Meeting

Advisory Committee on Novel Foods and Process. Minutes of the 164th Meeting held on the 7th of February 2024

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 164th meeting of the Advisory Committee on Novel Foods and Processes, held on the 7th of February as a hybrid meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Professor Dimitris Charalampopoulos

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Hamid Ghoddusi

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw Jones

Dr Elizabeth Lund

Professor Harry McArdle

Mrs Rebecca McKenzie

Professor Clare Mills

Dr Lesley Stanley - Deputy Chair for items 7,8, & 9

Prof Hans Verhagen

Dr Maureen Wakefield

Professor Bruce Whitelaw

Dr Cathrina Edwards

Professor George Bassel

Associate Members

Dr Kimon-Andreas Karatzas

Dr Antonio Peña-Fernández

Apologies

Dr Ray Kemp - Member

Dr Mark Berry - Member

Dr Christina Bosch - Associate Member

Assessor

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

Observers FSA

Dr Amie Adkin - Deputy Director Risk Assessment

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Mr Shaun Jacobs - Senior Policy Advisor

Mr Adekunle Adeoye - Senior Policy Advisor

Mr Wecktone Munyai - Senior Policy Advisor

Mr Jamie Luck - Senior Policy Manager

Liam Burke - Policy Advisor

Ms Sophie Burder - Policy Advisor, Novel Foods

Dr Daniel Lloyd - Senior Regulated Products Risk Assessor

Observers (External)

Professor Simon Pearson - Science Council

Observers Devolved administration

Mr Jeremy Mills - Policy, FSA Wales

Mr Peter Madden - Policy, FSA Wales

Mr Xose Alvarez - Policy, FSA Wales

Ms Lucy Smythe - Food Standards Scotland

Ms Siobhan Watt - Food Standards Scotland

Ms Aileen Livingstone - Food Standards Scotland

Mr Evangelos Katsoulis - Food Standards Scotland

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary PGT subcommittee

Mrs Priscilla Wanjiru - Lead Secretariat

Mr Ben Haynes - Science Secretariat

Dr Andrew Hartley - Science Secretariat

Dr Tahmina Khan - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Miss Lucy Thursfield - Science Secretariat

Mr Will Smith - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Dr Ray Kemp, Dr Mark Berry and Dr Christine Bosch sent their apologies for non-attendance.

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

Dr Anton Alldrick and Professor Harry McArdle previously declared interests in relation to CBD. The Chair and Secretariat advised that they would not be present for the discussion of these items.

The Chair informed that she would need to leave the meeting between 12 noon and 2pm to attend another urgent online meeting, and that Lesley Stanley would stand in as Chair during this period. Dr Lesley Stanley chaired items 7,8 and 9.

2. Welcome

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

3. Meeting Minutes for the 163rd Meeting

ACNFP/163/MINS

The Committee agreed the 163rd meeting draft minutes for publication on the ACNFP website as an accurate record, pending some amendments to be cleared by Chair's action.

4. Matters Arising from the last meeting.

ACNFP/164/MA

The Secretariat reported on actions from the 163rd meeting:

- Dried Miracle Berry - Following a review of the further information supplied for Dried Miracle Berry further queries were identified to be raised with applicant.
- Magnesium-L-Threonate - The draft Committee Advice Document for Magnesium-L-threonate was finalised by Chair's action following the meeting and will be published at the next publication point.
- Isomalto-oligosaccharides - The queries for clarification were raised with the exposure team and reflected in the Committee Advice Document. The Committee Advice Document was finalised by Chair's action and has entered the publication process.
- Olive fruit dry extract standardised in hydroxytyrosol - Queries to address identified data gaps on composition, specification, genotoxicity and toxicology have been raised with the applicant. This will inform refinement of the Committee Advice Document, for consideration at the next available meeting.
- Workshop on allergenicity of novel foods - Following the last meeting a core group of experts have met to further develop the plans for the workshop and finalise the final agenda. The event will be taking place on the 28th of February 2024.
- CBD application RP07 - The draft Committee Advice Documents for this application was subject to clearance by Chair's action. The Committee Advice Document is presented as item 12 on the 164th meeting to allow reflection in the text of any comments made during the discussion of the other CBD items.

5. Genetically modified maize and its sub-combinations NX603xT25xDAS-40278-9 - RP1791

ACNFP/164/01

The Committee reviewed the Committee Advice Document which had been prepared by the secretariat following review of the application by the ACNFP-PGT Subcommittee.

There was a discussion on whether the CAD adequately captured how the assessment for this application, which is for a stack consisting of previously authorised events, had been undertaken. Members sought to ensure that the CAD made clear that some aspects of the assessment of stacked GMOs, which focuses on potential interactions between events, were not simply based on the assumption that the events would behave in the same way in the stacked plant as they do individually. Reassurance was given to members that there had been verification during the assessment, including data from DNA sequencing and analysis of expression levels, that the events and their impacts remained as previously described/authorised following traditional crossing to produce the stacked GM plant.

Members provided comments on the drafting of the CAD and particularly emphasised the need to explain the evidence that underpinned the conclusion so the nature of the assessment could be clearly understood by the reader. The evidence was discussed at ACNFP-PGT in some depth, but the CAD did not necessarily reflect all of the evidence discussed. The Committee Advice Document was agreed subject to amendments to be finalised by Chair's action. Once finalised the outcome will move forward to publication.

Action: The Secretariat to update the Committee Advice Document for clearance by Chair action.

6. Calcidiol - RP956

ACNFP/164/02

The Committee reviewed this draft Committee Advice Document for this novel food which had been considered at several meetings. The Chair noted that there was further work to be done to refine the toxicology section, to explain the data used to support the safety of the novel food. This would be done after the meeting between the Secretariat and relevant Committee members with toxicology expertise.

The focus of the discussion at this meeting was additional new evidence identified from a recently published EFSA opinion in relation to the bioavailability of Calcidiol. The impact of the updated conclusion on bioavailability, for the conclusions on the safety of the proposed dose in children was explored. The members considered their conclusion remained unchanged and was appropriately reflected in the text of the draft Committee Advice Document.

Members agreed the Committee Advice Document subject to the changes identified which will be agreed by Chair's action before entering the publication process.

Action: The Secretariat to amend the draft Committee Advice Document and send to Chair for clearance.

7.Vitamin D2 mushroom powder - RP1550

ACNFP/164/04

The application for mushroom powder treated with UV irradiation for use in food supplements had been considered previously in the September 2023 meeting. Queries had been raised on the production process, composition, stability, the methods of analyses for microbial contaminants and allergenicity.

The Committee were asked to review and comment on the response from the applicant. Members noted that the response did not address issues around production, especially around the blending process of the product and how homogeneity of samples tested was assured. The response had also not fully addressed the questions raised on the management of potential risks from microbial growth and mycotoxin production especially during the packaging step of the process. The Secretariat was advised to seek further information from the applicant.
Members were asked to review and comment on the draft output for the assessment of this novel food. The Secretariat was advised to carry out some revisions and present the finalised Committee Advise Document at the next available meeting.

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

The Secretariat to amend the Committee Advice Document for review at a later meeting.

8. Corn protein - RP1238

ACNFP/164/03

The Committee reviewed this application at several meetings since April 2023. At the 162nd meeting further questions were raised on the production process, the specification, and the absorption, distribution, metabolism, and excretion (ADME) of the novel food. The applicant has responded. Their response and a draft Committee Advice Document were shared with the Committee for review and input.

The Committee advised the Secretariat to seek more detailed explanations on the control measures for monitoring potential microbiological and mycotoxin contamination in the production process.

Members also requested further information on the validation of the method used to determine the protein quality of the novel food. If this was not available for the method provided in the dossier, further information was needed to assess the protein quality of the novel food. This data would allow an assessment of whether the food would be nutritionally disadvantageous compared to the food it would replace.

Due to the scale of the outstanding queries on the novel food, the discussion of the Committee Advice Document was postponed until the necessary information was available.

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

9. Regulated Product Service and continuous improvements

ACNFP/164/09

The Committee were provided with an update on the work within the FSA to support the efficiency of the regulated products service. This included seeking the Committee’s input on some proposed changes to ways of working which had been reported to the FSA board at their December meeting. Members provided comments to inform the refinement of the processes going forward.

Action: Members to provide any further comments of response to the paper to the FSA team

10. CBD - RP350

ACNFP/164/05

The Committee reviewed a new application for Cannabidiol (CBD) isolate as outlined in application RP350 for the first time. The novel ingredient is proposed by the applicant for use in food supplements and as an ingredient incorporated into a variety of food matrices.

The Committee were also asked to review a draft Committee Advice Document for this application.

Members highlighted the importance that composition and safety data are obtained to a reliable standard through validated methodology. Where possible data should be generated with internationally recognised approaches to assure its accuracy and robustness. The Committee indicated that when undertaking stability studies applicants should analyse relevant cannabinoids including THC, as had been done in this case, to ensure characterisation of any degradation products from the novel food over time.

The proposed uses of the novel food were discussed, and it was noted the table with this information was to be updated to reflect the provisional Acceptable Daily Intake (ADI) of 10 mg CBD/day identified by the ACNFP and Committee on Toxicity in the joint statement published in October 2023. The Committee discussed the potential for foreseeable misuse of CBD and to what extent this could be reflected in their assessment. Members commented that dosed formats would make it easier for consumers to remain within the provisional ADI and FSA consumer advice. However, CBD is used in a wide array of products and it was advised that risk managers also consider the potential for multiple product intakes of CBD in a day. It was agreed that the risk assessment should provide an indication of the potential risk from foreseeable misuse to inform risk managers decision making processes.

Members also identified areas for the Secretariat to amend in the draft Committee Advice Document to accurately reflect the assessment that had been done. The document was agreed subject to amendments to be agreed by Chair’s action.

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

Action: The Secretariat to amend the Committee Advice Document for clearance by Chair's action.

11. CBD - RP427 (reserved business)

ACNFP/164/06

The discussion of this item was postponed to the April ACNFP meeting.

12. CBD- RP07 (reserved business)

ACNFP/164/07

The Committee advised that the proposed changes to the Committee Advice Document text for RP350 should also apply to RP07. The Committee Advice Document was agreed subject to amendments to be cleared by Chair's action.

Action: The Secretariat to amend the Committee Advice Document for clearance by Chair's action.

13. Approach to CBD applications where a conclusion on safety cannot be reach (reserved business)

ACNFP/164/08

This item was not discussed and would be considered at a later meeting.

14. Items for Information

14.1 Novel Food Policy Update - Written

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

14.2 GM Policy Update - Written

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

14.3 SACS Update - Written

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

Date of Next meeting

The next meeting will be held virtually on 17th April 2024.