Minutes

Advisory Committee on Novel Foods and Process. Minutes of the 165th Meeting held on the 17th of April 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 165th meeting of the Advisory Committee on Novel Foods and Processes, held on the 17th of April as a virtual meeting**.**

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Ms Alison Austin

Dr Meera Cush

Professor Susan Fairweather-Tait

Dr Sophie Foley

Professor Paul Fraser

Dr Hamid Ghoddusi

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw D. Jones

Dr Elizabeth Lund

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 Christine Bosch

Dr Kimon-Andreas Karatzas

Dr Antonio Peña-Fernández

Apologies

Professor Dimitris Charalampopoulos

Professor Harry McArdle

Dr Lynn McIntyre

Dr Isabel Skypala

Assessor

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

Observers FSA

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Mr Shaun Jacobs - Senior Policy Advisor

Mr Adekunle Adeoye - Senior Policy Advisor

Mr Jamie Luck - Senior Policy Manager

Dr Daniel Lloyd - Senior Regulated Products Risk Assessor

Observers (External)

Ivy Wellman - Defra

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 Aileen Livingstone - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA Northern Ireland

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary PGT subcommittee

Mrs Priscilla Wanjiru - Lead Secretariat

Dr Karin Heurlier - Lead Secretariat PGT subcommittee

Mr Ben Haynes - Science Secretariat

Dr Tahmina Khan - Science Secretariat

Dr Rhys William - Science Secretariat

Mr Matt Hall - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Mr Will Smith - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Professor Harry McArdle, Professor Dimitris Charalampopoulos, Dr Lynn McIntyre and Dr Isabel Skypala 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 these members would not be present for the discussion of these items. The Chair also noted that Professor Paul Fraser's and Professor Huw D Jones' involvement with Syngenta, and Professor Wendy Harwood's with Bayer. These were not considered to be conflicts of interest and that they would be present and able to contribute to the discussion of those items.

2. Welcome

The Chair welcomed the Members, including 2 new ones: Dr Meera Cush, Dr Sophie Foley, representatives from the FSA, the observers from the devolved administrations and the Secretariat team. Dr Lynn McIntyre and Dr Isabel Skypala who have also recently joined the Committee expect to attend the next full ACNFP meeting.

3.Meeting Minutes for the 164th Meeting

ACNFP/164/MINS

The Committee agreed the 164th meeting draft minutes for publication on the ACNFP website as an accurate record, pending some amendments to fully capture

the discussion on the GM item to be cleared by Chair's action.

4.Matters Arising from the last meeting

ACNFP/165/MA

The Secretariat reported on actions from the 164th meeting:

- Calcidiol - The Committee Advice Document was subject to revision to appropriately cross reference the recent EFSA opinion on the bioavailability of Calcidiol. The toxicological data was subject to in-depth review and significantly amended to ensure the information provided and its contribution to the assessment was clearly outlined. The updated document was cleared by the Chair and has entered the publication process.
- Corn protein - Further information was sought from the applicant on production process and nutrition for consideration at the next meeting.
- Regulated products service - Members were thanked for their comments and contributions. Members will be updated as the process is refined and implemented.
- Vitamin D2 mushroom powder - Further information on the production process was sought. The applicant's response was presented as item 5 in the 165th meeting along with the revised version of the Committee Advice Document.
- CBD application RP350 - The Committee Advice Document was updated in light of the comments received and agreed by Chair's action. It has now entered the publication process and is due to be published later in April.
- CBD Application RP07 – The Committee Advice Document for RP07 was updated in light of the comments received on RP350 for consistency and agreed by Chair's action. It has now entered the publication process and is due to be published later in April.

Updates from previous meetings:

- Clostridium Butryricum - To note in light of the feedback from the Committee on this application, the queries were explored with the applicant and the application was withdrawn.
- Publication of UK Safety assessments – 3 novel foods – Schizochytrium extension, IMO extension and Magnesium L threonate. 12 GMOs were also published in the last month (RP numbers 188, 212, 608, 652, 1123, 1232, 1372, 1506, 1565, 1566, 1569, 1585).

5. CBD RP427 (reserved business)

ACNFP/165/01

The minutes for this item will be published in due course.

6. CBD RP793 (reserved business)

ACNFP/165/02

The minutes for this item will be published in due course.

7. Committee Advice Documents from the oligosaccharides 2'-FL, 3'SL and 6'SL

ACNFP/165/03

The Committee first reviewed these three applications in September 2023. Further questions were raised on the identity of the novel food, the production process, compositional information, specification (2’-FL only), stability, nutritional information (3’-SL and 6’-SL only), toxicological information and the allergenicity of these novel foods.

For all three applications, Members discussed the potential risk of bacterial contamination during the novel food manufacturing process in conjunction with the further details on the HACCP plan provided by the applicant. The Committee considered the information in detail and while noting it was outside the scope of their review to comment on the applicant’s HACCP plan, they noted that the applicant may wish to consider further the risk of toxin formation to ensure this was minimised given the end user is a high-risk group. The compositional data concerning the microbiological criteria and toxin levels provided the Committee with sufficient assurance that the specification limits for these parameters were appropriate. They also noted that existing legislative requirements for infant and follow-on formula provided assurance that sufficient controls are in place the potential for microbial contamination and therefore the opportunity for toxin formation would be actively monitored.

The Committee also reviewed the responses received for 3**’-**SL and 6**’-**SL and noted that the response had addressed questions on the contribution the novel food would make to salt exposure in the users’ diet. They were reassured that this

has been considered and would not represent a significant contribution to salt exposure. Reassurance was received on a number of other clarifications that points raised on toxicology, production process and identification were not a food safety risk.

Members also reviewed the draft Committee Advice Documents (CAD) for each novel food. The Committee has identified areas where further editing by the Secretariat is required.

Members agreed the Committee Advice Documents for 2’-FL, 3’-SL and 6’-SL, subject to the changes identified, will be agreed by Chair’s action before entering the publication process.

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

8. Olive fruit extract standardized in hydroxytyrosol RP1074

ACNFP/165/04

The Committee reviewed this application at three meetings. A draft Committee Advice Document (CAD) for this novel food was developed. Following discussions at the previous meetings, further information on composition, specification and toxicology sections was requested from the applicant so as to address outstanding queries to help reach an appropriate conclusion on the safety of this novel food.

The focus of the discussion was on the toxicological data which had been provided from literature and related to various extracts from Olive fruits with varying compositions. Following discussions with the toxicological experts between meeting, views of the Committee were sought on the ability to reach conclusions on the safety of the novel food seeking authorisation based on the dataset provided.

It was noted that the data presented was mixed and the relevance to the novel food was not clear as compositional data for the test items used was not available. Where supportive results for safety of the novel food had been identified, the lack of an adverse effect did not support identification of a toxicological point of departure. It was agreed that the data did not support conclusions being reached and sub-chronic toxicological data on the novel food or

a test item of a similar composition would be needed to complete the assessment. It was , noted that signals from the literature data suggested the potential for concerns on genotoxicity. However, members were able to conclude that the novel food was not considered genotoxic based on the full extent of the data package provided.

Members advised that further data was needed from the applicant to complete the assessment and the safety of the novel food had not been demonstrated.

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

Action The Secretariat to identify the next steps for the application and if necessary, update the Committee Advice Document to reach a conclusion for clearance by Chair action.

9. Vitamin D2 mushroom powder RP1550

ACNFP/165/05

The Committee last reviewed this application at the February 2024 meeting where members advised further information was needed on the production process to complete the assessment. Members were provided with the response from the applicant and a draft Committee Advice Document for review.

Following discussions on the applicant’s response to the queries on the production process it was noted that this had not fully addressed the questions raised the blending process was producing a homogenous output of vitamin D2 powder. This is a key issue to underpin the accuracy of the safety data provided. Members advised the Secretariat to seek this information from the applicant to be able to conclude on the safety of the novel food.

The response on the questions of packing and storage had been addressed appropriately. A concern was raised on the potential for changes in moisture content and the impact on microbiological growth during transit and storage. The Committee were reassured that this was a known concern and there were standard practices in place to managing this when products are traded.

The Committee also reviewed the draft Committee Advice Documents (CAD) for this novel food where they identified areas that needed further editing by the Secretariat.

Action: The Secretariat to review the options for the assessment of this novel food and if appropriate seek further information from the applicant on production.

Action: Secretariat to explore with the Chair the next steps.

10. Committee Advice Documents from GM applications RP1868 and 1869 (reserved business)

ACNFP/165/06

The Committee reviewed these applications and the draft Committee Advice Document agreed by the ACNFP-PGT Subcommittee.

Members were made aware that a Request for Further Information response from the applicant is currently pending. The requested information relates to the allergenicity assessments of both RP1868 and RP1869. The Secretariat will provide this information to expert Members for review by correspondence. It was noted that the information does not impact the nature of the conclusion that can be reached on the application but may inform appropriate risk management.

Members discussed the draft Committee Advice Documents and highlighted minor amendments to be addressed by the Secretariat. It was agreed that a further commenting period by correspondence would be provided. Following which the two Advice Documents would be agreed subject to amendments to be finalised by Chair’s action.

Action: The Secretariat to amend the Committee Advice Documents for RP1868 and RP1869 for clearance by Chair’s action.

11. Update on the work to support development of regime to regulate precision breed organisms (reserved business)

ACNFP/165/07

The Committee received an update on the work to develop an assessment framework for precision breed organisms. This provided context for the workshop

with the Committee on the technical guidance to support the new regime that will take place on the 1 May 2024.

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.

Date of next meeting

The next full ACNFP meeting will be held in-person and online on 12th June 2024.

A workshop of the Committee to review and provide advice on the technical guidance to support the assessment of precision breed organisms will take place on the 1st May.