

Advisory Committee on Novel Foods and Process. Minutes of the 161st Meeting held on the 25th of July 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 161st meeting of the Advisory Committee on Novel Foods and Processes, held on the 25th of July as a virtual meeting.

Attendance

Committee Chair

Dr Camilla Alexander-White

Committee Members

Dr Anton Alldrick

Dr Mark Berry

Professor Susan Fairweather-Tait

Professor Paul Fraser

Dr Andy Greenfield

Professor Wendy Harwood

Professor Huw Jones

Dr Ray Kemp

Dr Elizabeth Lund

Professor Clare Mills

Mrs Rebecca McKenzie

Dr Lesley Stanley

Prof Hans Verhagen

Dr Maureen Wakefield

Professor Bruce Whitelaw

Apologies

Ms Alison Austin - Member

Professor Dimitris Charalampopoulos - Member

Dr Hamid Ghoddusi - Member

Professor Harry McArdle - Member

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

Professor Alastair Macrae - Co-opted Member

Assessor

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

Observers FSA

Ms Julie Pierce - Director of Information and Science

Mr Chris Rundle - Head of Regulated Products Risk Assessment

Dr Daniel Lloyd - Senior Regulated Products Risk Assessor

Mr Chris Stockdale - Head, Genetic Technology Policy

Mr Adekunle Adeoye - FSA Senior Policy Advisor

Ms Justine Gallie - GT Policy Advisor

Mr Hoa Chang - GT Policy Advisor

Ms Chun-Han Chan - Head of Stakeholder Engagement

Ms Chloe Jackson - Senior Communications Manager

Observers Devolved administration

Dr Karen Pearson - Food Standards Scotland

Mrs Siobhan Watt - Food Standards Scotland

Ms Lucy Smythe - Food Standards Scotland

Mr Joshua Evans - Food Standards Scotland

Mr Daniel Lynch - Policy, FSA NI

Mr Andrew Dodd - Policy, FSA Wales

Observers (External)

Ms Ivy Wellman - Defra Representative

Secretariat

Mrs Ruth Willis - Technical Secretary

Dr Rachael Oakenfull - Technical Secretary

Dr Karin Heurlier - Science Secretariat

Mr Will Smith - Science Secretariat

Mrs Afielia Choudhry - Science Secretariat

Dr Andrew Hartley - Science Secretariat

Dr Annalisa Leone - Science Secretariat

Mr Ben Haynes - Science Secretariat

Mr Liam Blacklock - Science Secretariat

Miss Lucy Thursfield - Science Secretariat

Miss Victoria Balch - Administrative Secretariat

1. Apologies and Announcements

Apologies were received from Mrs Alison Austin, Dr Hamid Ghoddusi, and Professors Dimitris Charalampopoulos, Harry McArdle, Alastair Macrae and Pete Lund for non-attendance. To note, they were given access and opportunity to comment on the draft statement (ACNFP161/01 Annex A) ahead of the meeting.

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.

Professor Bruce Whitelaw declared a conflict of interest by the way of holding a University of Edinburgh Commercialisation Licence with Genus plc regarding PRRSV-resistant pigs; this was noted, and it was agreed that if this particular case study was discussed, Professor Whitelaw would not be allowed to comment or provide an opinion on the case.

2. Matters Arising from the last meeting

ACNFP/161/MA

The Secretariat reported on actions from the previous meeting:

- The Committee and ACNFP-PGT Subcommittee previously held workshops to finalise the data requirements for two potential models of triaging/tiering to support safety assessment of PBOs for use in food and feed. The points raised were used by the Secretariat to generate a draft statement on the options (Model 1 and Model 2) for a proposed regulatory workflow of PBOs which was circulated for review ahead of this meeting. This statement formed the basis of today's workshop.
- The Secretariat informed Members that all other matters arising, and minutes, will be covered in the next ACNFP 162nd two-day meeting on September 18th and 19th.

3. Policy update

The Committee were provided with an oral update by the FSA Head of Genetic Technologies policy on the issues under consideration regarding PBO regulations. This included an update on the strategic direction being explored in preparation of the papers for the September 2023 FSA board meeting.

4. Precision Breeding workshop

ACNFP/161/01

The ACNFP reviewed a draft statement summarising the Products of Genetic Technology (PGT) Subcommittee's views on the data requirements of two potential models (Model 1 and Model 2) to support the safety assessment of Precision Bred Organisms in a tiered approach. The Subcommittee members confirmed that the draft represented a consensus position, following the PGT workshops in 2023. The ACNFP Committee thanked the PGT subcommittee for their technical input on this matter.

The ACNFP was updated on the work of the Subcommittee on the differential data requirements for the two potential approaches in Models 1 and 2. The ACNFP was asked to review these and assess the level of assurance they provide.

An update was also provided by the ACNFP-PGT Chair on the addition of example models in the Statement, Model 0 (no data requirements) and Model 3 (the most comprehensive data requirements possible), to put the discussion on proportionality and data requirements for Models 1 and 2 in context.

The Committee agreed it was important to clarify that the ACNFP - PGT Subcommittee and ACNFP itself, have not explored Model 0 or Model 3; these are only included to provide context for Model 1 and Model 2. The scientific justification for the data requirements developed in Models 1 and 2, outlined in Annex B of the statement, represents the conclusions from deliberations in PGT.

Prior to the ACNFP meeting, the Committee was tasked with providing feedback on the data requirements and the statement by correspondence. The Committee was asked to review the statement to ensure the opinions of the Committee were accurately captured, and that they are satisfied with the two models of data requirements for assessment of PBOs destined for food and feed purpose. Key points within the statement were discussed for further review and amendment.

The ACNFP was supportive that the general proposals and conclusions in the statement captured their views, but requested amendments to provide clarity which are outlined below.

It was noted that the intention of the change generated using PB, especially regarding how they may alter edible parts, is very important to understand to assess safety. The Secretariat were asked to make this clearer in both the statement and flow diagram figures, which summarise the potential regulatory approval process. There was also a desire to modify the flow diagrams to better highlight the differences between the two Models.

The Committee also requested the statement contain an overview explaining the process of TB, for example, how TBOs can be generated by a wide range of breeding processes. This would allow a better understanding of how the techniques used to generate TBOs compared to PB and why they are considered equivalent in the context of the new Act.

The Committee emphasised that applicants should share all relevant scientific data for their product even if not explicitly requested in guidance, where these are pertinent to the review of the safety of the organism.

The Committee provided detail on justification for the two models and the level of assurance each model provides. Model 1 requires the applicant to generate less characterisation data up front compared to Model 2. It is possible that in some cases this approach could result in a lower degree of assurance in the initial stages of review when using in Model 1 compared to Model 2. However, it was noted that any concerns identified using the Model 1 option of initial assessment can be explored by assigning applicants to Tier 2, if more assurance is needed to perform a safety assessment, supported by specific data requests on a case-by-case basis. Members agreed that allergenicity is the most complex trigger question, but concerns could be identified and captured in Tier 2 assessment, where required.

The Committee wished to include a line on potential off-target effects from using PB, noting that off-target effects can occur in both PBOs and TBOs.

Animal welfare was also discussed as it is not considered in detail in the statement. It was determined that it is within ACRE's remit to consider changes to the welfare of PBO animals due to the PBO edit; welfare issues will be a strong consideration for rejecting PBO applications. The welfare of animals fed PBO products was also discussed and considered to be within the remit of ACNFP and

will come under consideration during the assessment by the FSA for use as feed.

The Committee concluded with the remark that the statement provides scientific perspectives and appreciates this forms only part of the considerations for development of the FSA's chosen assessment approach; this document, at this point in time, acts as advice for the FSA Board. Once an approach is decided upon by the Board in their September meeting, technical guidance is expected to be needed to support the safety assessment of PBO dossiers received from applicants.

The Committee was satisfied that with the addition of their edits and some suggested changes to wording, the draft statement would then be circulated one more time to Members for a final review and would be suitable for submission into the FSA publication process. All members will be asked by correspondence whether they are supportive of the final edited statement, as a consensus statement to be published from the ACNFP.

Action: Secretariat to use comments to make corrections to the statement and its figures to reflect the comments of the ACNFP. Finalise a copy for publications before the board meeting.

5. Any other business

No other business was discussed.

Date of next meeting

The next 162nd hybrid meeting of the ACNFP committee is scheduled for 18th and 19th September 2023 to take place in London and online.