Statements

Statement on the Outcome of the Advisory Committee on Novel Foods and Processes (ACNFP) workshop on Precision Bred Organisms (PBOs) - September 2022

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View Statement on the Outcome of the Advisory Committee on Novel Foods and Processes (ACNFP) workshop on Precision Bred Organisms (PB as PDF (148.47 KB)

Held on 7th September 2022

Introduction

1. The UK Advisory Committee on Novel Foods and Processes (ACNFP) advises the Food Standards Agency (FSA) on any matters relating to products of modern biotechnology destined for food and feed purposes, including products from Genetically Modified Organisms (GMOs) and Precision Bred Organisms (PBOs).

2. As described in the Genetic Technology (Precision Breeding) Bill, organisms (and the food and feed derived from them) produced by modern biotechnology techniques, such as Genome Editing (GE), that could also have been produced through traditional breeding processes will be classified by Defra as PBOs and will no longer fall under the scope of GMO regulations.

3. An appropriate regulatory process for assessment of PBOs needs to be established to ensure consumer safety. This also provides the opportunity to reduce the regulatory burden for applicants by replacing GMO controls with more proportionate approaches, which relate to the nature of the product and the risks they may pose.

4. To support the development of a regulatory approach, the ACNFP has been asked to provide advice on the current scientific understanding of the

technologies used in precision breeding (PB). To address this matter, a Subcommittee of the ACNFP (the ACNFP Products of Genetic Technologies Subcommittee (ACNFP-PGT) held workshops on 22nd July and on 8th August 2022 to discuss the scientific and technical principles that could be used to underpin a proportionate regulatory framework. They used case studies to identify factors of potential concern relating to the safety or nutritional quality of PBOs for food and feed uses.

5. The Subcommittee reported their discussion at the 154th meeting of ACNFP held on 7th September 2022, when a further workshop using the wider expertise of the full committee allowed review of the current work of the Subcommittee.

6. This statement identifies areas of consensus on scientific issues identified to date by ACNFP. The views expressed here reflect a combination of Members' understanding of the relevant scientific evidence and their judgements as to the significance of that evidence, in respect of the policy context. This advice is intended to inform the FSA Board in making decisions on the approach to regulating PBOs in England.

ACNFP Committee Discussion

Context

7. Members noted that responsibility for the decision of whether a product of modern biotechnology is a PBO or a GMO lies with the Defra Secretary of State, following the receipt of a report from the UK Advisory Committee on Releases to the Environment (ACRE). Development of the regulatory process will consider how to review the safety of organisms designated as PBOs for food and feed uses in a proportionate manner, taking into account the decision process and supporting evidence requested by ACRE.

8. Members commented that identifying potential food and feed safety risks associated with use of modern biotechnologies now and in the future is difficult. It is not the technology as such that might cause an identifiable food safety issue, but rather, how it is used and the potential unknowns with respect to the resulting product as consumed. Some outcomes may be predictable, based on known risks associated with an organism, for example, exceeding intake boundaries of consumption for known antinutrients. It was noted that, as with any breeding process, there is the potential to create consumer safety risks using PB technologies and these may need to be identified, assessed and managed appropriately and proportionately on a case-by-case basis. The rapidly evolving

technical capability of PB techniques can itself also be a source of uncertainty. This makes it challenging to develop a set of generic assessment criteria, since it is difficult to predict how innovators may seek to use the technology.

9. It was noted that the Bill can be interpreted as making an implicit equivalence claim, namely, that TBOs and PBOs have similar risk profiles, precisely because PBOs could have been produced through traditional breeding processes and have similar genetic features as a result. When considering the desired proportionality principle, it will therefore be necessary to decide, based on the evidence available, whether the PBO assessment would require a different type of approach to that of a similar product produced using traditional breeding technologies.

10. Members recognised that whilst there were merits and scientific validity in taking a product-based approach in respect of assessing the safety of PBOs, this could be seen as disproportionate, given that significant risks requiring intervention for products produced using traditional breeding practices have been rare. In this context, how proportionality in the regulatory approach can be achieved is a key question being considered by the Committee.

11. The interaction between the regulation of PBOs and Novel Foods (NF) regulations was another point raised for consideration. Members recognised the potential for a PBO to also be a novel food and noted that there was a need to ensure that the assessment, whilst proportionate, took account of both aspects.

12. Lay representatives, supported by several other Members, highlighted the importance of understanding public perceptions and ensuring consumer confidence in this new technology. The work of the FSA in dialogue with stakeholders and consumers to inform policy decisions was noted and deemed extremely important for the acceptance of the approach for PBOs.

Conclusions Reached to Date

13. ACNFP Members recognised that many products of precision breeding will be similar in risk profile to their traditionally bred counterparts, where the level of risk has to date been accepted by default.

14. Members also acknowledged that some products produced through traditional breeding can also have risks regarding, for example, modification of antinutritional factors or alteration of the allergenic potential. It was noted, however, that the risks relating to existing priority allergenic foods are managed through current legislation and best practices as outlined in UK guidance.

15. Members agreed that a two-tier approach provided a mechanism that allows proportionate scrutiny of the consumer safety of PBOs and offers a regulatory safety net permitting further assessment of any PBOs that raise concerns based on existing evidence or significant uncertainties concerning their safety.

16. Further discussion is needed on the circumstances or evidence that might trigger entry into Tier 2 and the nature of further assessment as a consequence. However, it was felt that exploring a tiered approach provided the ability to review, in a proportionate manner, the full scope of products that could be created by modern biotechnology, with a focus on ensuring consumer confidence and safety.

Next Steps

17. The ACNFP PGT Subcommittee will be reviewing further case studies and scenarios to identify risk factors that would require a higher level (Tier 2) assessment and will present ACNFP with possible assessment approaches and criteria for the assignment of PBOs to the two anticipated tiers. A particular focus will be how proportionality in the regulation of these products can be achieved in practice based on scientific evidence and expert judgement concerning any potential risks.

18. A second part of the Committee’s work will be to build on the development of the tiered approach, to understand whether any new technical guidance, data generation and/or new types of assessment may be needed to support consumer safety review of a PBO.

ACNFP

September 2022

Statement of Interests:

ACNFP code of practice on declaration of interests and management of conflicts can be found on ACNFP website; the interests and personal interests are publicly available for each ACNFP Members. This is in agreement with the FSA good practice guidance to ensure interests are declared in a transparant way and managed as required.

Professor Bruce Whitelaw declared financially benefiting from a University of Edinburgh Commercialisation Licence with Genus plc regarding PRRSV-resistant pigs; this was noted and it was agreed that when discussing this particular case study, Professor Whitelaw would be present but only to answer questions on the case.

Abbreviations

ACNFP	Advisory Committee on Novel Foods and Processes
ACNFP-PGT	ACNFP Products of Genetic Technologies Subcommittee
ACRE	Advisory Committee on Releases to the Environment
Defra	Department for Environment, Food and Rural Affairs
FSA	Food Standards Agency
GE	Genome Editing
GMO	Genetically Modified Organism
NF	Novel foods
PB	Precision Breeding
PBO	Precision Bred Organism
PGT	Products of Genetic Technologies
TBO	Traditionally Bred Organism

UK United Kingdom