Minutes

Advisory Committee on Novel Foods and Process (ACNFP). Subcommittee on Products of Genetic Technologies (PGT). Minutes of the 5th PGT Meeting held on the 19th of December 2022

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 5th meeting of the Products of Genetic Technologies (PGT) Subcommittee of the Advisory Committee on Novel Foods and Processes (ACNFP), held on 19th of December 2022, 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 Pete Lund - Co-opted

Professor Alastair Macrae - Co-opted

Apologies

Professor Hans Verhagen - Member

Observers (FSA)

Professor Rick Mumford, Deputy Chief Science Advisor & Head of Science, Evidence, & Research Division

Mrs Alison Asquith, Senior GT Policy Advisor

Mr Hoa Chang, GT Policy Advisor

Mrs Justine Gallie, GT Policy Advisor

Mrs Chloe Jackson, Comms

Observers (External)

Dr Mike Ellis, Defra, ACRE Secretariat

Professor Peter Gregory, Science Council

Observers (Devolved Administration)

Mr Xose Álvarez, Policy FSA Wales

Dr Karen Pearson, Food Standards Scotland

Ms Siobhan Watt, FSA Northern Ireland

Mr Ciaran Weir, FSA Northern Ireland

Secretariat

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

Mr Donal Griffin, Team Leader, Regulated Products Risk Assessment (Feed and GT)

Dr Rachael Oakenfull, Senior Secretariat

Dr Rhys Williams, Senior Secretariat

Dr Karin Heurlier, Science Secretariat

Dr Andrew Hartley, Science Secretariat

Mr Matt Hall, Science Secretariat

Dr Annalisa Leone, 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 Hans Verhagen, Member of the ACNFP-PGT Subcommittee.

Professor Alastair Macrae was welcomed as a co-opted Member of the ACNFP-PGT Subcommittee, with expertise in animal nutrition, and other veterinary matters.

2. Matters Arising

ACNFP/PGT/5/MA

It was agreed that the updated minutes of PGT3 and PGT4 would be reviewed at this meeting. It was also agreed that the minutes and executive summaries of these meetings will be published to support the release of statements into the public domain. No objections were raised on the production of key notes from the meetings for the internal use of Members of the Subcommittee before the circulation of the full minutes. These are envisaged to aid the development of the high-level discussions taking place at the meetings and enable quick identification

of misunderstandings between the Subcommittee and the Secretariat.

The programme of GMO applications that will be brought to the Subcommittee over the upcoming meetings was briefly explained. An approach of producing draft opinions alongside the main papers for GMO renewal applications will be trialled to enable quicker progress through the assessment stage, provided the Subcommittee has no concerns with the content of the applications.

The Secretariat thanked all Members for their continued tolerance of the time pressure and occasional late release of working materials ahead of meetings.

3. Minutes of the ACNFP/PGT3, and ACNFP-PGT4 meetings

ACNFP/PGT/3/Min and ACNFP/PGT/4/Min

Minutes from the previous two meetings were reviewed by the Subcommittee.

Clarifications were sought for some phrases within the minutes, and they were edited during the meeting. Both sets of minutes were agreed, pending the suggested edits.

Actions – Secretariat to produce key notes with action points on ACNFP-PGT5 within a week or two of the meeting.

4. Precision Breeding Framework workshop

ACNFP/PGT/5/01

Session 1: Review of the triggers for tier 2 assessment

Building on the previous discussion of the Subcommittee, this session further explored the decision tree, associated text and the triggers that would determine tiering. Phrasing of the triggers in the decision tree was discussed and amended by the Members.

Box 1 (Novelty)

Discussions centred on the taxonomic level that should be examined when considering novelty, i.e. different species or different varieties of a single species. The consensus found that there would be no additional risks associated with a

different variety of a commonly eaten species, so differentiation at the species level was preferred. It was noted that this would also align well with the novel food regulations which are also based on the species level. Precedent for grouping species into larger groups was found in some allergenicity case studies, and this may be used as a starter if grouping of species is required.

Members agreed that the following three triggers were all part of an overarching "composition" category, for which they each would constitute a separate consideration:

Box 2 (Nutrition)

Members agreed it would be preferable to refer to "nutrition" for this trigger. The concept of comparing nutritional profile against comparators was accepted by Members; however, there should be no reference to products that PBOs are intended to replace, as the PBOs in question may not be directly replacing others.

Questions were raised over what changes in nutrient levels would be compared against and what data/nutritional information would be provided by the applicant to allow comparison. Footnotes were requested by Members to clarify what is being used to define increases/decreases in nutrients that would require tier 2 status.

It was confirmed that no nutritional information would be required by ACRE, but it was agreed that any developer marketing a product with increased nutrient levels would likely already have the data to support their claims.

The role of guidance documents was discussed in highlighting the types of information that would be needed to determine the risks in certain types of applications, in order to provide certainty for applicants. It was also agreed that changes in nutritional profile alone should not be sufficient for allocation to tier 2; rather, this should depend on the significance of the impact. Any impact of changes in nutrient profile would also depend on what food is being considered and its contribution to the diet e.g. whether it is a staple.

Clarification was sought over whether the box would also cover increases in nutrients as well as decreases in nutrients; nutritionally disadvantageous was interpreted as covering both increases and decreases. It was agreed that the phrase "nutritional quality" is already used in the industry and would be suitable to define the criterion (in guidance documents "nutritional profile" would be a better term). It was agreed that the decision tree should capture intended and

anticipated unintended changes, and this should be clarified.

The Subcommittee suggested that input could be sought from other members of the main ACNFP Committee who are also part of the SACN (Scientific Advisory Committee on Nutrition) Committee when guidelines for the applicants are developed.

Box 3 (Toxicity)

The scope of this box was considered in light of what is already regulated by General Food Law, and the Chemical Food Safety laws. It was suggested that footnotes be included to explicitly exclude any compounds that are already covered by these regulations. Only increases in toxicity would be relevant to the trigger to place a PBO in tier 2.

It was agreed that “comparison to traditionally bred counterparts” should be an overarching reference applicable to each part of the decision tree, where relevant. Using the phrase “Is the PBO designed to introduce changes that are expected to…” was viewed as reflecting the intent to capture intended and anticipated changes to toxins and/or anti-nutrients. While this criterion does not intend to capture unanticipated or unintended changes to levels of toxins, breeders are aware of the anti-nutrients/toxins that are present in their crops so may monitor this during product development. Intentional increases in toxins for pest resistance (for example) could also change the metabolic pathway of other, unrelated toxins.

Box 4 (Allergenicity)

Members were concerned about capturing all allergenic food crops solely on the basis of them being priority allergenic organisms. The basis of risk was considered to be broader and should focus on any expected changes that influence the allergenicity of the PBO. Footnotes should highlight an increased scrutiny of any application (at triage) concerning precision breeding of a priority allergenic organism, in order to understand any impact on the use of thresholds for allergenic foods.

It was suggested that the phrase “significantly alter” could be added; however, there are no benchmarks available that would allow definition of what constitutes a significant change for this type of risk. For a developer to claim reduced allergenicity, it would need to perform clinical trials.

There was discussion over whether the wording captured both increases and decreases in allergen levels. In the light of other work around allergenicity for the *Codex Alimentarius* reference, it was suggested that the criterion should remain sufficiently high level so that any changes arising from this work could be easily introduced into the decision tree or the accompanying guidance, as appropriate.

The distinction between alterations to the PBO that impact edible tissues and those that do not was discussed, and it was agreed that “any foods/feeds derived from the organism” specifically related to edible tissues.

Box 5 (other safety concerns)

It was agreed that this box was required in order to allow capture of future precision breeding applications that could not currently be anticipated, which might alter food/feed safety risks by introducing significant uncertainty. It was also agreed that it would be better identified as “Other safety concerns”. Guidance notes will be developed to offer more information on scenarios that could trigger this criterion for tier 2 assignment.

When considering the general approach to tier 2 assessment as presented by the decision tree, Members agreed on the following:

- Tier 2 assessments should be on a case-by-case basis and provide a spectrum of assessment types (i.e. depending on which of the criteria results in tier 2 status). There must also be an element of flexibility within the tier 2 assessment to enable the Subcommittee to ask the questions required to understand any risks.
- All PBOs must be tested against each criterion, in order to inform the nature of the assessment.
- As PBOs cannot be captured by the novel food regulation, triggering of the novelty criterion would result in an assessment in tier 2 that could be modelled on the novel food assessment framework. Similarly, elements of other assessment frameworks could also be used for a tier 2 assessment, if required to understand risks, on a case-by-case basis. This would be explored further in the development of the technical guidance.
- There should be a balance between gathering relevant information for review to ensure safety, and remaining efficient and focussed and thereby minimising burdens on industry where possible.
- It should be made clear how the proposed process for PBOs interlinks with the standard process of registering new varieties, especially if the decision tree is published and made available to the public. This is complicated if a

PBO is not to be cultivated in the UK, since it would not need to be added to the national seed register.

5. Precision Breeding Framework Workshop

ACNFP/PGT/5/02

Session 2: Model to the approach of the tier assessment

It was suggested and agreed in principle in PGT4 that FSA staff will be responsible for tiering applications, and there will be a quality assurance process for the first tranche of applications, whereby the Subcommittee would review the tiering decisions. Some Members thought that this should be revisited as it was foreseen that were some scenarios where expert Member involvement would be needed in the decision-making process.

Discussions centred on the data that will be available from ACRE, and what assessments would be possible with this information. Novelty could be determined from species name, and it is likely that there would be information provided by producers to ACRE that would allow an assessment of the nutritional profile, depending on information requirements to substantiate the purpose of the PBO.

Members suggested that clear guidelines for applicants would allow developers to anticipate the data that would be needed for tiering of their product, and it would be in their own interest to provide as much data as possible early in the process. Members also explored the potential to include an intermediary step prior to tier assignment, where additional information could be requested. This would support the system operating efficiently and restrict use of tier 2 to those PBOs where further review was scientifically justified.

The Committee explored how the system could operate in practice. It was noted that detailed analysis of compositional data (for example) in the pre-assessment phase (i.e. prior to tiering) could take longer than developers might expect and this would influence operational timelines.

Members discussed the output of a tier 1 assignment. Consensus was for a recommendation that the product be treated as a TBO. Part of this recommendation would include how it is to be marketed and any labelling requirements etc.

6. Any other business

An additional meeting of the main ACNFP Committee has been scheduled for Monday 16th January 2023 (10am-12pm), to allow a precision breeding workshop to consider a statement/proposal which will be drafted from the Subcommittee discussions (PGT4, PGT5); this is to support the FSA and its Board's position when the Bill resumes its path through Parliament, expected in the second half of January.

7. Date of next meeting

The next ACNFP meeting is scheduled for 16th January 2023 and is an online workshop on the PB framework. The next ACNFP-PGT meeting is scheduled for 1st February 2023 and will be held virtually on Teams.