Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 160th Meeting held on the 14th of June 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 160th meeting of the Advisory Committee on Novel Foods and Processes, held on the 14th of June 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 Susan Fairweather-Tait

Professor Paul Fraser

Dr Andy Greenfield

Dr Hamid Ghoddusi

Professor Wendy Harwood

Professor Huw Jones

Dr Ray Kemp

Professor Harry McArdle

Mrs Rebecca McKenzie

Professor Clare Mills

Dr Lesley Stanley

Professor Bruce Whitelaw

Prof Hans Verhagen

Professor Pete Lund - Co-opted Member - for item 4

Professor Alastair Macrae - Co-opted Member

Apologies

Dr Elizabeth Lund - Member

Dr Maureen Wakefield - Member

Professor Dimitris Charalampopoulos - Member

Professor Simon Pearson - Science Council

Assessor

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

Observers FSA

Mr Chris Stockdale - Head, Genetic Technology Policy

Mr Hoa Chang - GT Policy Advisor

Mr Shaun Jacobs - FSA Senior Policy Advisor

Ms Beth Sung - FSA Senior Policy Advisor

Mr Adekunle Adeoye - FSA Senior Policy Advisor

Mr Jamie Luck - FSA Senior Policy Manager

Mr Colin Clifford - Food Information and Labelling

Ms Sharon Thompson - Novel Foods & Feed Additives Policy Advisor

Daniel Lloyd - Microbiological Risk Assessor

Observers Devolved administration

Mr Lloyd Evans - Policy, FSA Wales

Mr Andrew Dodd - Policy, FSA Wales

Ms Hannah Reid - Policy, FSA Wales

Mr Xose Benitu Alvarez - Policy, FSA Wales

Mrs Siobhan Watt - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Ms Georgina Finch - Food Standards Scotland

Ms Krystle Boss - Food Standards Scotland

Dr Svetlozara Chobanova - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA NI

Observers (External)

Mr Martin Cannell - Defra Representative

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary

Mrs Priscilla Wanjiru - Science Secretariat

Dr Karin Heurlier - Science Secretariat

Mr Ben Haynes - 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

Mr Rhys Williams - 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

Professor Dimitris Charalampopoulos, Dr Elizabeth Lund, Dr Maureen Wakefield and the Science Council representative, Professor Simon Pearson sent their 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.

Professors Alastair Macrae, Pete Lund (Members of PGT Subcommittee) and Mr Martin Cannell joined for the PGT workshop under item 4.

2. Meeting Minutes for the 158th and 159th Meeting

ACNFP/158 & 159/MINS

The Committee agreed on the 158th meeting draft minutes for publication on the ACNFP website as an accurate record, pending a minor amendment. They also reviewed and commented on the 159th meeting minutes with amendments suggested, to be agreed on via correspondence before publication.

3. Matters Arising from the last meeting

ACNFP/160/MA

The Secretariat reported on actions from the previous meeting:

- The members were informed that there will be two outputs to the assessments: 1) the ACNFP Committee Advice Document (CAD) which will cover the outcomes and advice given by the committee in its review of the safety evidence and 2) the final Safety Assessment published by the FSA/FSS , the latter of which fulfils the role of the legal ‘opinion forming’ in the novel foods legislation. The Secretariat highlighted the differences between the two, with a number of publications expected in the next few months for applications going through the regulated novel foods process.
- A safety assessment for Magnesium-L-threonate for use as a food supplement was considered for the third time by the Committee. Further information was identified as being needed on identity, composition and production process. The Secretariat requested further information from the applicant.
- The Committee reviewed further information supplied by the applicant for the lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) mixture (LNFP-I/2'-FL) application and the 3-fucosyllactose (3’-FL) application and no further queries were raised. The draft Committee Advice Document developed had been previously considered by the Committee and would be signed off by Chair’s action.
- Corn Protein, a returning application, was reviewed for the second time. Further information was identified as being needed on production process, composition, specifications and ADME/digestibility. The Secretariat requested further information from the applicant.
- The Committee also reviewed the draft of the Committee Advice Document for Calcidiol. The Committee provided advice and drafting comments to the Secretariat to inform updating the document for their review at a future meeting.

- The members reviewed three new applications: Dried Miracle Berry, Olive fruit dry extract standardised in hydroxytyrosol and Pasteurised *Akkermansia muciniphila.* They identified various areas for each dossier where more data were required. The Secretariat requested further information from the applicant with Pasteurised *Akkermansia muciniphila* returning for assessment under item 2.
- The Committee was updated on the work of the PGT Subcommittee and agreed to the strategy and objectives set for the next two months on the development of the Precision Breeding framework for authorisation and in particular on data requirements to support the process.

4. Isomalto-Oligosaccharides - RP1033

ACNFP/160/01

The Committee first reviewed the application at the 157th meeting in February 2023, which resulted in further questions on the proposed uses of isomalto-oligosaccharides as a food supplement, and the contribution it would play in the diet in certain consumer sub-populations.

The Committee discussed the intended use of isomalto-oligosaccharides in food supplements. They requested the applicant provide further information on the format of the food supplements in which the isomalto-oligosaccharide was included, the quantity of isomalto-oligosaccharides per format and the calorific content per serving of novel food. This was to understand the potential for foreseeable misuse or over-use. The Committee reviewed the first draft of the safety assessment for isomalt-oligosaccharides. Members have proposed suggested amendments to the text which will be updated before it is returned alongside the response from the applicant.

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

5. Pasteurised *Akkermansia Muciniphila* - RP1468

ACNFP/160/02

The Committee reviewed an application for a novel food derived from pasteurised cells of the bacteria *Akkermansia muciniphila*. The proposed use of the novel

ingredient is within food supplements and in foods with special medical purposes (FSMPs). The novel food was previously reviewed by the Committee in April 2023 and was brought forward to the Committee again for further assessment. The novel food has been authorised for use within the EU but is new to the GB market.

The Committee further reviewed the application and suggest the FSA seek further information on identity, production process, proposed use, and toxicology. The focus of the discussion was on the proportion of the cells present that were viable and any impact on risk this may have. This was considered in the context of vulnerable consumers but also whether there was potential for the product to have an impact on metabolism.

In order to better understand the quality assurance measures in place for the production system, the Committee advised that information be sought on the criteria that trigger identification of the cells. This, along with information on the management of the process, in particular the cell banks, was needed to provide reassurance on the systems in place.

In reviewing the toxicological data, queries were raised on the evidence base presented for the proposed dosages outlined within the application given the potential for microbes similar to the novel foods to be consumed for effects on the microbiome. A query was raised on whether this has been sufficiently explored in the data presented. Further information was also sought on the composition in terms of viable cells in the test material used for the toxicological study in order to put these results in context.

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

6. Genetically Modified Cotton GHB811 - RP1232

ACNFP/160/03

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

A discrepancy was noted between protein expression data presented in the draft safety advice and the same data presented in the EFSA opinion on the same product. The Committee requested the Secretariat contact the applicant for an explanation for this discrepancy.

The Committee accepted the conclusions of the assessment and stated that they had no safety concerns regarding GHB811 cotton or any foods or feeds derived from it. Members agreed to the draft safety advice subject to minor amendments.

Action: Contact applicant to query data discrepancy.

Draft Committee safety advice to be amended by the Secretariat for agreement by correspondence/Chair's action.

7. Precision Breeding Workshop (reserved business)

ACNFP/159/04

Professor Bruce Whitelaw declared financially benefiting from a University of Edinburgh Commercialisation Licence with Genus plc regarding PRRSV-resistant pigs; this was noted, and it was agreed that if discussions arose on this particular case study, Professor Whitelaw would be present but only to answer questions on the case.

In their 159th meeting, ACNFP agreed that two models of approach should be developed for the authorisation of Precision Bred Organisms (PBOs) for use as food and feed, to reflect the two scientifically valid interpretations of proportionality discussed by the Subcommittee for Products of Genetic Technologies (PGT). ACNFP was updated on the work of the Subcommittee on the data requirements for the two potential approaches to Tier 1 assessment the risks, impacts, and benefits of the data requirements in each approach, and how these aligned with the interpretation of proportionality. The main Committee supported the proposals for the necessary data requirements for safety assessment of PBOs for food and feed in both Tier 1 and Tier 2.

The final recommendations and options will be revisited at the next PGT Subcommittee meeting in July and issued as a draft statement, which will be reviewed by the ACNFP in the subsequent week. The recommendations will support the FSA Board 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 (currently timetabled for September 2023).

Action: The Secretariat to summarise the conclusions on the data requirements to reflect the opinions of the Committee for the two

approaches to Tier 1 and data requirements for Tier 2, for further review by the PGT subcommittee in the first instance.

8. Items for Information

8.1 Novel Food Policy Update - Written

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

8.2 GM Policy Update - Written

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

8.3 SACS Update - Written

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

9. Any other business

The members were informed that the 2022 annual report would be circulated to the Chair for input by correspondence over the summer before presenting it to members at the next meeting. Discussions on a possible two-day meeting in September were also held.

There was also a discussion on opportunities to support the review of applications by the Committee and through the regulated products process more generally. This will be taken away by the Secretariat for further consideration and future discussion with the Committee.

Date of next meeting

The next meeting of the PGT sub-committee in London is scheduled for 19th June 2023, and the next 161st meeting of the ACNFP will be 25 July 2023 as an online meeting, to review the output of the PGT sub-committee.