Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 159th Meeting held on the 26th of April 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 159th meeting of the Advisory Committee on Novel Foods and Processes, held on the 26th of April at Clive House, London as a hybrid meeting**.**

Attendance

Committee Chair

Ms Alison Austin - Acting Chair

Committee Members

Dr Mark Berry

Professor Dimitris Charalampopoulos

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw Jones

Dr Elizabeth Lund

Dr Maureen Wakefield

Mrs Rebecca McKenzie

Dr Lesley Stanley

Prof Hans Verhagen

Professor Clare Mills

Professor Harry McArdle

Professor Pete Lund - Co-opted Member - for item 11

Professor Alastair Macrae - Co-opted Member - for item 11

Apologies

Dr Camilla Alexander-White - Chair

Dr Anton Alldrick - Member

Dr Hamid Ghoddusi - Member

Dr Ray Kemp - Member

Professor Bruce Whitelaw - Member

Assessor

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

Observers FSA

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Mr Hoa Chang - GT Policy Advisor

Mr Shaun Jacobs - FSA Senior Policy Advisor

Mr Jamie Luck - FSA Senior Policy Manager

Ms Sharon Thompson - Novel Foods Policy Advisor

Ms Sophie Burder - Novel Foods Policy Advisor

Observers Devolved administration

Mr Lloyd Evans - Policy, FSA Wales

Mrs Siobhan Watt - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA NI

Observers (External)

Mr Simon Pearson - Science Council

Dr Jennifer Garry - Department of Health & Social Care

Ms Celia Sabry-Grant - Department of Health & Social Care

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary

Mrs Priscilla Wanjiru - Science Secretariat

Dr Karin Heurlier - Science Secretariat

Mr Will Smith - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Andrew Hartley - Science Secretariat

Mr Matt Hall - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Mr Rhys Williams - Science Secretariat

Mr Ben Haynes - Science Secretariat

Miss Jenny Rees - Science Secretariat

Mr Liam Blacklock - Science Secretariat

Miss Lucy Thursfield - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

The Chair, Dr Camilla Alexander-White, and Members Dr Anton Alldrick, Dr Hamid Ghoddusi, Dr Ray Kemp and Professor Bruce Whitelaw sent their apologies for non-attendance.

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

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

Professors Alastair Macrae and Pete Lund (Members of PGT Subcommittee) are joined for the PGT update under item 11.

2. Meeting Minutes for the 157th and 158th Meeting

ACNFP/157/MINS

The Committee agreed the draft minutes for publication as final on the ACNFP website, as an accurate record of the 157th meeting held on 7th and 8th February 2023.

It was noted that the minutes for the 158th meeting, where on 28 March 2023 the ACNFP discussed the work of the CBD joint ACNFP/COT working group, had not yet been drafted and would be circulated in June to members along with the minutes for the 159th meeting for comment and input by correspondence.

3. Matters Arising from the last meeting

ACNFP/159/MA

The Secretariat reported on actions from the previous meeting:

- The Committee had previously reviewed Madhuca Longifolia, a traditional food from a third country application. Members were informed of the Risk Management outcome and the traditional food application was deemed invalid as it did not adequately fulfil all the requirements.
- The Committee previously reviewed the draft Committee Advice document for the 3-fucosyllactose (3’-FL) application and the lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture (LNFP-I/2'-FL) application. Members identified areas for the Secretariat to amend and identified further information was needed on the production processes for both applications. The responses were reviewed under item 3.
- The Committee reviewed the application for Calcidiol. The Secretariat were advised to produce a draft of the Committee Advice document for Committee review. This will be presented to the Committee for input under item 4.
- An application for Corn Protein was reviewed for the first time. Further information was sought. The response from the applicant on corn protein will be considered under item 6.
- The Committee also reviewed four other new applications; Isomalto-Oligosaccharides, Krill Protein Hydrolysate, Schizochytrium species Oil and *Mycobacterium aurum*. Further information was identified to be required for all four applications with the Secretariat requesting this from the applicants. These will be brought back for Committee consideration at future meetings.
- Cellobiose, a replacement for sugars, was also reviewed for the first time with the members identifying further information needed from the applicant. They also advised the Secretariat that once this information was provided, a Committee Advice document could be drafted for review at the next available meeting.
- The Committee reviewed the draft Committee Advice documents for four GM renewal applications: Genetically Modified soybean A5547-127, Genetically Modified soybean 40-3-2, Genetically Modified maize MIR162 and Genetically Modified cotton GHB614. Agreement of revised drafts in light of the comments were advised to be finalised by Chair’s action.
- The ACNFP Terms of Reference were also reviewed. The Committee agreed the proposed changes, pending minor amendments. These were by Chair’s action and have now been published on the ACNFP website.
- The Secretariat provided Members with an update of the work of the joint COT and ACNFP subcommittee on cannabidiol (CBD) and hemp derived products. The first output on pure form CBD was reviewed during the 158th

ACNFP meeting on 28 March 2023. The joint ACNFP/COT position paper was agreed and is being prepared for publication.

4. Magnesium-L-threonate - RP956

ACNFP/159/01

The Committee reviewed the response and supplementary information provided by the applicant. The Secretariat was asked to seek clarification on the quality of the translated documentation and confirmation that the analytical methodology utilised is internationally accredited.

The Committee assessed information regarding the identity of the novel food. Members requested the Secretariat seek further analytical data in order to quantify the main components in the novel food. Information concerning the potential presence of small particles, including nanoparticles, in the novel food, had been provided and was reviewed. This initiated a wider discussion into the assessment of nanomaterials and their toxicological concerns in foods. A detailed review of the response will be undertaken outside the meeting in order to inform further discussion on this point.

The Committee evaluated the applicant’s response regarding the manufacturing process of the novel food. Members agreed the Secretariat should request more information in respect of specific issues relating to food safety management within the production process.

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

5. Corn Protein - RP1238

ACNFP/159/02

The Committee reviewed further detail concerning the role of processing aids in the production process. Members suggested the Secretariat should request clarification of the applicant’s meaning when using non-standard scientific terminology in describing the role of these substances in the manufacture of the novel food. This would ensure a common understanding of the process and the potential hazards that may be present.

Proposed specification limits for the microbiological quality of the novel food were considered. Members requested that the Secretariat query these recommended levels with the applicant, in respect to the lower values reported in the batch data in order to understand any additional sources of variability in the production.

The Committee considered the digestibility studies provided by the applicant, but noted the approach described is not an internationally recognised method for assessing protein quality. It was recommended that further information be sought from the applicant which permits a comparison of the submitted data alongside internationally recognised methods for determining protein quality.

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

6. Lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2' FL) mixture (LNFP-I/2'-FL) - RP549

ACNFP/159/03

The Committee reviewed the information concerning the production process supplied by the applicant and no further queries were raised by Members.

Action: Assessment output to be signed off by Chair and the dossier to be moved to risk management phase to conclude the regulated products process.

7. Calcidiol - RP35

ACNFP/159/04

The Committee reviewed the draft Committee Advice document providing detailed drafting comments for the Secretariat to take on board. A revised draft will be brought back to the next available meeting.

In addition to the comments on this application a number of generic comments on the style, and consistency such as naming conventions for future Committee advice on safety were raised and noted.

Action: The Secretariat to amend the draft Committee Advice for further Committee review.

To develop a style guide and capture points of approach and presentation so that future draft Committee Advice documents are consistent.

8. Olive fruit dry extract standardized in hydroxytyrosol - RP1074

ACNFP/159/05

The Committee reviewed a new application for the first time for ‘olive fruit dry extract standardised in hydroxytyrosol’, a by-product from olive oil production. The novel ingredient is proposed by the applicant for use in food supplements. It was noted that the novel food ingredient is an extract of the Olea europea L. fruit and, standardized in either 10% or 20% hydroxytyrosol.

A first review of the dossier was undertaken and a number of data gaps around production process, identity and composition, stability, toxicology and proposed use. Clarity was sought on the product and its composition in order to identify the key characterising components in addition to the hydroxytyrosol.

Similarly, details were sought on the nature of the column-based extraction process to ensure all potential hazards had been identified and managed as appropriate. It was noted that data had been provided from literature to support the toxicological safety of the novel food. Further information was sought on how the data had been used and the relevance to the novel food under assessment. Further information was to be sought from the applicant to address the data gaps identified.

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

9. Dried Miracle Berry - RP1351

ACNFP/159/06

Professor Hans Verhagen declared an interest because he is engaged in work on a potential competitor product. It was agreed with the Chair that he not be present for the discussion.

The Committee reviewed a new novel food application for the first time for Dried Miracle Berry, pitted fruits from the Synsepalum dulcificum plant, for use in food

supplements. It was noted that the applicant proposes the novel ingredient would serve as a functional food to be taken prior to consumption of sour foods to improve palatability. Members had been provided with the 2021 EFSA opinion on the safety of the novel food, as background information to their review.

Data gaps were identified in identity, production process, composition, nutrition, Absorption Digestion Metabolism and Excretion (ADME) and toxicology sections of the information provided.

On the production process queries were raised on the controls in the process and how this impacted the variability in the composition of the final product. It was noted that the variability between growing seasons and climate conditions had been considered. Information on the other sources of variability were sought. Particularly where these could influence food safety considerations such as mycotoxin levels. Further information was sought on the other components in the berries such as polyphenols in order to better understand the nature of the product.

Members noted that the applicant had submitted ADME data on miraculin rather than the novel food itself and advised the Secretariat to request re-evaluation of ADME of the novel food with consideration of the impact of the other constituents of the food. In addition, further information was sought on the toxicological risk assessment of the fruit itself and an explanation how the data identified supports the safety of the novel food.

Further information was also sought on miraculin, a characterised protein in the novel food, and whether it was likely to have antinutritional or allergenic potential that would require further consideration. Further information will be sought from the applicant to address the data gaps identified.

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

10. Pasteurised *Akkermansia muciniphila* - RP1468

ACNFP/159/07

The Committee reviewed an application for a novel ingredient comprised of pasteurised *Akkermansia muciniphila* for the first time. The proposed use of the novel ingredient is as an ingredient in food supplements and foods with special

medical purposes (FSMPs). The Committee identified data gaps in the identity, production process, composition, and proposed use sections of the information provided.

Questions were raised on the identity and nature of the product. It was noted that a separate review of the genetics and microbiology would be needed and this would be considered further at the next meeting.

A number of queries were raised by the Committee on the production process. More information and detail were needed regarding the hazard analysis and critical control points (HACCP); including more clearly defined critical control points and data to show risks and hazards are managed sufficiently.

A number of points around the composition and the evidence that were supplied to support the review of the effectiveness of critical control points and stability data were raised. Further information was sought regarding the use of growth media and the potential for carryover of materials from the growth media, such as protein and/or allergens, into the final product.

The Committee explored the role in the diet for this novel food. Clarity was sought on the types of products it would be used in within the foods with special medical purpose (FSMP) category to ensure accurate calculation of potential exposure. Further information to address the data gaps will be sought from the applicant and a further review by members made at the next available meeting.

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

11. PGT Subgroup Update (reserved business)

ACNFP/159/08

The ACNFP Committee was updated on the work of the Subcommittee for Products of Genetic Technologies (PGT) and development of approaches to a scientific basis for the authorisation of Precision Bred Organisms (PBOs) for use as food and feed. ACNFP members were invited to provide feedback on different approaches that had been developed to date by the PGT subgroup, considering the potential data requirements for a new technical assessment of the safety of PBOs for food and/or feed. The proposed approaches were the result of in-depth discussion and capture the views of the PGT Subcommittee. This is a challenging and unprecedented technical activity and is being performed in consideration of

and with respect to the interpretation of the requirement for proportionality within the authorisation framework.

Members recognised the challenges of the Subcommittee's work, and thought that both approaches presented were scientifically justifiable. The Committee agreed that the PGT Subcommittee should pursue development and further discussion of the two approaches through detailed exploration of data requirements, building on their case studies approach. The outcome of the next phase of work of the PGT subcommittee will be reviewed again by the ACNFP in June and the final recommendations and options issued as a draft statement to be further reviewed by ACNFP later this year. The statement from the ACNFP will support the FSA Board (currently timetabled for September 2023) by providing relevant scientific background when they make their decision on the Precision Breeding Framework the FSA will adopt for authorising new PBOs, while considering the broad risk management context.

Action: The Subcommittee on products of genetic technologies to further develop both options identified to inform future discussions with the ACNFP and FSA board.

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.

13. Any other business

Discussion was held on whether the next meeting of the ACNFP could be virtual. Members shared their view given the complexity of the issues under

consideration and the Secretariat will take Members views away to inform meeting planning.

Date of next meeting

The next ACNFP hybrid meeting in London is scheduled for 14th June 2023. Members felt however that in view of the challenging technical nature of the PGT discussions that would be expected in June, in-person attendance by members should be actively encouraged.