Minutes

Advisory Committee on Novel Foods and Process (ACNFP). Subcommittee on Products of Genetic Technologies (PGT). Minutes of the 9th PGT Meeting held on the 18th of July 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 9th meeting of the Products of Genetic Technologies (PGT) Subcommittee of the Advisory Committee on Novel Foods and Processes (ACNFP), held on 18th of July 2023, at Foss House, York as a hybrid meeting.

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 *ex officio* Member

Apologies

Professor Alastair Macrae - Co-opted

Observers (FSA)

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

Donal Griffin, Team Leader, Animal Feed Risk Assessment

Mr Hoa Chang, Genetic Technologies (GT) Policy Advisor

Mrs Justine Galli, GT Policy Advisor

Erin Thompson, Food Policy Officer

Observers (External)

Professor Peter Gregory, Observer, Science Council

Mr Richard Lloyd Mills, Defra

Observers (Devolved Administration)

Dr Karen Pearson, Food Standards Scotland Science

Mrs Siobhan Watt, Food Standards Scotland

Secretariat

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

Mr Liam Blacklock, Science Secretariat

Mr Matt Hall, Science Secretariat

Dr Karin Heurlier, Senior Secretaria

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.

Apologies were received from Professor Alastair Macrae; it was noted he had reviewed and provided comments on the draft statement (PGT/9/01) ahead of the meeting.

2. Matters Arising

ACNFP/PGT/8/MA

- PGT7 minutes were updated following Members' comments and are returning for agreement; they were circulated ahead of this meeting, together with PGT8 minutes.
- Workshop PGT8 - The Subcommittee further developed the data requirements for two models of approach to the assessment of Precision Bred Organisms (PBOs). Members' input was sought by correspondence to answer outstanding questions on the process and data requirements for the triage / Tier 1 assessment. These supported the Secretariat in drawing flowcharts for each Model, which were used to update ACNFP in their 160th meeting. The discussion in that last meeting further clarified the differences in approach of the two models. Following this, a draft statement was developed by the Secretariat to be reviewed in this meeting by PGT and was circulated for comment by Members in advance.
- The Committee reviewed the draft safety advice prepared by the Secretariat for application RP1232 for the authorisation of genetically modified GHB811 cotton and provided comments by correspondence. This was subsequently presented to the ACNFP at its 160th meeting and agreed pending minor amendments and clarification with the applicant.

3. FSA update

Members were updated on the FSA's internal communications to aid Policy in the development of their options for the September board paper; these concerned the two models being developed by ACNFP on the data requirements for triage and tier assignment of PBOs.

4. ACRE / Defra update

Members were updated on recent workshops with PB stakeholders held by Defra on authorisation for marketing and information requirements for PBOs. They were also informed of the agenda for next ACRE meeting and the intention to include several GM applications for consideration of the environmental aspects, the food safety assessments of which will be coming to the PGT.

5. Minutes of the ACNFP-PGT7 and PGT8 meetings

ACNFP/PGT/7/Min and ACNFP/PGT/8/Min

The Subcommittee agreed the draft minutes of PGT7 as an accurate record of the 7th meeting held on 17th May 2023.

Comments on the minutes for PGT8 were invited to be sent by correspondence and agreed by Chair's action, should the nature of comments from Members permit.

Action - Members to comment on draft minutes for PGT8 within a week to support finalisation and agreement.

6. Precision breeding framework workshop

ACNFP/PGT/9/01

Building on previous discussions of the PGT Subcommittee, this session reviewed the proposed data requirements for two models of approach to the safety assessment of precision bred organisms (PBOs) discussed in PGT8 and ACNFP160. Once agreed, these would be included in the draft statement which will subsequently be presented to ACNFP at its 161st meeting for agreement.

Outstanding questions

The Secretariat identified outstanding questions on the specific data requirements and the process of safety assessment which required further clarification with the Subcommittee. These were the focus of the discussion:

- Do the initial data requirements for Model 1 include any compositional data?

Model 1 and the underlying principle which limits its data requirements to a minimum were discussed. It was clarified that descriptive data on anticipated changes consequential to introduction of the intended trait would be required for all PBOs in both Models. However, in Model 1, quantitative compositional data would only be expected from PBOs where the intended trait alters nutritional quality of food or feed and would be restricted to information required to verify that the intended trait has been achieved.

- Are compositional data part of the initial data submission for all applications in Model 2? If so, what compositional data should be included?

More extensive data requirements would be needed to allow the potential consequences of the genetic change relevant to food/feed to be assessed in Model 2. Members agreed that compositional data would be required for all PBOs in this model as part of the initial data request. Specific data should be tailored to the organism and the trait introduced. For example, in addition to any compositional data required to verify introduction of a trait, as required in Model 1, a typical Model 2 initial data submission may consist of proximate analysis (protein, carbohydrate, mineral and fat content) and relevant micronutrient analysis (e.g., for oil seeds: fatty acid content). Further compositional data regarding secondary metabolites may also be necessary for some PBOs. The issue of the comparator to be used was raised previously.

- Would the initial data required allow the triage question on allergenicity to be answered?

Members noted that allergenicity is the most complex triage question to assess in either Model. Absence of compositional data in the initial data request in Model 1 could result in more applications assigned to Tier 2 due to allergenicity concerns. However, requiring a comprehensive set of allergenicity tests in the initial data submission, even in Model 2 where more extensive data are required, was considered to be disproportionate.

Triage should consider the nature and the context of the genetic change(s), and potential impacts on allergenic potency. If any safety concerns are identified, an in-depth allergenicity assessment should be conducted in Tier 2.

- How does the novelty triage question relate to the current novel food definition?

It was clarified that PBOs used for food would trigger assessment for novelty in Tier 2 if they had no history of use in the UK and the EU prior to 1997, as outlined in the novel food definition in the Novel Food retained Regulation (EC) 2015/2283.

- The Novel Food regime doesn’t apply to feed: would the novelty triage question apply only for PBOs for food use?

It was clarified that the safety of feed with no prior history of use is ensured through several regulatory regimes and excluded from the novel food assessment. Members agreed that should a feed have no history of use, it should receive adequate scrutiny by any relevant assessing body; in particular, this should examine digestibility, which is specific to the animal species consuming a feedstuff.

- What are the factors likely to influence the composition of animal products?

The potential for traits achieved by PB to alter the quality and safety of food/feed from animals was discussed. Members agreed that whether precision breeding of animals influenced the composition of food or feed derived from them would depend on the nature of the PBO; however, it was noted that other factors (such as feeding regime) were likely to have more impact on this than the PB traits.

- Would the data requirements for products derived from animal PBOs, such as eggs or milk, be different from that of animal tissues?

Careful consideration should be given to changes in composition of foods such as milk and eggs, which are key dietary components for young children. Their nutritional profile should be provided and compared to reference databases or to the progenitor to offer reassurance that that the nutrition trigger is not met.

- Are the data requirements likely to evolve with time and experience of assessment of PBOs?

Members highlighted that after an appropriate time gaining experience in the use of an assessment framework, there should be a review to ensure the implemented model is operating as originally envisaged, offering an opportunity for further refinement, if required.

Draft statement

Members reviewed and amended the wording of the draft statement produced by the Secretariat.

SWOT Analysis

To provide wider context and to allow policy makers to understand the specific features of each model, Members reviewed the relative strengths and weakness of Models 1 and 2, in light of the wider policy context. The level of assurance each Model would provide on the safety of PBOs for food/feed was the core focus. Some consideration was also given to other legitimate factors, based on the Subcommittee's experience of potential wider impacts. The Subcommittee's conclusions were summarised in the draft statement.

Action – The Secretariat to review the draft statement in light of Members' input and to circulate with ACNFP ahead of their 161st meeting.

7. Any other business

- Members were informed that availability for PGT meetings in 2024 would be explored by correspondence**;** dates for PGT10 and PGT11 meetings have already been agreed (18/10, 12/12).
- As GM applications are expected to be returning for assessment in the next PGT meeting, the Secretariat explored with Members what would allow them to manage their reviewing time at their preference. Members were reminded that allocation of sections of GM applications by expertise was discussed and agreed earlier this year, so Members would not have to review full dossiers.
- Members were informed that a folder was set up to file all publications shared by email between Members.

8. Dates of next meetings

The next ACNFP meeting is scheduled for 25th July 2023 and will be held virtually on Teams. The next ACNFP-PGT meeting is scheduled for 18th October 2023 and will be held virtually on Teams.