

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

Date of next meeting

The next meeting will be held in person in London on 7th February 2024.