Advisory Committee on Releases to the Environment (ACRE)

Minutes of the 161st ACRE meeting held on 02 July 2025

This was a hybrid meeting with attendees present in person and online. The meeting was open to the public.

Attendees

ACRE members:

Prof Jim Dunwell (Chair)

Dr Kathy Bamford

Prof Huw D Jones

Dr Huw E Jones

Prof Peter Lund

Prof Jake Malone

Dr Andrew Millar

Prof Andrew Prentis

Prof Ben Raymond

Prof Andy Wilcox

Assessors:

Rachael Oakenfull, FSA Susan Grogan-Johnson, HSE Maria Taraktsoglou, HSE Will Askew, Natural England

Official observers:

Liam Blacklock, FSA
Andrew Hartley, FSA
Karin Heurlier, FSA
Annalisa Leone, FSA
Lucy Thursfield, FSA
Sophie Curson, GMI
Ged Kerrins, GMI
lain Williams, GMI

Lukasz Krawczyk, GMI
Kerstin Voelz, HSE
Mark Preston, Dept of Agriculture, Environment and Rural Affairs, Northern Ireland,
Colin Coates, Dept of Agriculture, Environment and Rural Affairs, Northern Ireland,
Debbie Kessell, Scottish Government
John Moulton-Brown, Scottish Government
Bill MacDonald, Welsh Government

Defra:

Louise Ball Janet Talling

ACRE secretariat

Martin Cannell Richard Kino Richard Lloyd Mills Sean Simpkins

1. Introduction

The Chair opened the meeting and welcomed officials, assessors and observers (members of the public, and official); and general housekeeping (e.g., evacuation procedure) was explained.

There was a tour-de-table with all Committee members introducing themselves.

An ACRE member declared a potential conflict of interest under item 7 as they worked in the same location, but for a different institute, as the developer of the precision bred potato lines. However, as the ACRE member is not connected to the project it was agreed that there was no conflict, and they could contribute to the discussion.

2. Matters arising

The secretariat confirmed that, for the GM research trials discussed at the previous meeting, a Ministerial decision has been made, and both ACRE's advice and the decisions have been published.

There have been 14 qualifying higher plant notifications since February 2024; 7 last year, and 7 so far this year.

The Food Standards Agency (FSA) provided an update on their recent work and that of their advisory committees, as follows:

The Advisory Committee on Novel Food and Processes (ACNFP) continues to review applications for GM for use in food and feed; specific details are available at https://acnfp.food.gov.uk/AnnualReport2024. The Products of Genetic Technologies sub-group is continuing to prepare for the start of the regime governing precision bred organisms.

The FSA recently concluded stakeholder engagement and user testing of draft technical guidance for precision bred plants for use in food and feed. Following feedback, the FSA is working with the ACNFP and other independent experts to further developed the guidance.

3. Policy update

The Genetic Technology (Precision Breeding) Regulations passed through both Houses of Parliament unopposed earlier this year. The legislation applies to precision bred plants intended for release into the environment for marketing and non-marketing purposes or use in food or feed. It will come into force in November.

Ahead of precision breeding legislation coming into force, Ministers agreed to reinstate the Precision Breeding Working Group (WG) composed of representatives from the length of the agri-food chain, including consumers. The WG is considering the route to market for precision-bred products.

Ministers have not yet decided on introducing regulations for precision bred animals. Defra's Animal Welfare Team is developing an evidence base that will underpin any regulations that are developed.

The Government's Industrial Strategy, the 10-year plan to boost business investment in 8 growth-driving sectors was published on 23 June. Precision breeding is recognised as a key part of engineering biology. Infrastructure for engineering biology is a major target of new research and development grants.

A statement on EU alignment recognises that the UK will retain its own rules in some areas; details will be negotiated over the coming months. Defra remains committed to implementing the precision breeding regulations.

4. Crop research trial consent variations

The secretariat introduced requests to vary consents for two GM wheat trials. The variations requested relate to extending the end date; adjusting the distance between the pollen barrier and the GM plants and including updated grid references.

ACRE discussed these variation requests and concluded that the changes would not alter its existing advice on the risk assessment of either release.

Defra will put the advice to Ministers and publish both ACRE's advice and the Ministerial decisions in due course.

5. Research trial (non-plant)

The secretariat informed ACRE that Defra had recently received <u>an application</u>, Defra ref: 25/R50/01, for the deliberate release of a genetically modified (GM) bacterium for research in human subjects testing vaccine efficacy.

An outline of the application was given, and initial questions invited.

Defra will formally submit the application to ACRE for its consideration and advice.

6. Imported food and feed advice

ACRE reviews the environmental risk assessments of applications to import and use GM crops in food and feed products. It regularly updates its standing advice to include newly assessed products. ACRE is currently reviewing its advice to ensure that it reflects current evidence. The advice is categorised by a crop's ability to persist in UK conditions. It is published on the ACRE pages of Gov.UK.

7. Precision bred potato

A developer has provided evidence to ACRE to support its conclusion that the potato lines it has developed meet the requirements of a precision bred organism.

ACRE considered the evidence provided, accepting the rationale, and then extended its discussion to cover hypothetical situations that could be more challenging to assess. It discussed the evidence it would need from developers to be able to advise Defra on these scenarios. This was further developed under the next agenda item.

8. Guidance on precision bred plants

Defra recently concluded an exercise gathering feedback from a selection of potential users of ACRE's <u>draft technical guidance on release and marketing of precision bred organisms.</u> Using this feedback, the ACRE Secretariat will work with ACRE to amend the draft guidance where appropriate and update it, improving its useability and clarity.

ACRE discussed the feedback, including whether the number and length of genetic changes should be quantified. ACRE reiterated its view, which underpins the approach taken in the Precision Breeding Act, 2023, that this would not be appropriate given the variability in the plasticity of genetic elements. ACRE agreed that in demonstrating whether something 'could have' occurred through traditional methods, a precedent isn't required, however notifiers should provide sufficient evidence that any change introduced to a plant could plausibly be achieved by traditional methods. ACRE will update its guidance, as required, based on its

experience of assessing evidence provided by notifiers to support claims that plants developed by modern biotechnology could have resulted from traditional processes.

9. Regulatory processes for precision bred plants

The Secretariat described the precision breeding regulatory processes and timeframes that ACRE may be involved in.

In response to questions from ACRE about how claims would be investigated about information provided in notifications being inaccurate, Defra confirmed that the GM Inspectorate had powers in the legislation to analyse plant material.

10. AOB

Defra has been asked by the Medicines and Health products Regulatory Agency to seek ACRE's advice on the environmental risk assessment aspects of a marketing application for a human gene therapy product containing, or consisting of, a GMO. Defra has set up a secure file transfer protocol to enable ACRE members to access this file securely and without the need to send/receive a large email attachment.

11. Next meeting

The ACRE Secretariat will arrange the next meeting in due course.