Statement of the ACNFP on Precision Bred Organisms - July 2023

In this guide

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View Statement of the Advisory Committee on Novel Foods and Processes (ACNFP) on Precision Bred Organisms (PBOs) - July 2023 as PDF (849.27 KB)

Executive Summary

The FSA has the mandate to assure all food on the market is safe and it is what it says it is. To support and inform the FSA’s policy development in the area, the Advisory Committee on Novel Foods and Processes (ACNFP) was tasked with considering the scientific basis of the technologies used in precision breeding.

This included providing scientific advice relating to the types of data that could be used in the safety evaluation of Precision Bred Organisms (PBOs) for use as food and feed. An expert Subcommittee on the Products of Genetic Technologies (PGT) was established to assist the ACNFP with this work in anticipation of the need for new technical guidance.

An organism is determined to be a PBO by Defra's Advisory Committee on Releases to the Environment (ACRE) if the changes introduced by modern biotechnology are considered to be equivalent to those that could have been produced through traditional breeding methods (TB). Full technical definitions of PBO and TB are available in the Genetic Technology (Precision Breeding) Act 2023 . In September 2021, the ACNFP was commissioned to advise on the science that could be applied in a tiered approach to the safety assessment of PBOs and the determination of criteria to be used to assign organisms to these tiers (FSA Board meeting papers, September 2021).

The first two statements of advice can be found on the FSA ACNFP website. These outline the basis for the ACNFP's agreement that a two-tier assessment process for PBOs allows a proportionate and scientifically justifiable level of scrutiny. Triage questions were also developed focussing on novelty, composition (covering aspects of nutrition, toxicity, allergenicity), and other safety concerns (on a case-by-case basis) to determine Tier assignment. 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.

This statement addresses the third phase of work commissioned by the FSA: namely the determination of what information (data requirements) should be requested from applicants to support the safety assessment of a PBO for food and feed.

The ability to assess the risk (if any) to consumers and animals from the consumption of PBOs and products of PBOs in food and feed, requires information and evidence on the nature (and novelty) of the product, on aspects of expected use/exposure, and understanding any potential hazard. The interpretation and integration of this information into effective scientific advice for policy making should be proportionate to the extent and nature of any risk identified.

All foods marketed in the UK need to comply with General Food Law (GFL) and this will also be true for PBOs no matter the approach taken to their assessment and regulation. Over many decades, due diligence within industry has been

accepted by the regulator as adequate for managing potential safety risks of traditionally bred organisms (TBO)s. This reflects the fact that food and feed safety concerns identified in TBOs have been few, and managed effectively within GFL. However, for PBOs, the ACNFP agrees that a two-tier risk assessment approach is diligent and proportionate for assessing organisms developed using this emerging technology.

To inform the development of data requirements, the ACNFP and its PGT subcommittee discussed and acknowledged the need for proportionality as required by the Genetic Technology (Precision Breeding) Act 2023 and the FSA board principles for the development of policy on PBOs (September 2021). In an attempt to determine the potential hazards that could be posed by PBOs, the ACNFP has considered both what is understood scientifically about PBOs and what remains unknown about this rapidly evolving technology and how it may be applied in future.

Two workable Models (see Figure 2 in the main paper) have been developed for evidence-based safety assessment, either of which could in principle be implemented. The preferred approach of the FSA for risk management will be chosen taking account of the level of scrutiny and safety assurance considered necessary for PBOs. These Models and the types of data that could be required in each are summarised briefly:

- Model 1 focuses on the equivalence between PBOs and TBOs, and on the genetic change and its intended phenotype. The data requirement for safety assessment is predominantly descriptive and confirmatory, with details of the change(s) provided and the description of the resulting product. Compositional data is typically not required in the initial submission. Quantitative data on phenotype is required but mainly focuses on verifying that the intended trait, if relevant to food or feed safety, has been achieved.
- Model 2 builds on Model 1 but focuses on the wider phenotypic consequences of precision breeding and the impact of these on the PBO as consumed. It requires a broader suite of compositional data to be submitted in the initial application. This reflects the view that the new nature of the technology justifies a level of additional scrutiny. Additional to the Model 1 data requirements, compositional data (nutrients and anti-nutrients, metabolite information, proximate analysis or alternative approach (for plants), and edible-by-products data (for animals)) would be routinely required as part of the submission of proposals to inform the considerations of any inherent potential for toxicity and / or allergenicity.

In both Models, the safety assessment is conducted in a tiered or structured approach after answering two questions:

- Question A: Does the PBO have a history of consumption as a food or feed? And
- Question B: Are there any concerns regarding nutritional disadvantage, toxicity or allergenicity?

Tier 1 PBOs are those where sufficient information is provided in an initial data submission to complete a safety assessment satisfactorily. If that is not the case, a more detailed safety assessment in Tier 2 is initiated. The nature of any additional data required will be determined on a case-by-case basis, dependent on the organism and any potential hazards identified.

The way PBOs are intended to be managed impacts the initial data requirements that support Tier assignment in each Model. Both Models use a risk- and evidence-based approach to PBO assessment, based on novelty and anticipated concerns. These Models offer two distinct data requirement options to the FSA. Which Model is preferred will depend not just on the level of safety scrutiny and assurance offered by each approach, but also on wider considerations of risk management and policy.

The technical justification, depth of assessment, and further discussion on the strengths and weaknesses of each model option are discussed within this statement. This paper provides context for the models developed and is intended to support further discussion by the FSA on an approach that meets its policy goals.