1. Introduction

In this guide

In this guide

1. The UK Advisory Committee on Novel Foods and Processes (ACNFP) advises the Food Standards Agency (FSA) on matters relating to the safety of products of modern biotechnology destined for food and feed purposes, including products from Genetically Modified Organisms (GMOs) and Precision Bred Organisms (PBOs). The ACNFP provides assurance through evidence and risk-based assessment of food and feed innovation, that food and feed on the market:

- is safe to eat
- does not mislead the consumer
- does not put consumers at a nutritional disadvantage

An expert Subcommittee on the Products of Genetic Technologies (PGT) was established to assist the ACNFP with this work.

2. As described in the Genetic Technology (Precision Breeding) Act 2023, organisms (and the food and feed derived from them) produced by modern biotechnology techniques, such as genome editing, that could also have been produced through traditional breeding (TB) processes, will be classified by Defra

as PBOs and will no longer fall under the scope of the Genetically Modified Organisms (Deliberate Release) Regulations 2002. The scope of the Act covers both precision-bred plants and animals. The decision whether a product of modern biotechnology is a PBO or a GMO lies with the Defra Secretary of State (SoS), following the receipt of a report from the UK Advisory Committee on Releases to the Environment (ACRE). Further detail on this process will be released by Defra.

3. Ministers have been granted powers in that Act to make regulations that will allow the FSA to establish a regulatory framework for the safety assessment of PBOs used in food and feed. The FSA will consider how to assess the safety of organisms designated as PBOs for food and feed uses, in a proportionate and effective manner to offer assurance of consumer safety. A recommendation that takes account of a range of factors will be made by the FSA for final decision by the DHSC SoS.

4. In addition to the scientific uncertainty that is present in all safety assessments, it is noted that the technology involved in the generation of PBOs is rapidly evolving and any process and guidance needs to be future proofed for the coming years, as well as satisfying the needs of today. This is reflected in the advice of the ACNFP on the approach to the assessment of PBOs that was detailed in the statements from the Committee published in September 2022 ACNFP statement and January 2023 ACNFP statement.

5. To support the development of a regulatory approach to safety assessment, the ACNFP (as supported by the work of the PGT Subcommittee) reviewed a number of different case studies detailed in Annex A (plants and animals) to gain insights into current scientific understanding of the safety of food and feed produced by technologies used in precision breeding (PB). In developing its advice, the ACNFP discussed the scientific and technical principles that could be used to underpin the data requirements for operating a proportionate and effective regulatory framework, thereby meeting the policy commission.

6. The ACNFP, through the review of case studies, has seen no evidence that PBOs are intrinsically more hazardous than traditionally bred organisms (TBOs). It was noted that in terms of genetic changes, any TB technique is likely to introduce a greater number of new genome variants than that obtained through technologies used to produce a PBO. It is recognised that a range of phenotypic outcomes is possible from both TB and PB, although these may be more easily achieved with PB technologies. It is this impact on phenotype that the triage questions seek to understand.

7. The ACNFP concluded in its first statement that, as with any breeding process, use of PB technologies has the potential to create safety risks for consumers and these need to be identified, assessed, and managed appropriately and proportionately. A two-tiered assessment process for PBOs was therefore proposed by the FSA, to provide clarity for applicants while allowing appropriate scrutiny of the possible risks as part of the assessment process.

8. As further detailed in ACNFP statements 1 and 2, the definition of Tier 1 and 2 as defined in the FSA September 2021 board paper are:

- “Tier 1: All applications for PB food and feed authorisations are screened for similarity to traditionally bred varieties where the risk is understood and not of concern for consumers. Organisms that meet Tier 1 criteria will be authorised more quickly than Tier 2. The detailed criteria for assessing Tier 1 applications are still being developed, informed by expert scientific advice from the independent Advisory Committee on Novel Foods and Processes (ACNFP).”
- “Tier 2: Applications for PB food and feed authorisations where the Tier 1 screening does not allow the risk to be understood are subject to an additional step. These applications require a proportionate risk assessment to determine the level of risk for consumers”.

9. An overview of the safety assessment process with two tiers was provided by ACNFP in the ACNFP's second statement. Following notification of a PBO from ACRE, a series of triage questions, focussing on novelty, composition (toxicity, nutrition and allergenicity), and other safety concerns, can be used to guide assignment to Tiers. Tier 1 PBOs are those for which the answers to the triage questions provide sufficient information to determine that no further review is required. Where answers to the triage questions identify the need for further specific scrutiny, these PBOs would be assessed in Tier 2. Tier 2 allows further scrutiny and requests for further data to be generated if concerns are identified and there is potential for increased risk to consumers. The justification for further data must be explained. The criteria and associated triage questions are listed in Table 1.

Table 1. Criteria and associated triage questions to support the assignment of PBOs to Tier 1 or 2

(ACNFP second statement)

Criteria	Associated triage question
Novelty	Is the PBO from a species that has no significant prior history of safe consumption in the UK or EU?
Composition – Nutrition	Is the PBO designed to introduce significant changes to the nutritional quality of the organism currently consumed that are likely to be disadvantageous to the consumer?
Composition – Toxicity	Is the PBO designed to introduce changes that are expected to elevate significantly the toxicity of any foods/feeds derived from the organism?
Composition – Allergenicity	Does the PB introduce changes that are expected to alter the allergenicity of any foods/feeds derived from the organism?
Other safety concerns	Are there any additional features of the PBO that cause food/feed safety concerns?

10. Whilst there is no evidence that the current system of due diligence is ineffective for TBOs, it is noted that the scientific logic underpinning the framework and data requirements for PBOs could also be applied to TBOs meeting similar criteria. In the case of PBOs, in the early years of adoption of these new technologies, it should be reassuring to consumers that the innovative nature of the methods involved in PBO production are being carefully considered by producers as part of a regulatory process.

11. In developing the possible PBO specific data requirements, the ACNFP was mindful of the wider policy context in which it operates. Within the Genetic Technology (Precision Breeding) Act 2023 there is a requirement that the assessment of safety is proportionate. The Committee noted the potential for different interpretations of proportionality and therefore the level of assurance required from the assessment. This has informed the development of two model options the FSA could adopt with different initial data requirements to address these differing interpretations. One focuses on the technical equivalence of PBOs and TBOs and the other focuses on the uncertainties and unknowns around how

the rapidly evolving PB technology could be used in the future to develop organisms with intentionally designed traits for food and/or feed use.

12. This statement summarises the initial data that could be required in the two model options, in order to review PBOs for potential food and feed safety risks. It also outlines the information needed for both Tier 1 and Tier 2 assessments.

13. Both Models 1 and 2 use a risk- and evidence-based approach to tiered assignment of PBOs. The Models' requirements provide transparency on what may be necessary to provide assurance of the safety of PBOs for food or feed.

14. The depth of assessment, and further discussion on the strengths and weaknesses for each model are discussed within the statement. This, along with the technical justification for data provisions in Annex B, provides context for the potential data requirements that are outlined.

15. It is noted that risk managers, in making their decision on the level of data required to provide adequate assurance of the safety of PBOs, will be taking account of a range of other factors in addition to safety-relevant data. These include burdens on industry, public attitudes, the possibility that more in-depth review might unnecessarily heighten safety concerns about PBOs, barriers to innovation and the potential benefits of this new technology. Consideration of each of these other legitimate factors may make one or other of the proposed data model options more or less preferred.

16. There is provision in the Act for consideration of other legitimate factors in overall decision-making by the Secretary of State (SoS) in authorising PBOs. These could include, for example, impacts on animal welfare. However, since this was beyond the remit of the ACNFP, other factors were not considered. While animal PBOs are expected to be subject to additional legislation including consideration of animal welfare, the ACNFP advice on data requirements has been developed so that it can apply to both animal and plant PBOs as food and feed when applications are received.