

Advisory Committee on Novel Foods and Process (ACNFP). Subcommittee on Products of Genetic Technologies (PGT). Minutes of the 7th PGT Meeting held on the 15th of March 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 7th meeting of the Products of Genetic Technologies (PGT) Subcommittee of the Advisory Committee on Novel Foods and Processes (ACNFP), held on 15th of March 2023, online using Microsoft Teams.

Attendance

Committee Chair

Dr Andy Greenfield

Committee Members

Professor Paul Fraser

Professor Wendy Harwood

Professor Huw Jones

Dr Elizabeth Lund

Professor Clare Mills

Professor Hans Verhagen

Professor Bruce Whitelaw

Professor Pete Lund - Co-opted

Professor Alastair Macrae - Co-opted

Apologies

Dr Ray Kemp - Member

Professor Peter Gregory - Observer, Science Council

Observers (FSA)

Mr Adekunle Adeoye, Regulated Services, Senior Policy Officer

Mr Hoa Chang, Genetic Technologies (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)

Mr Richard Lloyd Mills, Defra

Observers (Devolved Administration)

Mr Xose Álvarez, Policy, FSA Wales

Mr Ciaran Weir, FSA, Northern Ireland

Dr Karen Pearson, Food Standards Scotland Science

Ms Georgina Finch, Food Standards Scotland

Mrs Tamara Satmarean, Food Standards Scotland

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.

Apologies were received from Dr Ray Kemp and Professor Peter Gregory; Professor Alastair Macrae advised he 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 PGT5, which have now been finalised and cleared by the Chair. These will be released in the public domain in a timely manner.
- The Subcommittee reviewed an application for the authorisation of genetically modified cotton (GHB81) for the first time. Committee advice on the application has been used to inform the Committee Advice document

which is expected to return to the Subcommittee for review in a subsequent meeting.

- The Subcommittee reviewed an application for the renewal of the authorisation of genetically modified cotton (GHB614), together with a draft of Committee Advice Document for the application. This was agreed and was escalated for review by the full ACNFP Committee in their 157th meeting. This was subsequently agreed, subject to minor amendments.
- The format of a table listing the scientific publications used to provide examples (case studies) of possible precision bred organisms (PBOs) to aid discussions of the Subcommittee in developing the Precision Breeding framework, was reviewed. The table has been updated in light of Members' input and circulated for further comment prior to publication.

3. Minutes of the ACNFP/PGT6 meeting

ACNFP/PGT/6/Min

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

Action - The Secretariat to update the draft minutes for PGT6.

4. Precision Breeding Framework workshop

ACNFP/PGT/7/01

Proportionality of the assessment framework

The Subcommittee discussed how proportionality should be taken into account in developing the framework for the assessment of PBOs, particularly as PBO traits are defined in legislation as being equivalent to those that could be obtained through traditional breeding methods. A range of Member views was expressed:

- Some Members reiterated the view expressed in the first ACNFP statement that there is no evidence that PBOs are intrinsically more hazardous than traditionally bred organisms (TBO).
- These members highlighted that there is no legal requirement for the phenotypic traits of Traditionally Bred Organisms (TBOs) to be scrutinised pre-market, beyond due diligence. Considering this, triage and Tier assignment should not require any pre-market assessment beyond that

required for equivalent TBOs.

- Other Members were of the view that the production methods for PBOs are new, therefore not the same as for TBOs, and that this makes a difference when considering what pre-market assessments can be justified. A range of outcomes is possible from this rapidly developing technology. These justify scrutiny to ensure that risks are identified and effectively managed and justify requesting sufficient data to allow an appropriate level of scrutiny in triage / Tier 1.
- The Subcommittee discussed the idea that while the end result of traditional and precision bred processes might be predicted to be the same, this new technology could have unanticipated effects: (i) PB could be used to introduce traits that would have taken a very long time to develop (and might not have been attempted) through traditional breeding; (ii) reduced development times for PBOs might shorten the period of time available for their characterisation; and (iii) the production methods for PBOs do not yet benefit from a history of safe use, as those used in traditional breeding do, which for other products has been sufficient justification for some level of additional scrutiny. It was also noted that ACRE are likely to take these points into consideration when determining the status of an organism as a PBO, but that PGT reserves the right to make its own assessment of the matter in relation to food safety.

In light of concerns raised by stakeholders in the engagement on the Precision Breeding Bill, some Members considered that increased scrutiny (as part of triage and Tier 1) could be justified, while less is known about the technology and its outcomes. It was noted that this approach could provide reassurance to those unsure about the safety of the technology. It was also noted, however, that the way PBOs would be handled could have repercussions for how TBOs are regulated in future.

Given the range of views expressed, and noting that both positions can be justified, it was suggested that two models be further developed as a basis for identifying the data requirements for tier assignment under the process. One model would emphasise the significance of the safety profile of PBOs being aligned with TBOs, given that the outcomes of the breeding techniques are equivalent. At the time of the meeting, it was suggested that this model focus exclusively on genetic information on the PBO. However, discussions since the meeting have suggested limited additional data to that requested by ACRE to determine PBO status may be required. A second model would determine the nature of pre-market data requirements based on the phenotypic traits

introduced by precision breeding. This could include compositional information, in addition to that sought under model 1. This approach, consisting of two distinct models arising from two different interpretations of proportionality, will inform the Secretariat in further developing proposals for discussion with the Subcommittee.

Action - The Secretariat to develop two possible approaches for the data required to assign tiers under the process, representing the two views expressed in the Subcommittee.

Decision tree assessment and tier assignment piloting using case studies

Professor Bruce Whitelaw declared an interest in regard to one case study, since his Institute is developing a chicken similar to the ALV1-resistant animal discussed in the workshop. This was noted and it was agreed that this was not a direct conflict of interest, allowing Professor Whitelaw to take part in the discussion of this particular case study, should he wish to.

Members discussed the range of information necessary for a tier assignment and assessment, using five case studies from recent literature and the decision tree from the January 2023 ACNFP Statement on Precision Breeding to support development of the assessment. The examples represented both animal and plant PBOs, resistance to pathogens, improved yield, herbicide tolerance and change in fatty acid composition. It was noted that the question of proportionality would influence whether or when additional data would be requested, and that data should only be requested if scientifically justifiable; clarity on data requirements would benefit both developers and the regulator.

In all cases, knowing the parental variety/species, the gene function/targeted trait, whether naturally occurring mutants in the same gene or with the same trait existed, tissue-specific gene expression (where relevant), identification of any anticipated impacts on metabolic pathways, and whether products from organisms with equivalent traits and roles in the diet were already in the food chain, were all necessary background information for Members to identify the concern(s) each PBO could raise.

Some members thought that, for plants, data previously requested in the substantial equivalence assessment process under regulation 258/97EC (i.e. macronutrients, fatty acids, minerals, vitamins) could form the basis for composition information to support tier assignment. These could be revisited to include secondary metabolites relevant to the species and/or to the trait

developed, to answer both nutritional and toxicity triage questions, depending on the model adopted.

For animals, there was a need to better understand how breeders currently benchmark the nutritional quality of their lines. In the case of nutritional change, knowledge of the role in the UK diet (i.e. as a source of key nutrients) could influence assignment to Tier 1 (non-staple source) or to Tier 2 (staple source).

Once assigned to Tier 2, information on management of nutritional disadvantages through marketing could be further explored. If data previously used to support substantial equivalence was deployed in this context and showed an increase in compounds of concern, requests for further toxicity or allergenicity data could be triggered as part of Tier 2. Knowledge of products with similar traits in major allergenic food, where tests or history of use have evidenced unchanged allergenicity, would prevent triggering Tier 2 for allergenicity. It was noted that chemical and microbial contaminations would be captured by other regulations.

When considering the information that could be required to support triage and Tier 1 assessment, Members observed that it would generally be part of standard characterisation performed by developers on their products or would be available in the literature. It could be submitted upon organisms destined for foods or feed receiving confirmation of their PBO status, in the form of a concise data package different from the one requested by ACRE.

Members noted that further discussion was needed to develop the data requirements to support the assessment approach, in light of the discussion of the distinct models, case studies and proportionality requirements.

5. Any other business

- It was agreed that the Secretariat would recirculate the revised table of literature references for publication, for Members to comment on within two weeks.
- The Subcommittee was informed that the dates for PGT8, PGT9 and PGT10 would be decided and communicated to them in the coming week.

6. Date of next meeting

The next ACNFP meeting is scheduled for 26th April 2023 and will be held as a hybrid meeting in London and online on Teams. The next ACNFP-PGT meeting is scheduled for 17th May 2023 and will be held virtually on Teams.