Minutes

Advisory Committee on Novel Foods and Process (ACNFP). Subcommittee on Products of Genetic Technologies (PGT). Minutes of the 6th PGT Meeting held on the 1st of February 2023

These minutes are subject to confirmation by the Subcommittee.

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 6th meeting of the Products of Genetic Technologies (PGT) Subcommittee of the Advisory Committee on Novel Foods and Processes (ACNFP), held on 1st of February 2023, online using Microsoft Teams.

Attendance

Committee Chair

Dr Andy Greenfield

Committee Members

Professor Paul Fraser

Professor Wendy Harwood

Professor Huw Jones

Dr Ray Kemp

Dr Elizabeth Lund

Professor Clare Mills

Professor Bruce Whitelaw

Professor Hans Verhagen

Professor Pete Lund - Co-opted

Apologies

Professor Alastair Macrae - Co-opted

Observers (FSA)

Mr Chris Stockdale, Head, Genetic Technology (GT) Policy

Mr Adekunle Adeoye, Regulated Services, Senior Policy Officer

Mr Hoa Chang, GT Policy Advisor

Mrs Justine Gallie, GT Policy Advisor

Mr Solomon Okoruwa, Food Policy, Senior Policy Advisor

Dr Joshua Ravenhill, Food Policy, Head of Policy Priorities

Observers (External)

Dr Mike Ellis, Defra, ACRE Secretariat

Professor Peter Gregory, Science Council

Professor Thomas Richard, Royal Society Policy Associate

Observers (Devolved Administration)

Mr Xose Álvarez, Policy FSA Wales

Mr Andrew Dodd, Policy, FSA Wales

Mr Ciaran Weir, FSA Northern Ireland

Dr Karen Pearson, Food Standards Scotland

Ms Georgina Finch, Food Standards Scotland

Mrs Tamara Satmarean, Food Standards Scotland

Ms Siobhan Watt, FSA Northern Ireland

Secretariat

Mrs Ruth Willis, Head Regulated Products Risk Assessment; Technical Secretary ACNFP

Dr Rachael Oakenfull, Team Leader, Regulated Products Risk Assessment (GT)

Dr Rhys Williams, Senior Secretariat

Mr Liam Blacklock, Science Secretariat

Mr Matt Hall, Science Secretariat

Dr Andrew Hartley, Science Secretariat

Dr Karin Heurlier, Science Secretariat

Dr Annalisa Leone, Science Secretariat

Miss Jenny Rees, Science Secretariat

Miss Victoria Balch, Administrative Secretariat

1 . Apologies and Announcements

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

Apologies were received from Professor Alastair Macrae; Professor Clare Mills advised she would only be able to attend in part.

2. Matters Arising

ACNFP/PGT/6/MA

- The Secretariat took on board comments raised by members concerning the minutes for ACNFP PGT3 and ACNFP PGT4. The minutes of PGT meetings 1 to 4 were published on 23rd January 2023, together with associated executive summaries for PGT3 and 4, and the second ACNFP statement on the precision breeding framework.
- The Secretariat thanked all Members for continuing to accommodate shorter than usual times for looking at papers ahead of meetings.

3. Minutes of the ACNFP/PGT5 meeting

ACNFP/PGT/5/Min

Minutes from the fifth Subcommittee meeting were reviewed and agreed, pending minor amendments.

Action - The Secretariat to update the draft minutes for PGT5.

4. Genetically modified cotton GHB811 RP1232 (Reserved Business)

ACNFP/PGT/6/01

Professor Paul Fraser declared a potential conflict of interest relating to his work involving a related enzyme. It was agreed that this was not directly relevant to the application and the member remained in the meeting but did not contribute directly to the discussions.

An application for the authorisation of genetically modified cotton (GHB81) was reviewed for the first time. The Secretariat has been asked to draft Committee advice on the application, to inform the development of the Safety Evaluation Outcome.

Action - The Secretariat to produce a draft of the Committee's advice on the application for subcommittee review to inform the safety assessment outcome.

5. Genetically modified cotton GHB614 RP608 (Reserved Business)

ACNFP/PGT/6/02

An application for the renewal of the authorisation of genetically modified cotton (GHB614) was reviewed for the first time, together with a draft of the committee advice on the application. This was agreed and will be reviewed by the full ACNFP Committee at their next available meeting.

Action – The ACNFP Committee to review the agreed draft Committee advice on the application in order to inform the safety assessment outcome.

6. Precision breeding framework workshop

ACNFP/PGT/6/03

Review of case study table of reference

The Subcommittee reviewed a preliminary table of reference for case studies that is to be published as supporting information for the precision breeding assessment framework and prior statements published in November 2022 and January 2023. The Subcommittee noted that the listed case studies were used to support the development and testing of the approach to the safety assessment of Precision Bred Organisms (PBOs). It was agreed that the table would be updated accordingly when further case studies are used.

Members agreed that the case studies provided a range of examples of future potential precision bred organisms, based on the academic literature. Members commented that information on the precision breeding techniques should be provided, as well as potential safety concerns or potential benefits, where appropriate to the risk assessment of PBOs.

It was suggested that the Secretariat seek further review of the table of references from ACRE and update it accordingly.

Action – The Secretariat to seek further review and to update the table of references.

Decision tree and tier assessment piloting using case studies

Members discussed the range of information necessary for a tiered assessment. Case studies from recent literature were presented to test the tiered approach. It was noted that some of the case studies were more limited in respect of details or type of information provided, due to the fact they were derived from academic

publications; consequently, they did not all provide the level of detail required to support a regulatory approval.

Members discussed two case studies to support exploration of the assessment approach, specifically the basis for tier assignment, using examples with potential for a high degree of novelty or significant impact on nutrition. Members agreed that information may be needed on all or some of the following: the parental variety/ species, gene function, the gene target rationale, information on the insertion site where relevant (for cisgenic PBOs), tissue-specific gene expression where relevant and identification of any anticipated impacts on metabolic pathways. Members discussed allergenicity considerations for PBOs and what evidence would be required from the applicant to inform a safety assessment.

Members discussed the benefits and limitations of seeking certain data at specific points in the process and how this could support greater certainty for applicants in how their application would be managed through the process.

With regards to novelty, Members agreed that applicants must demonstrate that the progenitor used to derive a PBO has a history of consumption and provide information on history of use. Early identification of applications requiring a tier 2 assessment on the grounds of novelty would support the applicant gathering data and a proportionate review by the Subcommittee.

With regards to nutrition, members explored what data would be necessary to determine whether a resulting nutritional change was disadvantageous or not. The first aspect of any assessment is likely to involve determining changes in nutritional quality and understanding their impact by comparison to an appropriate reference, e.g., upper intake levels, or other foods with similar properties that are consumed. In some cases, predicted wider impacts may also require consideration, for example, information on manipulation of enzymes involved in the production of secondary metabolites. It was recommended that any safety concerns regarding intakes to a population subgroup would assign the PBO to a tier 2 assessment for further review of the impact.

In initially considering guidance for applicants, the Members emphasised that the assessment will be determined by any safety concerns relating to the introduced trait itself. Members agreed that case studies should continue to be used in workshops to study tier 1 and tier 2 PBO assignments, to pilot use of the decision tree and further explore likely tier 2 scenarios.

7. Any other business

- Conflicts of interests, perceived conflicts of interests and the processes that manage these were discussed. Members, together with the Secretariat, agreed that the management processes and policies in place are appropriate. Information on interests of members will be updated on the website as they arise.
- Members discussed the potential structuring of meetings and agreed on a flexible approach to the allocation of applications to manage the increasing demand for review of GM applications, in addition to PBO workshops.
- The Secretariat presented a proposed Precision Breeding (PB) Glossary. Members agreed to adopt the glossary and recommend additions to it as required. Ongoing review of this as discussions evolve was requested by the Secretariat.

8. Date of next meeting

The next ACNFP meeting is scheduled for 7th and 8th February 2023 and will be held as a hybrid meeting in London and online on Teams. The next ACNFP-PGT meeting is scheduled for 15th March 2023 and will be held virtually on Teams.