Minutes

Advisory Committee on Novel Foods and Process (ACNFP). Subcommittee on Products of Genetic Technologies (PGT). Minutes of the 1st Meeting held on the 22nd of July 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 1st meeting of the Products of Genetic Technologies (PGT) Subcommittee of the Advisory Committee on Novel Foods and Processes (ACNFP), held on 22nd of July 2022, online using Microsoft Teams.

Attendance

Committee Chair

Dr Andy Greenfield

Committee Members

Professor Paul Fraser

Professor Huw Jones

Dr Ray Kemp

Dr Elizabeth Lund

Professor Hans Verhagen

Apologies

Professor Wendy Harwood

Professor Bruce Whitelaw

Observers (FSA)

Mr Chris Stockdale, Head Genetic Technology Policy

Mrs Alison Asquith, Senior GT Policy Advisor

Mr Hoa Chang, GT Policy Advisor

Mrs Justine Gallie, GT Policy Advisor

Mrs Kate Shield, Senior Strategy Advisor

Mrs Narriman Looch, PB Policy Manager

Mrs Lisa Nelson, Comms

Mrs Priscilla Wanjiru, Regulated Products Risk Assessor

Observers (External)

Professor Pete Lund, ACRE Member

Dr Martin Cannell Defra, ACRE Secretariat

Observers (Devolved Administration)

Mr Xose Álvarez Policy, FSA Wales

Ms Svetlozara Chobanova, Food Standards Scotland

Dr Karen Pearson, Food Standards Scotland

Ms Tamara Satmarean, Food Standards Scotland

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 Andrew Hartley, Science Secretariat

Dr Karin Heurlier, Science Secretariat

Dr Annalisa Leone, Science Secretariat

Miss Victoria Balch, Administrative Secretariat

1 . Apologies and Announcements

Apologies were received from Professors Wendy Harwood and Bruce Whitelaw.

Professor Clare Mills will be attending Subcommittee meetings on an ad hoc basis when expertise in allergenicity is foreseen to be particularly relevant. She was not present at the first meeting.

Professor Pete Lund represented the Advisory Committee on Release to the Environment (ACRE, Defra) as an observer. His contribution to future meetings will be reviewed after this meeting. The Secretariat’s intention is that the ACRE representative will provide expertise on environmental risks of GM products that are required to be assessed under the regulation, in addition to supporting the discussion on Precision Breeding regulation.

2. Matters Arising

ACNFP/PGT/1/MA

- Members reviewed the Terms of Reference (ToR) which were presented to the ACNFP in November 2021; several amendments were made to update

terminology and a section was added on ways of working to clarify the governance by ACNFP. The final ToR will be circulated to all ACNFP Members before they are adopted and published on the website.
- Members were invited to provide their initial thoughts on the principles outlined in the letter to the then Minister Jo Churchill by FSA CEO Susan Jebb. All answers were collated.
- Members were also asked to contribute to the establishment of a portfolio of precision breeding (PB) case studies, with a view to exploring a tiered approach to assessment. The portfolio will be reviewed at the end of the PGT 1 workshop.
- The Chair of ACNFP will be looking forward to hearing about PB developments in the Subcommittee and will be supporting working connections between the main ACNFP committee and the Subcommittee.

3. Our ways of working

ACNFP/PGT/1/01

The governance arrangements between ACNFP and the ACNFP PGT Subcommittee were explained. As with FSA Joint Expert Groups (JEGs), the opinions and other key outputs developed by the Subcommittee will be subject to review and adoption by the ACNFP. This will also allow input from the wider assessment expertise available in the Committee.

Observers were reminded that the Subcommittee meetings are closed meetings and the discussions considered sensitive. While the FSA and ACNFP are committed to openness, as a highly sensitive area the papers and minutes will be treated as reserved business. The agenda and executive summary will be published on the ACNFP website after giving sight to FSA Comms. Reserved minutes will be kept for FSA and Committee records until such information can be appropriately released in a managed way when milestones are achieved.

The Subcommittee was given advice on how to manage contacts and questions from the public and how the Secretariat would coordinate responses in these situations. A Member asked if there was a record of all questions received from the public and stakeholders so that they can familiarise themselves with what to expect; this will be explored by the Secretariat.

Action – The Secretariat to explore sharing a list of questions received from the public on the topics being addressed by the subcommittee to put their work in

context.

4. Determination of PBO status

ACNFP/PGT/1/02

A representative of the Secretariat for the Advisory Committee on Releases to the Environment (ACRE, Department for Environment, Food, and Rural Affairs, (Defra)), introduced ACRE's scientific approach to determining precision bred organism (PBO) status. This was to provide context on the process that would be completed prior to any review of food and feed aspects. Information was also supplied on the thinking to date from ACRE concerning data that would be requested from applicants seeking to establish PBO status.

Members explored these data requirements with the ACRE representative. The introduction of genomic features that might impact the composition of the PBO, and whether composition would be a factor considered in ACREs assessment, were discussed. Similarly, Members asked whether applicants would be required to state how far from the previously observed range the PBO deviated, in respect of composition, when the edible part of a crop was altered to change the nutritional value of a PBO. The ACRE representative explained that whilst applicants would be expected to describe the genetic alteration, its purpose and how the organism is intended to be used, food composition would not be considered as part of the ACRE assessment. The potential for a crossover with the novel foods regulations was also explored in this initial discussion.

Members sought to understand the range of outcomes that might be thought to be comparable to those that could occur through traditional processes. As part of this discussion, the Chair clarified the role of ACRE versus the ACNFP and its associated subcommittee, explaining that while it is the role of ACRE to determine the status of a PBO, the role of the FSA and this Committee is to determine whether a PBO requires a safety assessment and the nature of any such assessment.

The ACRE representative was invited by the Chair to intervene in the following items if Defra/ACRE's thoughts were being misunderstood.

5. Framework for the assessment of products from precision breeding

ACNFP/PGT/1/03

An update on the parliamentary process was provided by the FSA PBO policy team, highlighting the pace of its movement through Parliament, and the increased media/political attention on the FSA's enabling powers and how these will be used. It was noted that the Bill grants power to the FSA to build a framework for regulating PBOs and to create a new public register of authorised PBOs (to align with the commitment to transparency). Any new framework would require secondary legislation.

The item sought to outline the key questions the Subcommittee are being asked to address and the likely timetable for when the input would be needed to support development of the regulatory framework. In the coming months, the Subcommittee will be asked: to consider/agree the approach for the authorisation process and, specifically, whether a tiered approach can be supported; to agree the definitions for the tiers; to develop criteria for allocation to each tier; and to determine the data requirements to support the review approach.

6. Precision breeding framework workshop

ACNFP/PGT/1/04

Prior to the workshop, the Chair sought agreement on the definitions of genome editing (GE), genetic modification (GM) and PB across the Subcommittee, and asked Members for examples of organisms that could not easily be categorised as traditionally bred or produced by genetic technologies. Chimeric organisms were raised as an example. Members were also keen to avoid conflation of "traditional" with "natural", considering that traditional processes, as defined in the Bill, employ a wide range of techniques, some of which require a significant level of human intervention. Members agreed that the terminology used by the Subcommittee must be consistent with the Bill and requested that a glossary of definitions be compiled with input from the Secretariat.

Members then explored the questions raised for Committee consideration to provide a basis for developing a regulatory framework. Several cross-cutting considerations were identified. The Subcommittee saw some merit in developing a trait-based system, i.e., one in which the nature and level of assessment of an organism is not related to the process by which it was produced, but by its individual phenotypic traits. However, to apply this approach to PBOs could be seen as disproportionate since a near-identical organism produced using traditional processes would not be similarly regulated. It was recognised that

traditionally bred organisms (TBOs) may present similar levels of risk to PBOs, but there is wide acceptance of these risks due to the long history of safe use, which supports a due diligence approach to their regulation.

Since the term ‘PBO’ defines an organism as one with genomic features that could have arisen through traditional processes, TBOs and PBOs are very likely to present similar risk profiles. This observation invites similar levels of regulatory scrutiny of the two, but this conclusion does not itself determine the nature of a new regulatory framework for PBOs. The need for proportionality, and its consequences for the regulatory framework, were discussed further.

Members highlighted the potential for interactions with novel food regulations and how these could be managed. The question was asked whether ‘extreme’ natural variation in the levels of a component of a food would be captured by novel foods legislation; the Secretariat confirmed that this would be unlikely for TBOs. Members also commented that defining “natural variation levels” would be difficult, but this could be a useful tool in assessing risks of PBOs.

The Subcommittee then explored scenarios that could suggest risks where further assessment of PBOs may be beneficial and justifiable. It was suggested that these might be products that meet the Bill definition of PBO, but in which the genetic event(s) is very rare. Examples discussed included an increase in gene expression by the introduction of multiple copies of a cisgene, or expression of a cisgene from a sexually compatible plant that is not normally eaten.

A scenario in which genomic features introduced into a PBO increase the levels of known allergens or toxins, particularly in those species that are already known to contain allergens or toxins, was raised as a potential area of concern. Applicants would need to confirm that there are no inadvertent changes in such levels. Developers of traditionally bred allergen/toxin-containing organisms would typically check levels of allergens/toxins throughout product development, but don’t necessarily test for everything in new products – the example of potato developers monitoring levels of glycoalkaloids was provided. This reflects the difference between genetic changes and changes in composition. It was clarified that allergenicity/toxicity risks are not unique to any technological process and the need for proportionality again constrains approaches to PBO assessment.

The possibility of producing a flow scheme/decision tree that highlights the route of decision-making that would be used to classify PBOs (into tier 1 or tier 2) and identifies the questions needed to make the decisions was raised. The Subcommittee considered the following features that might be criteria used in a

tiered regulatory approach: the degree of phenotypic change; whether any hazard that may be altered could be managed under existing regulations; and whether the organism is engineered to produce something that it doesn't produce normally (rather than a change in level of production). But in all such cases, the need to act proportionately, with regard to TBOs with equivalent traits, was to the fore. Members highlighted the need for case studies, even hypothetical case studies, that could be considered as requiring further review, to understand the nature of the risks presented by a range of PBOs, and how these might differ from TBOs. This would help determine the criteria for distinguishing the tiers in a tiered system.

Clarification of the nature and level of information required by ACRE/Defra was identified as potentially being important. It was noted that, in some cases, asking for additional data at the outset may address uncertainties and potential areas of risk, avoiding the need for further review. For example, understanding the levels of nutrients in an enhanced nutrient crop, in the context of other contributions of that nutrient to the diet, could avoid the potential for further review

Members suggested that a more in-depth assessment, as a minimum, could be required when changes in phenotype of a PBO introduce traits that are significantly different to those currently observed in the progenitor species, where the impact of such changes is less well understood or where the progenitor species itself is less well understood. They suggested that further review could be warranted in cases where there were unintended changes that may interact with other pathways (particularly those that affect toxins and/or allergens). Several examples were identified to be explored in more detail at future meetings.

Actions – The Secretariat to prepare a glossary of terms and associated definitions of terms used in the description of the framework

The Secretariat to capture the discussion of the Subcommittee in a Statement

The Secretariat to identify case studies which would likely require further assessment in the proposed approach

7. Applications for Genetically Modified (GM) food and feed

ACNFP/PGT/1/05

The Committee was introduced to the range of applications received by the FSA relating to GM, namely: full applications, renewal applications, applications for extension of scope, and applications submitted prior to the end of the EU exit transition period. The Subcommittee was asked to provide feedback on the content and format of the reports on bioinformatic analyses produced by Fera Science Ltd. Members were informed that the Secretariat was approaching experts in Veterinary sciences to provide expertise on animal nutrition in feeds assessment.

As part of this introductory discussion, Members raised the potential to consider further aspects of the assessment and the opportunity to improve the assessment process, with the use of toxicological data cited as an example. Additionally, Members highlighted the need to review the guidance on allergenicity as a matter of priority given the nature of the allergic population in the UK. It was agreed that these were intended actions for the Subcommittee once the challenging work of developing a framework for the assessment of PBOs had been completed.

8. Genetically modified soybean A5547-127 (RP188)

ACNFP/PGT/1/06

An application has been received for renewal of A5547-127 soybean for food and feed uses, import and processing, excluding cultivation. A5547-127 soybean has been genetically modified to express the PAT protein to confer tolerance to glufosinate ammonium herbicide. The Subcommittee reviewed the application and found no reason to change the original positive opinion.

Action – The Secretariat to prepare an opinion for the Subcommittee to review

9. Genetically modified soybean 40-3-2 (RP212)

ACNFP/PGT/1/07

An application has been received for renewal of 40-3-2 soybean for foods and food ingredients, animal feed, and products other than food. The scope of the application does not cover cultivation. 40-3-2 soybean has been developed to confer tolerance to glyphosate, and not change any compositional or nutritional parameters. The Subcommittee reviewed the application and found no reason to change the original positive opinion.

Action – The Secretariat to prepare an opinion for the Subcommittee to review

10. Genetically modified maize MIR162 (RP652)

ACNFP/PGT/1/08

An application has been received for renewal of MIR162 maize for food and feed uses, import and processing, excluding cultivation. MIR162 maize is modified to express an insecticidal protein and an enzyme that enables to plant to utilise mannose as a primary carbon source. The sub-committee reviewed the application and found no reason to change the original positive opinion.

Action – The Secretariat to prepare an opinion for the Subcommittee to review

11. Date of next meeting

The next meeting is scheduled for 8th August 2022 and will be held as a hybrid meeting.