Advisory Committee on Releases to the Environment (ACRE)

Minutes of the 158th ACRE meeting held on 25 July 2023

The meeting format was a 'blended' approach with some attendees joining via MS Teams and some present in 2 Marsham Street, London

Attendees

ACRE members:
Prof Jim Dunwell (Chair) – present
Dr Andy Wilcox – present
Dr Ben Raymond – online
Prof Peter Lund – present
Dr Kathy Bamford – present
Prof Huw D Jones – online
Dr Huw E Jones – online
Prof Andrew Millar – present

Assessors:
Luke Driscoll (Scottish Government) – online
Carmen Whiteley (Welsh Government) – online
Zoonii Kayler (Welsh Government) – online
Chris Johnson (HSE) – online
Chris Stockdale (FSA) – present
Rhys Williams (FSA) – present
Gerard Kerins (GMI) – online
James Blackburn (GMI) – online
Jessie O'Shaughnessy (SASA) – online

Defra:
Martin Cannell, ACRE Secretary – present
James Halpin, ACRE Secretariat – present
Sean Simpkins – present
Janet Talling – present
Oli Watson – online
Lucy Foster – online
Richard Lloyd Mills – online

Apologies were received from Emily Jones (Welsh Government), Mark Preston (Northern Ireland), Heather Campbell (Scottish Government), Beverley Boyce (HSE), Susan Grogan-Johnson (HSE), Rachael Oakenfull (FSA), Laura Bowden (SASA) and Iain Williams (GMI).

1. **Minutes**

Minutes for the 157th meeting, 26 April 2023. ACRE adopted these minutes, and they have since been published as formal minutes on the gov.uk website.[1]

2. **Matters arising**
Three new ACRE members had recently been appointed by the Secretary of State and were in attendance. Committee members were invited to introduce themselves. The Chair gave a summary of ACRE's approach to committee meetings, the usual areas of discussion and general ways of working. The new members were also provided with induction materials and will meet with the Chair and Secretary for further introductory discussions in due course.

3. **Updates from other committees**
Professor Lund gave an overview of work being undertaken by the Advisory Committee on Novel Foods and Processes (ACNFP) (as an ex-officio member of that committee) on developing proposals for regulating food products produced from precision bred organisms (PBO). This work stems from the passing into law of the Genetic Technology (Precision Breeding) Act and was requested by the Board of the Food Standard Agency (FSA). The ACNFP and its sub-group (PGT – Products of Genetic Technologies) were subsequently asked to provide advice on details of an appropriate regulatory system. Two models were described that envisage a two-tier system for i) products that require little scrutiny following Defra's confirmation of PBO status and ii) products that might require additional scrutiny (based on potential concerns relating to allergenicity and nutrient levels, for example). Whilst the two models of data requirements are similar, they differ mainly in the initial information required to be submitted as part of the application for authorisation. The FSA Board meets in September when they will decide on recommended options for the PBO food and feed regulations.

Professor Lund also reported back from a recent meeting of the Science Advisory Council on Genetic Modification (SACGM), who advise the Health and Safety Executive on matters relating to the Contained Use (GMO) Regulations. A key element of the meeting had been an agenda item updating SACGM about the Genetic Technology (Precision Breeding) Act (PB Act).

SACGM members had noted that laboratory (contained) work involving precision bred plants and animals will still be controlled by the Contained Use (CU) regulations for 'larger GMOs' when the PB Act is implemented by the relevant secondary legislation. Thus in future, some precision bred plants and animals may be classed as GMOs under the CU regulations and as Precision Bred Organisms under the new regulations. Defra policy officials confirmed that they and their HSE counterparts are aware of this and continue to work together to ensure that planned legislation is operable and assures safety to human health and the environment.

4. **Update on the Genetic Technologies (Precision Breeding) Act (INF2)**
A Defra policy official explained progress on implementing the Genetic Technologies (Precision Breeding) Act, and on the drafting and bringing into force

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1 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1174609/Advisory_Committee_on_Releases_to_the_Environment_ACRE_-_Meeting_Minutes_-_26_April_2023.pdf

of secondary legislation, which remains on schedule for delivery around Q3/4 of 2024. A key area where ACRE may be called upon for guidance is around the development of notification systems for Precision Bred Organism (PBO) research trials and for PBO marketing.

ACRE may be asked to consider certain case studies, selected to test the boundaries of its published guidance on determining 'qualifying higher plant' status (which will form the basis of potential guidance underpinning the determination of PBO status for the new notification systems).

A working group has been announced, comprising industry representatives from across the food system (including breeders, growers, manufacturers, retailers and agritraders) to plan an approach for initial PBO products to reach supermarket shelves. Officials have also been engaging with the Department for Science Innovation and Technology (DSIT) on Engineering Biology

Officials continue to gather evidence on different countries' approaches to the regulation of organisms produced by technologies such as gene editing. Of most interest recently in this topic was the publication of the EU proposal for the regulation of New Genomic Techniques (NGTs).

ACRE discussed certain aspects of the EU proposal reflecting on similarities and differences between the legislative developments taking place in England.

5. General science update (INF3)

The Secretariat presented a paper describing relevant updates for ACRE regarding scientific developments across Government. The key responsibilities and aims for the newly created Department for Science, Innovation and Technology (DSIT) were explained as well as how DSIT engaged with Defra and other departments. DSIT's recently published Science & Technology Framework was also set out.[2] The framework outlines ten key actions to achieve the goal of making the UK a science and technology superpower by 2030 and identifies five technologies that are most critical to the UK to build strategic advantage, one being engineering biology which is closely related to ACRE's work.

Current relevant research and development programs involving Defra were also set out. Programs described included:

- UKRI's Engineering Biology Mission Hubs where projects using precision breeding technologies are within scope for funding.[3]
- Farming Innovation Programme (FIP), which aims to stimulate innovation and boost sustainable productivity in agriculture and horticulture.[4] The FIP will look to provide a pathway to support R&D in precision breeding.
- Funding recently announced by the Prime minister and Secretary of State on crop genetic improvement via Genetic Improvement Networks (GINs).[5]

[2] https://www.gov.uk/government/publications/uk-science-and-technology-framework
[3] https://www.ukri.org/opportunity/engineering-biology-missions-hubs-and-mission-awards/
[4] https://farminginnovation.ukri.org/
[5] https://www.gov.uk/government/publications/outcomes-from-the-uk-farm-to-fork-summit/an-update-following-the-uk-farm-to-fork-summit-held-at-10-downing-street-on-16-may-2023

The renewed programme will seek to capitalise on the UKs regional advantage following royal assent of the Genetic Technology (Precision Breeding) Act.

- The UK government's recently released new prospectus, Pioneer, which outlines plans for science, research, technology and innovation (SRTI) in the event that association to Horizon Europe is not possible.[6]
- DSIT and UKRI's moonshot engagement programme to identify ambitious research and innovation priorities for the UK.[7]

6. Veterinary medicines marketing authorisation application (P4)

The Secretariat presented a paper describing the key elements for ACRE to consider on the marketing authorisation applications for three GMO veterinary medicines. Two products are vaccines against diseases in cattle whereas the latter is a vaccine against diseases in chickens. Two of the applications contain the same GMO; one of which also contains a number of other active compounds/antigens that are not within ACRE's remit to assess). The GMO risk assessment therefore is essentially the same for both products. In summary, the GMO is based on a modified, attenuated Bovine Herpes Virus vector and has the intended effect of reducing the clinical signs of infectious bovine rhinotracheitis (IBR). ACRE discussed the relevant information taking into account risks to the environment and human health and the contribution of a co-opted expert on GMO veterinary medicines. The Committee agreed that negligible or no risks would result from the presence of the GMO component following commercial use of these two cattle vaccines.

ACRE also discussed the relevant information from the marketing authorisation application for a vaccine for use in chickens (again in the context of contributions from a co-opted expert in this area). This vaccine is based on the Herpes Virus of Turkeys (HVT) which provides protection against Marek's disease. It also contains the VP2 gene from Infectious Bursal Disease (IBD) Virus which encodes a structural protein that acts as an antigen for the immunological response. ACRE noted that this product is very similar to others that ACRE have assessed. It noted that the molecular analysis of the genetic modification had been performed to a high standard and concluded that the method used in the construction of this vaccine differed from that used to make a related trivalent vaccine that ACRE had previously assessed. ACRE was content that the risk to the environment, humans and non-target/target species is low to negligible and noted that the spread and dissemination of the GMO is self-limiting in the target species and does not induce any adverse events or clinical symptoms.

7. New GM food and feed applications (P5)

Information relating to four marketing authorisation applications for GM food/feed products was provided to ACRE by the Food Standards Agency (FSA). The table below contains key information regarding these applications – the organism,

[6] https://www.gov.uk/government/publications/pioneer-global-science-for-global-good
[7] https://www.ukri.org/news/moonshots-for-the-uk-transforming-tomorrow-together/

identifier, trait/phenotype and whether a European Food Safety Authority (EFSA) opinion has been published.

Organism (FSA code)	Event Identifier	Phenotype / Trait	EFSA opinion
Cotton (RP1232)	GHB811	Tolerance to two different herbicides: glyphosate and 4-hydroxyl-phenyl-pyruvate dioxygenase (HPPD) inhibitors	Positive opinion adopted July 2021
Oilseed rape (RP1372)	DP-Ø73496-4	Tolerance to glyphosate (via expression of bacterial glyphosate acetyltransferase)	Positive opinion adopted May 2021
Maize (RP1506)	DP4114 x MON810 x MIR604 x NK603	Tolerance to coleopteran and lepidopteran pests (five different Bt 'cry' proteins) plus tolerance to glyphosate-containing and glufosinate ammonium-containing herbicides	Positive opinion adopted January 2022
Oilseed rape (RP307)	MS11 x RF3	Male sterility and restoration of fertility, tolerance to glufosinate ammonium- containing herbicides	EFSA opinion on environmental aspects of MS11 is available and separate opinion also available for RF3 as part of different stacks (not including MS11).

The first three applications were for products that ACRE has not considered before. EFSA has adopted a positive opinion for each these.

The fourth application concerns oilseed rape (OSR) product MS11 x RF3 (which is intended to be used in conjunction with a second OSR product - MS11).

No EFSA opinion is available for MS11 x RF3 (EFSA will not assess this stack until the compositional analysis is completed for MS11 alone). However, EFSA and ACRE have both previously advised on the RF3 (fertility restorer) event as part of assessments of different stacks (MS8 x RF3, MS8 x RF3 x GT73 and MON 88302 x MS8 x RF3) and did not identify environmental safety concerns that were not accounted for by stipulated measures.

Regarding MS11, EFSA have adopted a positive opinion on MS11 that covers environmental aspects only. Furthermore, ACRE previously advised on MS11 in 2020 and did not identify any environmental safety concerns that were not accounted for by stipulated measures.

ACRE was content to apply its generic advice for maize, rapeseed and cotton to these four products. The Secretariat agreed to update the published tables accordingly.

8. Potential first UK National Listing trial of a GM crop (INF4)

A Defra evidence specialist presented this paper which concerned certain blight resistant, genetically modified potatoes created by The Sainsbury Laboratory (TSL) in collaboration with a commercial partner. These potatoes have undergone repeated research trials in England, according to national GMO legislation, and

ACRE has advised on the environmental risk assessment in each case. The anticipated benefits of growing these potatoes commercially include significant reduction in the application of synthetic crop protection chemicals as well as post-harvest benefits such as improved cold storage and reduced potential for discolouration.

To commercially cultivate GM potatoes for marketing in England, after receiving the necessary GMO authorisation, they will then need to be registered as a new variety in accordance with the provisions of legislation concerning Plant Varieties and Seeds. New plant varieties of agricultural and vegetable crops must undergo trialling (usually two years) to ensure they are 'Distinct, Uniform and Stable (DUS)' and (for agricultural crops only), have 'Value for Cultivation and Use (VCU)' before they can be added to the GB and NI Variety Lists of plant varieties and be marketed (or National List). This ensures that no new variety can be marketed unless it is genuinely new and an improvement on varieties already being marketed.

ACRE discussed the regulatory process for undertaking trials involving GMOs and the arrangements for testing and trialling potato varieties.

The TSL GM potatoes were developed within the Maris Piper genetic background, and only differ from this variety in having high levels of resistance to the potato late blight fungus and certain post-harvest quality traits.

The International Union for the Protection of New Varieties of Plants (UPOV) has disease resistance in DUS protocols for other species (for example, lettuce) where testing for distinctness can be a challenge. Such traits are usually tested as part of the VCU regime. Any new methodology such as that required to be developed for TSL's potatoes, or the adoption of a VCU trait as a special characteristic, requires oversight by the National Listing and Seeds Committee (NLSC) and agreement at the plant varieties and seeds committee (PVSC) before adoption.

9. Technical advances (INF5)

The Secretariat outlined three examples of recent developments in the application of genetic technologies of interest to the work of the Committee. The first example was the use of gene editing to prevent the production of a major allergen in chicken eggs – ovomucoid.[8] The Committee discussed the nature of the sequence alteration in the context of the Genetic Technology (Precision Breeding) Act. It also discussed wider implications that might need to be considered as part of any potential assessment of such applications.

The second example presented to the Committee concerned an investigation into the use of transgenic rootstock plants to deliver transcribed RNA to grafted scions.[9] The researchers had demonstrated that the addition of transfer-RNA like sequences to CrispCas9 and gRNA inserts was required to enable their movement

[8] R. Ezaki, T. Sakuma, D. Kodama, R. Sasahara, T. Shiraogawa, K. Ichikawa, M. Matsuzaki, A. Handa, T. Yamamoto and H. Horiuchi, *Food Chem. Toxicol.*, 2023, **175**, 113703. See article
[9] L. Yang, F. Machin, S. Wang, E. Saplaoura, F. Kragler, *Nat. Biotechnol.*, 2023, **41**, 958-967. See article

from graft to scion. Targeted gene-editing of germline cells was subsequently demonstrated as seeds and progeny containing the desired mutations were produced. The process represents a method for producing transgene-free gene edited plants that is less resource intensive than selecting null segregants or transient delivery of the editing machinery to cells in culture.

A similar example that was described to the Committee concerned a method involving Agrobacterium strains containing T-DNA(s) which are transferred to the plant nucleus but do not become integrated into the genome.[10] In this way introduced T-DNA encoded gene editing proteins and gRNAs may be delivered to the nucleus and operate transiently to generate the desired mutations in germ cells.

10. AOB

None

11. Date of next meeting

It was agreed the optimum timing would likely be early November. The Secretariat agreed to fix a date and time.

[10] Purdue University Newsroom, https://www.purdue.edu/newsroom/releases/2023/Q2/purdue-biology-innovation-allows-the-introduction-of-valuable-traits-in-plants-without-creating-transgenic-plants.html#:~:text=Purdue%20biologists%20have%20developed%20Agrobacterium,-DNA%20aren't%20needed, (accessed July 2023).