Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 162nd Meeting held on the 18th and 19th of September 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 162nd meeting of the Advisory Committee on Novel Foods and Processes, held on the 18th and 19th of September at Clive House, London, as a hybrid 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

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

Apologies

Professor Paul Fraser

Assessor

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

Observers FSA

Mr Hoa Chang - GT Policy Advisor

Mr Shaun Jacobs - Senior Policy Advisor

Mr Adekunle Adeoye - FSA Senior Policy Advisor

Mr Jamie Luck - Senior Policy Manager

Ms Sharon Thompson - Novel Foods & Feed Additives Policy Advisor

Mr Liam Burke - Policy Advisor, Novel Food and Radiological

Ms Sophie Burder - Policy Advisor, Novel Foods

Dr Daniel Lloyd - Senior Regulated Products Risk Assessor

Professor Simon Pearson - Science Council

Observers Devolved administration

Mr Jeremy Mills - Policy, FSA Wales

Mr Joshua Evans - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA NI

Mr Xose Benitu Alvarez - Policy, FSA Wales

Ms Lucy Smythe - Food Standards Scotland

Ms Aileen Livingstone - Food Standards Scotland

Secretariat

Mrs Ruth Willis - Technical Secretary

Mrs Priscilla Wanjiru - Lead Secretariat

Dr Karin Heurlier - Lead Secretariat

Mr Ben Haynes - Science Secretariat

Dr Tahmina Khan - Science Secretariat

Mr Matt Hall - Science Secretariat

Mr Will Smith - Science Secretariat

Dr Andrew Hartley - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Miss Jenny Rees - Science Secretariat

Miss Lucy Thursfield - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Professor Paul Fraser sent his apologies for non-attendance.

The Chair welcomed the Members, representatives from the FSA, the observers from the devolved administrations and the Secretariat team. The Chair also welcomed two new Members of the Committee Dr Cathrina Edwards and Professor George Bassel and three new Associate Members Dr Kimon-Andreas Karatzas, Dr Christine Bosch and Dr Antonio Peña-Fernández. The Chair outlined the role of the Associate Member to the Committee.

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 interests in relation to *Schizochytrium sp.* Oil and Professor Harry McArdle declared interests in relation to 3'-sialyllactose sodium salt (3'-SL) and 6'-sialyllactose sodium salt (6'-SL). The Chair and the Secretariat agreed that the stated interests could present a conflict of interest in these discussions. Professors Verhagen and McArdle were advised that they would not be able to participate in the review of the respective applications. Similarly, Dr Anton Alldrick and Professor Harry McArdle previously declared interests in relation to CBD and the Chair and Secretariat advised that they would not be present for the discussion of those items.

2. Meeting Minutes for the 160th and 161st Meeting

ACNFP/160 & 161/MINS

The Committee agreed the 160th meeting draft minutes for publication on the ACNFP website as an accurate record, pending a minor amendment. Members reviewed and commented on the 161st meeting minutes from the meeting held on 25th July 2023 with amendments suggested, to be agreed via correspondence before publication.

3. Matters Arising from the last meeting.

ACNFP/162/MA

The Secretariat reported on actions from the previous 160th meeting:

- The Committee had reviewed the isomalto-oligosaccharides application and advised the Secretariat to seek further information from the applicant. Members had reviewed the initial draft Committee Advice Document and suggested areas for amendments. The applicant's response, once received, would be reviewed at the next available meeting.
- The Committee previously reviewed a returning application for Pasteurised cells of *Akkermansia muciniphila* and had identified further information was needed from the applicant. The applicant's response, once received, would be reviewed at the next available meeting.
- The Committee previously reviewed Genetically Modified Cotton GHB811 for food and feed. The Secretariat were asked to seek clarification from the applicant regarding a discrepancy in the data provided to the UK compared to the EU in order to report the assessment accurately. Members were invited to comment on the Committee Advice Document that had been reviewed and agreed by the ACNFP-PGT Subcommittee. Members provided final input and the Committee Advice Document was agreed by Chair's action.
- The Committee previously held a precision breeding workshop. The ACNFP were updated on the work of the ACNFP-PGT Subcommittee and further explored the data requirements for the two potential approaches to triage as well as tier 2 assessment.

The Secretariat reported on actions from the previous 161st meeting:

- A workshop on Precision Bred Organisms was held. A statement on the outcomes of the ACNFP's discussions to date was further developed and finalised for publication.

4. *Schizochytrium sp*. Oil rich in DHA and EPA - RP1411

ACNFP/162/01

Professor Hans Verhagen was deemed to have a conflict of interest in relation to *Schizochytrium sp*. Oil rich in DHA and EPA and did not participate in the review of the application.

The Committee first reviewed the extension of use application at the 157th meeting in February 2023. This resulted in further information being sought from the applicant on the extended uses in meat and fish analogues, stability in food matrices and how the application differed to existing authorisations.

The Committee had reviewed the applicant's responses and agreed that the new information supplied was sufficient. The Secretariat had invited Members to review a draft Committee Advice Document. Members identified areas for the Secretariat to amend in order to finalise the draft for their agreement and clearance by Chair's action.

Members advised the Secretariat that for future extension of use applications, a summary of key considerations from the original assessment would help to support the assessment.

Action: The Secretariat to amend the draft Committee Advice Document and seek agreement on a final version for clearance by Chair's action.

5. Cellobiose - RP1109

ACNFP/162/02

The Committee first reviewed the Cellobiose application in the 157th meeting in February 2023. Members had suggested the Secretariat seek further information on the production process, proposed uses and intake levels, ADME and further consideration for consumption by sensitive subpopulations.

The Secretariat invited Members to review the applicant's response and a draft Committee Advice Document.

The Committee reviewed the additional information and raised further queries on the production process. Members advised that the Secretariat seek further

information on the enzymes used in the manufacture of Cellobiose in order to evaluate any potential allergenicity concerns. In addition, further information and clarification was requested on the method of analysis for residual proteins. The Committee reviewed the draft Committee Advice Document and identified areas for the Secretariat to amend.

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

6. Calcidiol – RP35

ACNFP/162/03

The application was not discussed due to meeting time constraints. A review of the returning application was postponed for the next available meeting.

7. Corn Protein - RP1238

ACNFP/162/04

The Committee first reviewed the Corn Protein application in the 157th meeting in February 2023 and again at the 159th meeting. Members had suggested the Secretariat seek further information on the specifications, production process and absorption, distribution, metabolism and excretion (ADME). Queries had been raised regarding control measures for potential mycotoxin contamination and sought further information on protein quality.

The Secretariat invited Members to review the applicant’s response.

The Committee raised further queries regarding the effectiveness of control measures in addressing the potential for microbial contamination and queried the sources of variation in microbial parameters from the compositional batch analyses. Members advised that further information was also needed to compare the applicant’s methodology for obtaining protein quality data to internationally recognised approaches.

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

8. Olive fruit dry extract standardised in hydroxytyrosol - RP1074

ACNFP/162/05

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 suggested the Secretariat seek further information on the production process, identity, composition, stability, toxicological information and proposed uses.

The Committee agreed that the information provided by the applicant was sufficient and advised the Secretariat to produce a draft Committee Advice Document for review at the next available meeting.

Action: The Secretariat to produce a draft Committee Advice Document for the application.

9. Magnesium-L-threonate – RP956

ACNFP/162/06

The Committee reviewed the magnesium-L-threonate application for a third time in the 159th meeting in April 2023. Members had suggested the Secretariat seek further information on the production process, identity and composition. The Committee subsequently undertook a detailed separate review on whether the potential for small particles and nanoparticles in the novel food product had been considered and it was confirmed that sufficient information had been provided to confirm the novel food is not in a nano form.

The Secretariat invited Members to review the applicant’s response.

The Committee agreed that the information provided by the applicant was sufficient and drew their conclusions on the safety assessment of the novel food.

Members considered the details of the production and whether the production controls were sufficiently characterised. This followed a detailed review of the HACCP plan provided. While not a data gap that prohibits the completion of the assessment, Members highlighted that risk managers will wish to consider whether measures such as refining the specifications are needed in the authorisation to ensure appropriate management of the production process.

Action: The Secretariat to produce a draft Committee Advice Document for the application

10. Vitamin D2 Mushroom Powder - RP1550

ACNFP/162/07

The Committee reviewed a new novel food application. The novel food consists of *Agaricus bisporus* mushrooms exposed to UV light thereby increasing vitamin D2 levels. The novel food is ground to a powder and proposed uses include conventional foods and beverages in addition to food supplements. While UV irradiated mushrooms have been authorised previously as a novel process, there is a need to seek authorisation for each product where the nature of the process is different and alters the composition of the end product.

The Committee raised queries on the production process and how this controls the potential hazards foreseen in the production process. This was also linked to seeking to better understand the potential sources of variation in composition. Queries were raised on whether the product is blended and whether this had occurred for the compositional data presented in order to place the data in context.

Members commented that the company had provided data on their production in America and this was subject to a different approach to hygiene controls than that used in the UK and EU. Clarification was sought on how the production controls ensured compliance with the UK approach to food safety management.

The novel production method applied to the mushrooms was not a specific issue that would affect the completion of the assessment. However, it was noted that the proposed wide range of uses could require risk management to ensure individuals with a mushroom allergy were aware that mushrooms were being added to a wider range of products.

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

11. 2022 Annual Report

ACNFP/162/08

The Secretariat invited the Committee to review a draft 2022 annual report outlining the work of the Committee for 2022 and seeking final input and agreement for publication. The Committee made suggestions for changes that might be beneficial to consider for this and future reports. Members encouraged the Secretariat to explore the possibility of an open meeting or alternative event with external stakeholders and interested organisations. This would raise awareness of the Committee's work and the standard needed from application dossiers for review by the Committee.

The final draft was agreed for clearance by Chair's action before publication, pending minor amendments.

Action: The Secretariat to publish the 2022 ACNFP Annual Report following clearance 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.

13. Any other business

Scientific Advisory Committee (SAC) recruitment campaign

The Secretariat provided an update to Members regarding the latest FSA Scientific Advisory Committee (SAC) recruitment campaign seeking to fill key positions within the ACNFP. The Secretariat invited Members to participate in the campaign and thanked those Members who were actively involved.

Ways of working: draft Committee Advice Documents

The Secretariat proposed a trial for a new way of working for some applications. The Secretariat informed Members that a draft Committee Advice Document had been prepared for items 14, 15 and 16 (Human Milk Oligosaccharides applications) on the agenda. This was undertaken by the Secretariat due to several Human Milk Oligosaccharides (HMOs) having been reviewed by the Committee previously. The Secretariat invited Members to provide feedback and any comments which would inform future ways of working. Members liked the use of Committee Advice Documents and the Secretariat would consider how this could inform future ways of working.

14. 2'-Fucosyllactose (2'-FL) - RP1476

ACNFP/162/09

The Committee reviewed a new application for the first time that was presented by the Secretariat as an extension of use for 2’-FL. It was noted that several Human Milk Oligosaccharides (HMOs) had been reviewed by the Committee previously and that 2’-FL, a type of HMO, had several previous authorisations from separate applicants in place. The applicant had sought changes to the conditions of use of the novel food in three ways: use of an alternative microbial production organism, alterations to the specifications and for extended uses in food supplements for infants in addition to current authorised uses. The Committee considered the information from previous authorisations and agreed the assessment should look at all aspects of the novel food. This was due to the novel nature and extent of the changes proposed, which Members agreed would not be appropriate for an extension of use type review.

A draft Committee Advice Document had been prepared and the Secretariat invited Members to review the draft and provide comments.

Members advised the Secretariat to seek further information on identity, compositional and stability data including the methods of analyses, the specifications, toxicological information and the production process.

Members discussed in detail the identity and characteristics of the genetically modified microorganism (GMM) used to produce the novel food and agreed that further information was needed to understand any impact on the assessment.

Queries were raised on the compositional analysis and data gaps identified that needed to be addressed to ensure that the novel food was appropriately characterised.

Members highlighted the need for applicants to provide sufficient information on their food safety management system and demonstrate that potential risks and hazards have been fully identified with evidence to show that these are being sufficiently controlled and monitored.

The Committee highlighted that Risk Managers should consider the labelling of the product to ensure that consumers did not take multiple products on the same day.

The Committee reviewed the draft Committee Advice Document and identified areas for the Secretariat to amend. This will be updated based on further information supplied by the applicant for further review by the Committee.

Action: The Secretariat to request further information from the applicant and amend the draft Committee Advice Document for further review by the Committee.

15. 3'-Sialyllactose sodium salt (3'-SL) - RP1477

ACNFP/162/10

Professor Harry McArdle was deemed to have a conflict of interest in relation to 3’-sialyllactose sodium salt (3’-SL) and 6’-sialyllactose sodium salt (6’-SL) from his work with EFSA and did not participate in the review of the application.

The Committee reviewed a new novel food application for the first time. The novel food, a type of Human Milk Oligosaccharide (HMO), is to be used in a range of foods and beverages, including food supplements, intended for the general population.

A draft Committee Advice Document had been prepared and the Secretariat invited Members to review the draft and provide comments.

The Secretariat explained in their introduction that a previous authorisation for the novel food was held by another applicant with data protection in place. As such, for the applicant to place their product on the market, a full application was required. A full application had been provided to the Committee for review.

Members advised the Secretariat to seek further information on identity, compositional data, the specifications, toxicological information and the production process.

Members discussed in detail the identity and characteristics of the Genetically Modified Microorganism (GMM) used to produce the novel food and agreed that further information was needed to understand any impact on the assessment. They also sought clarification on the data supplied to demonstrate that the production organism is effectively removed from the final food.

Queries were raised on the compositional analysis and data gaps identified that needed to be addressed to ensure that the novel food was appropriately characterised. This included clarification on the testing undertaken to inform the allergenicity risk assessment.

The Committee noted that it was the sodium salt form of the human milk oligosaccharide that is produced. Members advised the Secretariat to seek further justification for any impacts on consumers from the additional dietary salt exposure from the proposed uses.

Members highlighted the need for applicants to provide sufficient information on their food safety management system and demonstrate that potential risks and hazards have been fully identified with evidence to show that these are being sufficiently controlled and monitored.

The Committee highlighted that Risk Managers should consider the labelling of the product to ensure that consumers did not take multiple products on the same day.

The Committee reviewed the draft Committee Advice Document and identified areas for the Secretariat to amend. This will be updated based on any further information supplied by the applicant for further review by the Committee.

Action: The Secretariat to request further information from the applicant and amend the draft Committee Advice Document for further review by the Committee.

16. 6'-Sialyllactose sodium salt (6'-SL) - RP1478

ACNFP/162/11

Professor Harry McArdle was deemed to have a conflict of interest in relation to 6’-sialyllactose sodium salt (6’-SL) and 3’-sialyllactose sodium salt (3’-SL) and did not participate in the review of the application.

The committee reviewed a new novel food application for the first time. The novel food, a type of Human Milk Oligosaccharide (HMO), is to be used in a range of foods and beverages, including food supplements, intended for the general population.

A draft Committee Advice Document had been prepared and the Secretariat invited Members to review the draft and provide comments.

The Secretariat explained in their introduction that a previous authorisation for the novel food was held by another applicant with data protection in place. As such, for the applicant to place their product on the market, a full application was required. A full application had been provided to the Committee for review.

Members advised the Secretariat to seek further information on identity, compositional data including the methods of analyses, the specifications, toxicological information and the production process. Members discussed in detail the identity and characteristics of the Genetically Modified Microorganism (GMM) used to produce the novel food and agreed that further information was needed to understand any impact on the assessment.

Queries were raised on the compositional analysis and data gaps identified that needed to be addressed to ensure that the novel food was appropriately characterised. This included clarification on the testing undertaken to inform the allergenicity risk assessment.

The Committee noted that it was the sodium salt form of the human milk oligosaccharide that is produced. Members advised the Secretariat to seek further justification for any impacts on consumers from the additional dietary salt exposure from the proposed uses.

Members highlighted the need for applicants to provide sufficient information on their food safety management system and demonstrate that potential risks and hazards have been fully identified with evidence to show that these are being sufficiently controlled and monitored.

The Committee highlighted that Risk Managers should consider the labelling of the product to ensure that consumers did not take multiple products on the same day.

The Committee reviewed the draft Committee Advice Document and identified areas for the Secretariat to amend. This will be updated based on further information supplied by the applicant for further review by the Committee.

Action: The Secretariat to request further information from the applicant and amend the draft Committee Advice Document for further review by the Committee.

17. Dried Miracle Berry - RP1109

ACNFP/162/12

The application was not discussed due to meeting time constraints. A review of the returning application was postponed for the next available meeting.

18. *Clostridium butyricum* - RP1396

ACNFP/162/13

The Committee reviewed a new novel food application for the first time. The novel food is a live strain of *Clostridium butyricum*, a strictly anaerobic spore-forming bacteria belonging to the Gram-positive *Clostridium* genus. The intended use is in food supplements. It was noted that there was a previous authorisation for *Clostridium butyricum* as a novel food but for a different live strain and therefore a full review was needed.

The Secretariat were advised to request further information on the production process including the food safety management system and further information on proposed uses and toxicological information.

Members discussed in detail the type of bacterial strain proposed and advised the Secretariat to seek further information on the identity and characterisation of the bacterial strain. Further evidence was also needed to understand what food safety risks, if any, it would pose.

The Committee raised queries on potential risks of consumption of the novel food by vulnerable groups. Members requested further information be sought from the applicant on this. A wider discussion on novel foods of microbial nature and potential risks associated with exposure and consumption by vulnerable groups took place.

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

19. Update on the work of the CBD Subgroup (reserved business)

ACNFP/162/14

It was noted that Dr Anton Alldrick and Professor Harry McArdle were deemed to have standing conflicts of interest in relation to CBD and were not present for the update.

The Committee were provided with an oral update on the ongoing work and progress of the ACNFP/COT subgroup. They discussed how the review undertaken by the Joint ACNFP/COT subgroup on the toxicological data in the applications would be taken forward. In addition, issues common to several applications were discussed, along with how the information to complete the assessment on toxicological aspects could be gathered and collated to inform individual application assessments.

The results of the discussion and a completion of the toxicological data review will further inform the assessments for CBD novel food applications.

20. CBD – RP07 (reserved business)

ACNFP/162/15

It was noted that Dr Anton Alldrick and Professor Harry McArdle were deemed to have standing conflicts of interest in relation to CBD and were not present for the application review.

The Committee reviewed the application for a third time in the 152nd meeting in March 2022. The Secretariat were asked to review a draft Committee Advice Document for the application.

Members identified areas for the Secretariat to amend.

Action: The Secretariat to amend the draft Committee Advice Document for review at the next meeting.

21. CBD – RP350 (reserved business)

ACNFP/162/16

The CBD application was not discussed in detail due to meeting time constraints. Members agreed that the learning from the CBD application discussed in detail under agenda item 15, would be applied to this assessment. This review was postponed to the next available meeting.

22. CBD – RP427 (reserved business)

ACNFP/162/17

The CBD application was not discussed in detail due to meeting time constraints. Members agreed that the learning from the CBD application discussed in detail under agenda item 20, would be applied to this assessment. This review was postponed to the next available meeting.

Date of next meeting

The next meeting of the ACNFP PGT sub-committee is scheduled for 18th October 2023 as a virtual meeting. The next 163rd meeting of the ACNFP is scheduled for 15th November 2023 as a virtual meeting.