Minutes

Advisory Committee on Novel Foods and Process. Draft minutes of the 150th Meeting held on the 24th November 2021

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.

This meeting was held online using Microsoft Teams.

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Dr Mark Berry

Professor Susan Duthie

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Hamid Ghoddusi

Professor Wendy Harwood

Professor Huw Jones

Dr Elizabeth Lund

Ms Nichola Lund

Dr Rohini Manuel

Professor Harry McArdle

Mrs Rebecca McKenzie

Professor Clare Mills

Dr Lesley Stanley

Prof Hans Verhagen

Dr Maureen Wakefield

Assessor

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

Observers FSA

Mr Hoa Chang - FSA GM Policy Advisor

Mr Shaun Jacobs - FSA Senior Policy Advisor

Ms Gemma Jones - FSA Novel Food Policy Advisor

Monique Von Tonder - FSA Novel Food Policy Advisor

Ms Lisa Nelson - FSA Communications team

Mr Donal Griffin - Head of Regulated Products Risk Assessment (Feed and GM)

Ms Shila Sultana - Regulated Products Risk Assessor

Dr Elli Amanatidou - Trade Risk Assessor

Dr Olivia Osborne - Chemical Risk Assessor

Dr Erica Kintz - Microbiological Risk Assessor

Mr James Donarski - Exposure Assessment & Trade

Ms Chloe Thomas - Exposure Assessment & Trade

Observers Devolved administration

Ms Alexia Sully Karlis - Policy, FSA Wales

Mr Andrew Dodd - Policy, FSA Wales

Ms Hannah Reid - Policy, FSA Wales

Ms Nuala Meehan - Regulatory Compliance, FSA NI

Ms Siobhan Watt - Food Standards Scotland

Observers (External)

Ms Claire Nicholson - Science Council

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Tahmina Khan - Senior Secretariat

Mrs Priscilla Wanjiru - Science Secretariat

Dr Karin Heurlier - Science Secretariat

Mr Will Smith - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Andrew Hudson - Science Secretariat

Mr Matt Hall - Science Secretariat

Dr Johann Trotter - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Ms Aisling Jao - Administrative Secretariat

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1. Apologies and Announcements

Apologies were received from the FSS Science team.

Recognition was given to the milestone reached by the ACNFP. This was the 150th meeting with the work of the Committee on food innovation spanning 20 years and still as necessary and relevant as when the Committee first started.

The Committee also welcomed all in attendance.

2. Meeting Minutes for 149th Meeting

ACNFP/149/MINS

The Committee reviewed the draft minutes of the 149th meeting and it was agreed that further substantive revisions were necessary to capture the discussions as transparently as possible and at an appropriate level of technical detail. The minutes would be revisited by the secretariat and the Chair and the Committee would have the opportunity to comment on the revised version.

3. Matters Arising from the last meeting.

ACNFP/150/MA

- The Committee discussed at the previous meeting an application for Mung Bean Protein under the Novel Food Regulation. Further information was requested from the applicant and was considered under item 4.
- The application for Barley Rice Protein also under the Novel Food Regulation was discussed with further information requested for a number of areas of the assessment. Information detailing areas identified was drafted by the Secretariat and sent to the applicant. A response had been received just prior to the meeting.
- The Committee reviewed an application for a synthetic CBD. Feedback on various aspects of the dossier including toxicology was drafted by the

Secretariat with further information requested and sent to the applicant.
- There was no follow up to the paper on other legitimate factors and regulated products processes.
- The output statement for GE data needs was finalised. This will be published as part of the wider work being done by the FSA on Genome Editing (GE).

4. Mung Bean Protein (Dossier Number RP 32)

ACNFP/150/01

The dossier was considered by the Committee in April and September 2021; the latter resulted in a further request for additional information. Committee members considered the response to the second request for information, and whether this addressed outstanding questions on the dossier. Discussion was held on the production process, proposed use and intake, toxicology and allergenicity aspects of the application.

The Committee advised that the applicant's response still did not provide sufficient clarification on the quality assurance processes in use and requested further information in particular on how pesticide residues are controlled.

The applicant informed the Committee that the proposed uses had been changed. Committee members noted the change and advised that further information be obtained on how the product was to be used specifically, to fully understand the intake and proposed uses in context to enable a full review of potential for nutritional disadvantage. This remained an evidence gap.

The Committee discussed the applicant's response to the potential for cross reactivity between the novel food in consumers with allergy to other legumes. Members advised that the next tier of allergenicity testing be provided in order to characterise the risk for mung bean protein allergy to arise in legume allergic consumers in the UK. The Committee noted the importance of having this information to provide proportionate and risk based management and to ensure accurate information for potentially allergic consumers.

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

5. Calcidiol (Dossier Number RP 35)

ACNFP/150/02

The Committee first considered the dossier for Calcidiol in June 2021. The Committee advised at that time that further information be sought from the applicant. The Committee reviewed the response from the applicant and how this informed on the risk management process of issues on identity, production process, proposed use and intake, and toxicology.

The Committee considered the information provided on identity and advised that further confirmations should be sought on the molecular structure of the novel ingredient in the form produced by the applicant.

Members assessed the HACCP plan provided by the applicant. It was advised that the HACCP plan did not cover the full requirements needed to understand the risks managed in the production process.

The Committee reiterated that further consideration is needed of the anticipated levels of exposure of consumers to the novel ingredient and in relation to other sources of vitamin D more widely. The applicant’s indication of bioavailability of the product was noted. The Committee advised that further information be sought on how the proposed use from the applicant related to recommendations in the UK around vitamin D exposure. Information was also sought on whether the changes brought by pregnancy and lactation would present different safety risks to the general population when supplementing with Calcidiol.

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

6. Cetylated Fatty Acids (Dossier Number RP 200)

ACNFP/150/03

The Committee reviewed this full Novel Food application for the first time. The novel food is proposed to be used in food supplements. Areas where further consideration was felt necessary to complete the assessment included Production Process, Absorption, Digestion, Metabolism and Excretion (ADME) and Toxicology

The Committee discussed the production process and remarked that the applicant had not fully described the science behind the manufacturing process. Members were satisfied that the major risks had been identified and could be managed. Members requested further clarification on the catalyst and reaction conditions used during the production of the cetylated fatty acids.

The Committee members reviewed the information concerning the history of use of the ingredients used to manufacture the novel food ingredient. Members agreed that there was no information available for the use of cetylated fatty acids as a food ingredient. The Committee agreed that the information on the metabolic pathways of the fatty acids and cetyl alcohol was well understood. Members discussed the ADME of cetylated fatty acids and concluded that further clarification was required.

The Committee reviewed the toxicological data supplied by the applicant. Members agreed that the results from the genotoxicity studies gave no cause for concern. The Committee reviewed the sub chronic data and the approach to setting a safe upper level of consumption by EFSA and agreed the safe upper level of consumption.

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

7. Approach to assessment of CBD (Reserved business)

ACNFP/150/04

Dr Alldrick declared a potential conflict of interest relating to his previous employment and was not present during this item.

Prof Harry McArdle declared his work with EFSA’s novel food committee in considering data requirements for CBD. While not seen as a conflict, to avoid Prof McArdle being subject to information that would influence his EFSA work, it was agreed that he would not be present in discussions for this item, but could supply comments for consideration by the Committee upon review of the minutes.

The Committee reviewed an approach to assessing a potentially high volume of CBD dossiers in an efficient and effective manner.

Action: The Secretariat to begin organising dossiers according to the agreed approach in preparation for future meetings.

Action: The Secretariat to consider how to communicate the process being followed for CBD on the website.

8. Consideration of data requirements for assessment of the toxicological risk of CBD (Reserved business)

ACNFP/150/05

Dr Alldrick declared a potential conflict of interest relating to his previous employment and was not present during this item.

Prof Harry McArdle declared his work with EFSA's novel food committee in considering data requirements for CBD. While not seen as a conflict, to avoid Prof McArdle being subject to information that would influence his EFSA work, it was agreed that he would not be present in discussions for this item, but could supply comments for consideration by the Committee upon review of the minutes.

The Committee were asked to consider the core data needed to assess novel food applications for CBD. The views of the Committee will support a consistent approach to requesting information in suitability checks for these dossiers.

Action: The Secretariat to communicate the Committee's view to applicants that data should be provided to support literature-only submissions for toxicology sections.

Action for the Secretariat to explore identify opportunities to minimise the use of animals in informing safety of CBD novel ingredients for example through collaborative working.

9. Proposal for a subgroup of the ACNFP to consider issues ACNFP/150/06 of Genetically Modified Organisms and Genome Edited food and feed (Reserved business)

The Committee reviewed a proposal to establish a Subgroup of the ACNFP to consider Genetically Modified Organisms (GM) dossiers and develop guidelines for the assessment of Genome Edited (GE) products. The formation of a Subgroup of the ACNFP was formally agreed.

Action: The Secretariat to take forward the establishing of the sub group and associated governance structures.

10. Items for Information

10.1 Novel Food Policy Update - Oral

The Committee was provided with an oral update on the issues under consideration regarding novel foods.

10.2 GM Policy Update - Oral

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

10.3 SACS Update - Written

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

11. Any Other Business

Discussion on preferences for safety measures to support holding meetings in person

12. Date of next meeting

The next meeting is scheduled for 2nd February 2022. A face-to-face meeting is being considered.