Meeting

Advisory Committee on Novel Foods and Process. Minutes of the 157th Meeting held on the 7th and 8th of February 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 157th meeting of the Advisory Committee on Novel Foods and Processes, held on 7th February 2023 at Clive House, London and 8th February 2023 at Broadway House, London as hybrid meetings**.**

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

Dr Maureen Wakefield

Mrs Rebecca McKenzie

Dr Lesley Stanley

Prof Hans Verhagen

Professor Bruce Whitelaw

Professor Clare Mills

Professor Alastair Macrae - Co-opted Member

Professor Pete Lund - Co-opted Member

Apologies

Professor Harry McArdle - Member

Assessor

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

Observers FSA

Ms Rebecca Sudworth - Director of Policy

Mr Chris Stockdale - Head, Genetic Technology Policy

Mr Hoa Chang - GT Policy Advisor

Mrs Justine Gallie - GT Policy Advisor

Mr Shaun Jacobs - FSA Senior Policy Advisor

Mr Jamie Luck - FSA Senior Policy Manager

Mr Donal Griffin - Regulated Products Risk Assessment Team Leader (Feed and GM)

Ms Sophie Hardy - Regulated Products Engagement & Partnerships Coordinator

Ms Sharon Thompson - Novel Foods & Feed Additives Policy Advisor

Ms Sophie Burder - Novel Foods Policy Officer

Observers Devolved administration

Mr Andrew Dodd - Policy, FSA Wales

Mr Lloyd Evans - Policy, FSA Wales

Mr Xose Benitu Alvarez - Policy, FSA Wales

Ms Hannah Reid - Policy, FSA Wales

Mrs Siobhan Watt - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Ms Georgina Finch - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Mr Ciaran Weir - Policy, FSA NI

Mr Daniel Lynch - Policy, FSA NI

Observers (External)

Professor Thomas Richards - Royal Society Policy Associate

Secretariat

Mrs Ruth Willis - 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

Ms Katie Schultz - Science Secretariat

Mr Ben Haynes - Science Secretariat

Mr Nathan Allen - Science Secretariat

Miss Jenny Rees - Science Secretariat

Ms Shila Sultana - Science Secretariat

Mr Liam Blacklock - Science Secretariat

Miss Lucy Thursfield - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Professor Harry McArdle 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 reminded Members of the need to announce any potential conflicts of interests prior to the discussions on each item.

Dr Anton Alldrick declared potential conflict of interest in relation to CBD. To facilitate this, the agenda had been arranged to separate the ACNFP/ COT subgroup update from the other items for discussion.

2. Meeting Minutes for the 155th and 156th Meetings

ACNFP/155/MINS and ACNFP/156/MINS

The Committee agreed on the draft minutes for publication on the ACNFP website as an accurate record of the 155th and 156th meetings held on 16th November 2022 and 16th January 2023, respectively.

3. Matters Arising from the last meeting

ACNFP/157/MA

The Secretariat reported on actions from the previous meeting:

- The Committee had previously reviewed a dossier and further information supplied by the applicant for Magnesium-L-threonate. Members provided input to the FSA on the information provided and identified further information was needed from the applicant. The response will be reviewed by the Committee at a future meeting.
- The Committee previously reviewed the final draft Committee Advice for Cetylated Fatty Acids and Barley Rice Protein. The Committee agreed that the outcomes are an accurate conclusion of the assessment and the advice provided. These documents are to be published on the ACNFP website and moved to risk management.
- The Chair actioned minor amendments to the 2021 ACNFP Annual Report that had been agreed and finalised by the Committee, and the report was published on the ACNFP website.
- The Committee were asked to advise on the data needed to assess the safety of extraction solvents used in novel food production processes for products seeking authorisation. Members agreed that the Secretariat should explore gathering information taken from other UK frameworks for chemicals, such as UK REACH, to provide an additional evidence base to inform review.
- The ACNFP Committee and ACNFP-PGT Subcommittee held a joint workshop on Precision Bred Organisms in January 2023 and agreed on the proposed framework. A statement on the outcome of the workshops was finalised. The PGT Subcommittee reviewed the processes, underpinned by policy, that manage real and perceived conflicts of interests of Members. The statement

on the outcome of the workshops was published on the ACNFP website on January 23rd 2023.

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

ACNFP/157/01

The Committee first reviewed the application in the 153rd meeting in June 2022, which resulted in a request for further information on the level of variability in the batch analyses and the presence of endotoxin contaminants.

The Committee reviewed the applicant's response and justifications. Queries were raised on changes the applicant made to their manufacturing process as part of upscaling and continued process refinement and suggested the Secretariat seek further information.

The Committee reviewed the draft Committee Advice on the application and identified areas for the Secretariat to amend.

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

5. 3-fucosyllactose (3'-FL) - RP1202

ACNFP/157/02

The Committee first reviewed the application in the 153rd meeting in June 2022, which resulted in a request for further information on the level of variability in the batch analyses and the presence of endotoxin contaminants.

The Committee reviewed the applicant's response and justifications. Queries were raised on changes the applicant made to their manufacturing process as part of upscaling and continued process refinement and suggested the Secretariat seek further information.

The Committee reviewed the draft Committee Advice for the novel food and identified areas for the Secretariat to amend.

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

6. Madhuca Longifolia - RP1804

ACNFP/157/03

The Committee reviewed a new traditional food application, Madhuca Longifolia, to inform risk management advice for Ministers.

Members sought clarification on the identity of the novel food and the parts of the flower that are to be used in the final product. It was highlighted to risk managers that the proposed uses sought were not consistent with how the product was used traditionally. Therefore, risk managers may wish to consider whether the novel food meet the criteria for a traditional food from third countries.

Data gaps were identified in composition, nutrition and production process that did not allow a risk assessment to be completed. Members suggested that the specification would benefit from clarification to allow appropriate identification of the product if authorised.

The Committee raised the potential for allergenicity from pollen and suggested that further information would be needed on whether the pollen containing parts were used and a further consideration of the potential for cross reactivity to this product from those with allergies to pollen.

Action: Risk management to review Committee Advice as a basis for whether reasoned safety objections should be raised.

7. Calcidiol – RP35

ACNFP/157/04

The Committee reviewed the application for a third time in the 153rd meeting in June 2022 and had suggested the Secretariat seek further information on the novel food’s structure, the analysis for identification, the food safety management system and management of potential risks in relation to the proposed dosage.

It was noted that the applicant had provided a Ph. Eur. Monograph with a description of the analytical method for identification, the certificates of analyses and a rationale for the alternative study to NMR. This provided reassurance that the structure of the molecule had been evidenced. It was noted that the applicant

provided sufficient detail regarding the HACCP plan and addressed the queries raised on management of any potential risks. Additionally, the applicant had provided information to support the proposed use levels in children in addition to referencing the EFSA 2021 opinion on the safety of Calcidiol.

Members noted the response to the queries on the proposed uses of the novel ingredient. Members highlighted that the applicant, as the ingredient manufacturer, has a duty of care in consideration for all proposed uses, to ensure intakes are clear to the consumer. The applicant had provided information on how they would discharge their responsibilities.

The Committee agreed that the information provided was sufficient and requested the Secretariat produce a draft of the Committee's Advice for Committee review.

Action: The Secretariat to produce a draft of the Committee's Advice on the application for Committee review.

8. Isomalto-Oligosaccharides - RP1033

ACNFP/157/05

The Committee reviewed a new extension of use application for Isomalto-Oligosaccharides for use in additional uses including ice cream and dairy desserts, instant coffee and tea, table-top sweeteners, cakes, muffins, pies, pastries, breakfast cereals, condiments/relishes, gravies and sauces, gelatines, puddings, fillings, jams and jellies, yoghurts, milk-based drinks, snack foods, and sweet sauces, toppings and syrups, and food supplements.

Members noted that the applicant had sought approval for the extension of use of an already approved novel food in the EU. There were no significant differences between the application and the original EU application other than the additional uses sought.

Members suggested that the Secretariat seek clarification on the intended uses. In particular, the reason for seeking the dose proposed for food supplements. Members suggested clarification be sought on the rationale for the proposed labelling that warns the consumer not to consume the supplement with other sources on the same day. Queries were also raised regarding estimated intakes of the novel food in vulnerable sub-population groups and whether the potential impact on these groups had been evaluated.

Action: The Secretariat to request further information from the applicant and produce draft Committee Advice on the application.

9. Corn Protein - RP1238

ACNFP/157/06

The Committee reviewed a new novel food application for the first time for Corn Protein. Corn Protein is intended to be used as a substitute for other protein-based ingredients for a range of applications.

The Committee considered the compositional analyses for Corn Protein Concentrate (CPC) and Corn Protein Isolate (CPI). Members suggested that further information was needed to understand how the composition of the two novel food forms differed. Of particular interest was the amino acid composition and whether this impacted on the nutritional quality of the novel food.

The Committee raised queries regarding the production process and the role of hydrogen peroxide. It was noted that there was batch to batch variability and further information was sought to understand the sources of variability and to what extent these were controlled.

Members also advised the Secretariat to request evidence from the applicant regarding the ADME of Corn Protein. It was suggested that it would be useful to understand the digestibility of the novel ingredient as a measure of protein quality and to inform understanding the digestion and absorption of the novel ingredient in consumers.

Action: The Secretariat to request further information from the applicant and produce draft Committee Advice on the application.

10. Krill Protein Hydrolysate - RP1290

ACNFP/157/07

The Committee reviewed a new novel food application for Krill Protein Hydrolysate for the first time. The novel ingredient is to be used in a range of foods including food supplements.

Members highlighted that while described as an animal alternative, protein derived from a crustacean is animal derived and should be corrected in information to consumers to ensure consumers are not misled.

Members advised the Secretariat to seek further information and clarification on the composition and specification of the novel food. Queries were raised regarding ash in the final product, analyses for salt and fluorine and the maximum level set for fluorine. Members highlighted data discrepancies and data gaps in relation to the stability studies and requested justification be sought regarding the variation in enterococci levels.

Regarding production process, clarification was requested on the steps in the HACCAP plan, what temperature controls are in place and to further understand how a consistent end product would be ensured.

In relation to the proposed uses, Clarification was sought on the rationale for the proposed labelling that warns the consumer not to consume the novel food with other sources on the same day. The potential impact of not following the labelling statement was not clear or how it is related to the risks the applicant already identified and seeks to manage.

Regarding ADME and toxicity, Members noted that a deeper review of the available data was required and further time would be needed for this activity. Members raised queries regarding the appropriateness of the 90-day toxicity study, and the literature provided, to the product to be marketed and agreed to review the data in more detail to reach a conclusion on this.

Concerns were raised over the wide range of proposed uses where a crustacean would not normally be expected, as this represents a serious risk for crustacean allergic consumers. Members recommended to risk managers that they consider the range of potential uses in order manage the risk for those with food allergies to crustaceans.

Action: The Secretariat to request further information from the applicant and Members to review the ADME and toxicological evidence in more detail.

11. *Schizochytrium sp*. Oil - RP1411

ACNFP/157/08

The Committee reviewed a new novel food application to extend the uses of oil from *Schizochytrium* species. Members noted that the applicant had sought approval for the extension of use of an already approved novel food in the EU. The applicant is seeking to use the novel food in meat and fish analogues.

It was suggested that it was unclear how this application fitted with the range of applications authorised for the various forms of oil from *Schizochytrium sp*. Information was sought on this to put the application in context. Members noted that the species of organism and composition have been key criteria for structuring authorisations for these products.

The Committee reviewed the extended food categories for the novel food and requested the Secretariat seek further clarity on the intended uses within the categories identified. Information on whether food matrices impact the stability of the novel food was also sought.

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

12. *Mycobacterium aurum* - RP1046

ACNFP/157/09

The Committee reviewed a new application for a novel food consisting of heat killed whole cells of the bacteria *Mycobacterium aurum*. The proposed use of the novel ingredient is as a food supplement. The novel food was previously reviewed by the Committee in April 2016 under its member state assessment responsibilities under EU regulation 258/97 EC. No EU authorisation exists.

The Committee requested the Secretariat seek further information and clarity on the identity of the novel food organism. In particular, it was noted that the organism is distantly related to those with pathogenic characteristics. However, evidence to show how related this species is from pathogenic strains had not been provided. Clarity was also sought on how the identity of the microbe had been confirmed as being the same species as available in reference collections.

A number of queries were raised regarding the production process and further data was considered needed to demonstrate and clarify the commercial scale of the production. More detail on the methods used and a food safety management plan were requested. This was in the context of recognising that alterations in production environment can alter the composition and behaviour of organisms in culture.

Further information was sought to validate the effectiveness of the heat kill step and to verify the consistency of production at a commercial scale. Queries were also raised on how the final product would be managed to minimise any risk of

contamination with other microbes.

A number of queries were raised by Members regarding composition and stability. Compositional data was needed to understand the nature of the product and whether it had any nutritional properties. In particular, microbiological analysis was needed to verify the effectiveness of production controls.

Members also raised the need to gain further data on the full range of proposed uses and the exposure that this provided for consumers. Members considered this important if a Margin of Safety were to be calculated. Information was also sought on how the product would be presented so that the consumer was aware of the nature of the product and could use it safely.

Regarding toxicology, Members commented that there remains a lack of literature on the organism regarding virulence and pathogenic potential. No further need for animal studies was considered necessary. However, it was suggested that there remained a data gap on the impact of the novel ingredient on immune responses and a tier 2 immunotoxicological study should be considered. This was linked to the potential for immunostimulatory effects of the organism.

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

13. Cellobiose - RP1109

ACNFP/157/10

The Committee reviewed a new novel food application for the first time for Cellobiose for use in various food categories as a replacement for sugar or lactose.

The Committee advised that further information be sought on the production process, purity of the enzymes used in the production process and how it is assured that the product is produced consistently. It was noted the comments in relation to the stability of the novel ingredient and information was sought on how the impact of water would be managed.

In relation to the proposed use, further information was sought to understand the intake in relation to a meal rather than a maximum level. This reflected that high consumption over a meal was more likely to be linked to gastric effects than consumption over a day. Information was also sought on the potential impact for sensitive populations and in particular, those with coeliac disease or other

conditions impacting uptake of nutrients from the gut. The potential for foreseeable misuse was highlighted and information sought on how this could be managed.

Regarding ADME, Members advised the Secretariat to request further information on the digestibility of Cellobiose. This would inform understanding of how the novel ingredient would behave in the gut.

Action: The Secretariat to request further information from the applicant and produce draft Committee Advice on the application.

GM renewal applications

The Committee reviewed draft Committee Advice prepared based on discussions at the Products of Genetic Technology Subgroup. In addition to reviewing the drafts, a series of general points were made on the four applications. This included providing more information on the nature of the change made and the intended purpose in order to make the Committee Advice documents more accessible for a non-technical audience. The Committee also noted that environmental risks including the evaluation of the post-market environmental monitoring plan, were outside the remit of the Committee. It was recommended that advice on the non-food safety impacts were considered by other experts in these fields.

14. Genetically Modified Soybean A5547-127 - RP188 (reserved business)

ACNFP/157/11

The Committee reviewed a renewal application for a genetically modified food and feed. The Secretariat invited Members to review a draft safety assessment outcome that had been reviewed and agreed by the ACNFP-PGT Subcommittee.

The Committee accepted the conclusions to the assessment and stated that they had no safety concerns regarding soybean A5547-127 or any foods or feeds derived from it. Members agreed the draft Committee Advice subject to minor amendments.

Members noted that the modern biomolecular techniques used were appropriate for the analyses and highlighted that any concerns over cultivation applied to the

country of origin and not the UK who are the importer.

Action: Draft Committee Advice to be amended by the Secretariat for agreement by Chair's action.

15. Genetically Modified Soybean 40-3-2 – RP212 (reserved business)

ACNFP/157/12

The Committee reviewed a renewal application for a genetically modified food and feed. The Secretariat invited Members to review a draft safety assessment outcome that had been reviewed and agreed by the ACNFP-PGT Subcommittee.

The Committee accepted the conclusions to the assessment and stated that they had no safety concerns regarding Soybean 40-3-2 or any foods or feeds derived from it. Members agreed the draft Committee Advice subject to minor amendments.

Members noted that the modern biomolecular techniques used were appropriate for the analyses.

Action: Draft Committee Advice to be amended by the Secretariat for agreement by Chair's action.

16. Genetically Modified Maize MIR162 – RP652 (reserved business)

ACNFP/157/13

The Committee reviewed a renewal application for a genetically modified food and feed. The Secretariat invited Members to review a draft safety assessment outcome that had been reviewed and agreed by the ACNFP-PGT Subcommittee.

The Committee accepted the conclusions to the assessment and stated that they had no safety concerns regarding Maize MIR162 or any foods or feeds derived from it. Members agreed the draft Committee Advice subject to minor amendments.

Members noted that the modern biomolecular techniques used were appropriate for the analyses.

Action: Draft Committee Advice to be amended by the Secretariat for agreement by Chair's action.

17. Genetically Modified Cotton GHB614 – RP608 (reserved business)

ACNFP/157/14

The Committee reviewed a renewal application for a genetically modified food and feed. The Secretariat invited Members to review a draft safety assessment outcome that had been reviewed and agreed by the ACNFP-PGT Subcommittee.

The Committee accepted the conclusions to the assessment and stated that they had no safety concerns regarding Cotton GHB614 or any foods or feeds derived from it. Members agreed the draft Committee Advice subject to minor amendments.

Members noted that the modern biomolecular techniques used were appropriate for the analyses.

Action: Draft Committee Advice to be amended by the Secretariat for agreement by Chair's action.

18. Items for Information

18.1 Novel Foods Policy Update - Written

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

18.2 GM Policy Update - Oral

The Committee were provided with an oral update on the issues under consideration regarding GM.

18.3 SACS Update - Written

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

19. Any other business

ACNFP Terms of Reference update

The Secretariat sought input and agreement on minor amendments to the ACNFP Terms of Reference. It was noted that the Secretariat had additionally reviewed the Terms of Reference specific to the PGT Subcommittee, and no amendments were sought. It was noted that the proposed changes were to remain consistent with the evolving responsibility of the Committee regarding Precision Bred Organisms, and to ensure consistent transparency and clarity.

The Committee agreed the proposed changes, pending minor amendments for agreement by Chair's action.

Action: Terms of Reference to be amended by the Secretariat for agreement by Chair's action.

ACNFP/COT subgroup update

It was noted that Dr Anton Alldrick had standing conflicts of interest in relation to CBD and was not present for the update.

The Committee were provided with an oral update on the ongoing work and progress to date of the ACNFP/COT subgroup.

Date of next meeting

The next ACNFP hybrid meeting in London is scheduled for 26th April 2023. The next ACNFP-PGT virtual meeting is scheduled for the 15th March 2023.