Minutes

Advisory Committee on Novel Foods and Process (ACNFP). Subcommittee on Products of Genetic Technologies (PGT). Minutes of the 8th PGT Meeting held on the 17th of May 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 8th meeting of the Products of Genetic Technologies (PGT) Subcommittee of the Advisory Committee on Novel Foods and Processes (ACNFP), held on 17th of May 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 Hans Verhagen

Professor Bruce Whitelaw

Professor Pete Lund - Co-opted

Professor Alastair Macrae - Co-opted

Observers (FSA)

Mr Chris Rundle, Head, Regulated Products Risk Assessment (RPRA)

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

Ms Aristy Rhodes, Strategy Project Manager

Ms Beth Sung, Senior Policy Advisor

Mr Adekunle Adeoye, Regulated Services, Senior Policy Officer

Mr Hoa Chang, Genetic Technologies (GT) Policy Advisor

Mr Solomon Okoruwa, Food Policy, Senior Policy Advisor

Observers (External)

Dr Mike Ellis, Defra, ACRE Secretariat

Professor Peter Gregory, Observer, Science Council

Ms Caroline Povey, Defra, Animal Welfare Team

Observers (Devolved Administration)

Mr Xose Álvarez, Policy, FSA Wales

Mr Andrew Dodd, Policy, FSA Wales

Dr Karen Pearson, Food Standards Scotland Science

Mrs Siobhan Watt, Food Standards Scotland

Secretariat

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

Dr Rachael Oakenfull, Team Leader, RPRA (GT); Technical Secretary PGT

Dr Rhys Williams, Senior Secretariat

Mr Liam Blacklock, Science Secretariat

Mr Matt Hall, Science Secretariat

Dr Andrew Hartley, Science Secretariat

Dr Karin Heurlier, Senior Secretariat

Dr Annalisa Leone, Science Secretariat

Ms Lucy Thursfield, Science Secretariat

Miss Victoria Balch, Administrative Secretariat

1 . Apologies and Announcements

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

Professors Hans Verhagen and Peter Gregory advised they would only be able to attend in part.

2. Matters Arising

ACNFP/PGT/7/MA

- The Secretariat addressed the Members' comments on the minutes of ACNFP PGT6, which have now been finalised and cleared by the Chair. These will be released in the public domain in a timely manner.
- Following the discussion at PGT 7 and the proposal to develop two models for the approach to the data requirements for the initial assessment of precision bred organisms (PBOs), the work by the PGT Subcommittee to date

was used to update ACNFP in their 159th meeting. ACNFP agreed that both models were scientifically justified, and that PGT should develop data requirements for both, to inform a future policy decision on the framework by the FSA Board (likely in September 2023).

3. ACRE / Defra update

Defra representatives provided updates on progress with the secondary legislation to follow the Precision Breeding Act, and on the planned work of the Defra-led Animal Welfare Group.

4. Precision Breeding Policy update

An oral update was provided on all FSA Policy strands of work relating to the Precision Breeding Framework development taking place in addition to that of the Subcommittee.

5. Minutes of the ACNFP-PGT7 meeting

ACNFP/PGT/7/Min

Minutes from the seventh Subcommittee meeting were reviewed. Areas needing clarification were identified. The minutes will be updated accordingly and recirculated with Members for agreement.

Action - The Secretariat to amend the draft minutes for PGT7 and share with Members for review.

6. Precision breeding framework workshop

ACNFP/PGT/8/01

Professor Bruce Whitelaw declared an interest in regard to the PRRSV-resistant pig case study; this was noted and it was agreed following discussion that, should this particular case study be used in the discussion, Professor Whitelaw would be present, but only to answer questions on the case.

The main objective of this workshop was to identify the data requirements to support triage and assessment (in Tier 1 and Tier 2) of the safety of PBOs for food or feed in two models:

- Model 1, where the interpretation of proportionality limits the requirements for the triage stage to requests for minimal initial data in addition to the data requested by ACRE for determination of the PBO status;

- Model 2, where the novelty of the method, and associated uncertainties, are taken into account to justify more in-depth initial data requirements.

Session 1 – Principles of assessment and data requirements identified in the discussion to date.

Members were invited to review principles compiled by the Secretariat from the discussions in previous meetings, which are key in determining the development of the assessment framework. This was to ensure a common starting point on the meanings of terms and the principles governing any good assessment framework when further developing the data requirements to support the assessment framework. During their discussion, the following points were raised:

- The level of assessment should be proportionate to the risk and will take into account existing food regulations and the sources of risk mitigation that may already be in place.

- The definition of “traditionally bred counterparts”, used as a reference in the decision tree described in ACNFP January 2023 Statement on PB Framework, needs to be flexible enough to encompass a number of possible comparators. The traditionally bred counterpart should be understood as the nearest available traditionally bred equivalent, e.g. an identical phenotype expressed in the same species and where the mutation was produced by traditional breeding practices, or the same phenotype in a different species, or even a ‘conceptual’ phenotype – one that could conceivably be obtained by traditional breeding (and might be identified if sufficient screening were performed). All these were considered to be distinct from the progenitor, which is the organism, with unchanged phenotype, prior to precision breeding.

- When reviewing the data submitted, the Subcommittee should take account of information derived from their wider knowledge and expertise in order to support an appropriate level of assessment.

- When considering the data requirements for triage and Tier 1 in Model 1, Members observed that although it would not require significant amounts of compositional data, in some scenarios, informed by the nature of the trait (e.g. biofortified and allergen-free foods), limited compositional data would be required

to demonstrate that the intended phenotypic trait had been introduced as described.

- An opportunity to request further information at triage, if needed in a Model 1 approach, would support assignment of an application to the appropriate tier.

- The Subcommittee confirmed the importance of the triage question concerning “other safety concerns”, which will help to capture risks that could not be foreseen and that would not be suitably addressed by the nutritional, toxicology, or allergenicity triage questions.

- Members confirmed that, where an answer to a triage question(s) triggers Tier 2, the particular nature of the question will inform the further data requirements for assessment in Tier 2 in both models. It was suggested that assigning an organism to Tier 2 should not ordinarily allow scrutiny of additional issues not already considered in the triage questions.

Action – The Secretariat to review the principles in light of Members’ comments, and to provide them to the whole ACNFP to inform future work on the development of the scientific underpinning of the PBO framework

Session 2 – Identification of the key data submission required at each stage of the safety assessment to allow an adequate assessment of safety.

When considering the two models of how best to assess the safety of PBOs for food or feed, the Subcommittee further clarified that while both primarily examine the novelty and other safety concerns of a PBO, Model 1 focusses on the intended phenotypic change, while Model 2 introduces additional consideration of data concerning changes in composition that might arise as a result of the genetic change.

The initial data package needed to characterise a PBO, as concluded from previous discussions, was reviewed as a starting point for all models of triage. It was acknowledged that while the data obtained according to the ACRE guidance might provide much needed information, they are not required to be particularly detailed. This could result in variations in the level of detail of information obtained and provided to the FSA.

Members identified the additional data likely to be needed to be able to complete triage in Model 1, noting that Tier 2 would permit requests for additional information where concerns were identified:

- data should be provided that demonstrate that the genetic change has resulted in the intended phenotype as described. The advantage of requesting this data only when the expected phenotype is relevant for food/feed was discussed: the focussed nature of this request would avoid unnecessary data concerning traits irrelevant for food safety (e.g. wheat height and yield advantage); however, it was noted that such data would, whether relevant to food or feed or not, already be available to the applicants.

- the opportunity to request additional minimal, bespoke data where the information is insufficient would provide flexibility within Tier 1 to ensure that key information is available to support Tier assignment.

The Subcommittee noted that where ‘radical’ changes were expected in food/feed from PBOs, these organisms would likely be assigned to Tier 2, e.g. a pest resistance introduced by changing metabolites to reduce palatability; or significant alterations to peanut allergens which would significantly alter the nature of the organism.

Members discussed how unintended yet anticipated effects could be captured, to be able to complete triage in Model 2, by requiring compositional data not limited to verifying that the intended trait had been achieved as part of the initial data package for every PBO. The significance of changes could be determined by comparisons against a control, such as the progenitor or the nearest equivalent TBO (when available), though the progenitor would be preferable since the equivalent TBO may possess many additional changes due to the nature of breeding.

During their discussions, Members considered what scenarios may raise “other safety concerns”, based on the decision tree from the January statement, and trigger a Tier 2 assessment. There was consensus that this would require a case-by-case approach to additional data required in Tier 2. assessment.

Action – The Secretariat to develop decision trees representing the two possible models for the data required to assign to Tiers under the process;

Session 3 – Review session to ensure the assessment works holistically.

This session did not take place due to time constraints; instead, it was agreed that comments would be sought by correspondence.

Action – The Secretariat to identify outstanding questions on data requirements and seek responses by correspondence.

7. Genetically modified cotton GHB811 RP1232 (Reserved Business)

ACNFP/PGT/8/02

When reviewing the application for the authorisation of genetically modified GHB811 cotton (RP1232) in their February meeting, the ACNFP PGT Subcommittee recommended that an outcome document summarising the Subcommittee's safety advice be generated for GHB811 cotton, for agreement with the ACNFP.

The Secretariat thanked Members for the comments already received on the draft safety advice that was shared ahead of the meeting. It was agreed that further comments would be sought by correspondence.

Action – Members to review and comment on the draft safety advice for RP1232 within two weeks, by correspondence.

8. Any other business

- The Subcommittee was reminded that the dates for PGT9, PGT10 and PGT11 had been decided and communicated to Members. However, the work of the Subcommittee, together with the main ACNFP committee, might require additional meetings.
- The Secretariat noted the regular sharing of literature between Members and informed them of the upcoming creation of a folder to archive these additional references as a valuable resource.

9. Dates of next meeting

The next ACNFP meeting is scheduled for 14th June 2023 and while initially planned as virtual, the Secretariat will explore the possibilities of holding it as a hybrid meeting in London and online on Teams. The next ACNFP-PGT meeting is scheduled for 18th July 2023.