

Advisory Committee on Releases to the Environment (ACRE)

These minutes are subject to approval following formal adoption at the next ACRE meeting

Minutes of the 157th ACRE meeting held on 26 April 2023

The meeting format was a 'blended' approach with some attendees joining via MS Teams and some present in Horizon House, Bristol

Attendees

ACRE members:

Prof Jim Dunwell (Chair) – present
Dr Andy Wilcox – online
Dr Ben Raymond – present
Prof Peter Lund – present
Dr Kathy Bamford – online
Co-opted expert:
Prof Huw Jones (Aberystwyth) – online

Assessors:

Heather Campbell (Scottish Government) – online
Laura Bowden (SASA) – online
Chris Stockdale (FSA) – present
Rachael Oakenfull (FSA) – online
Susan Grogan-Johnson (HSE) – present
Beverley Boyce (HSE) – online
Iain Williams (GMI) – present
James Blackburn (GMI) – online

Defra:

Martin Cannell, ACRE Secretary – present
James Halpin, ACRE Secretariat – present
Solomy Kaweesi, ACRE Secretariat – present
Sean Simpkins – present
Rachel Davis – present
Oli Watson – present
Lucy Foster – online
Mike Ellis - online

Apologies were received from Emily Jones (Welsh Government), Mark Preston (Northern Ireland), Chris Johnson (HSE) and Gerard Kerins (GMI).

1. **Minutes** for the 156th meeting, 21 July 2022. ACRE adopted these minutes, and they will be published as formal minutes on the gov.uk website.

2. **Matters arising**

The Chair paid tribute to committee member Alan Raybould following his sudden death in October 2022. Alan had served on the Committee since 2020 and was a key member and will be greatly missed on both a personal and professional level.

The Secretariat updated the Committee on several international meetings they had attended including: 'Viruses, Replicons and Vaccines: opportunities, risks and regulation' organised by the Netherlands Commission on Genetic Modification (COGEM); the Ninth meeting of the European Advisory Committees on Biosafety (MEACB) also organised by COGEM; the International Conference on GMO Analysis and New Genomic Techniques (Secretariat will share output report from the conference when/if it is published); OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB).

The Chair reminded members and co-opted experts to notify the Secretariat of any new or updated conflicts of interest.

3. **Update on Genetic Technology (Precision Breeding) Act and next steps (timeframes for implementing secondary legislation)**

The Defra policy team working on the Genetic Technology Act gave an update on current activity and next steps towards converting the Act into law. They summarised activity to date including the passage of the Bill through Parliament and the work of ACRE to develop advice which informed policy development, specifically the implementation of a statutory instrument for 'qualifying higher plants'. Looking forward, there is a significant programme of work required to support developing secondary legislation (including on 'precision bred' food and feed - which is an FSA lead) in order that the provisions of the Act can be put into practice. Among other elements, this includes the development of a notification system for precision bred organisms and enforcement regulations. The team flagged that ACRE are likely to be asked to provide scientific advice on different aspects as the work proceeds.

4. **Update from FSA on precision bred (PB) organisms for food and feed**

Policy officials from the FSA gave an outline of their work relating to the implications of the Act. This included reference to the area in the Act where powers are granted to the FSA (Part three) and the subsequent need for an implementing framework that will allow the FSA to regulate PB food and feed. It is envisaged that the FSA will implement a pre-market assessment and authorization process for PB food and feed, including a public register explaining what has been authorised. There are provisions in the Act to enable traceability measures, which the FSA are also

looking into, plus a significant programme of evidence gathering (including across government) to inform how the powers will be implemented overall. A description of the work of the FSA's Advisory Committee on Novel Foods and Processes (ACNFP) was given highlighting potential steps leading to FSA authorisation of PB food and feed products. The ACNFP are considering a two-tiered approach, where Tier 1 products are deemed not to require any additional assessment (following Defra's confirmation of PB status), and Tier 2 products are deemed to require an additional assessment step. A triage system was described involving questions that would enable PBOs to be assigned to Tier 1 or Tier 2. The ACNFP are currently working on the data requirements that applicants would be required to submit to support the triage stage.

Policy officials described some of the FSA's social science research into measuring consumer awareness and perception concerning precision bred organisms. This work has informed discussions at FSA board level for example around the issue of food labelling. More generally there is still some work on stakeholder engagement to be undertaken for example on industry expectations with regard to the application process and how the public register is implemented. There followed a short discussion clarifying a hypothetical point with regard to authorisation of 're-edited' PBOs, engagement of the supermarkets and media responses to the Bill being passed.

5. ACRE/APR2023/P3 - ACRE subgroup advice on QHP status of The Sainsbury Laboratory potatoes

The Secretariat presented this paper summarising the provision of ACRE scientific advice on the regulatory status of certain genetically transformed potato lines. A sub-group of ACRE had discussed this issue and applied ACRE's guidance on 'qualifying higher plants' (QHPs) to the question of whether any of the lines may be classed as QHPs. This Committee meeting provided a final opportunity for questions in relation to the work of the sub-group. ACRE members noted that they may be asked for this type of advice more frequently following last year's amendment to the regulations which facilitate research trials of QHPs. The Committee agreed that all advice for these requests would continue to be published - in accordance with statutory requirements.

6. ACRE/APR2023/P1 – Application for consent to trial *Camelina sativa*

The Committee considered an application ([ref. 23/R08/01](#)) for consent to perform a deliberate release of genetically modified camelina for research and development purposes: to investigate the synthesis and accumulation of seed storage compounds.

The Committee discussed the information provided in the application relevant to the molecular characterisation of the lines intended to be grown. Several concerns were identified in particular around the level of clarity provided within the application as to the identity and molecular characterisation of the GMOs intended for release. Additionally, the Committee identified concerns around the lack of detail in answers to parts of the application and suggested that further evidence was required regarding phenotypic characterisation and consideration of

environmental risks. ACRE recommended that this information should be requested by the Secretariat, noting that this would 'stop the clock' with regard to the statutory timeframe within which a Ministerial decision is normally required to be provided.

7. ACRE/APR2023/P2 – New GM food and feed applications

The Secretariat reminded ACRE that it had previously agreed to assess marketing applications for GM food and feed received from the FSA using information provided by the Secretariat that would enable it to identify environmental risk. ACRE also previously agreed that its generic advice was still fit for the purpose. Members noted that should ACRE identify from a new application a plausible risk not previously considered, it will ask the Secretariat to provide further evidence-based information that will allow further investigation and characterisation of the risk.

Prior to the meeting, the FSA had provided the ACRE Secretariat with information relating to four new GM food/feed marketing applications (including European Food Safety Authority opinions, post market environmental monitoring plans and their associated reports). These were all applications to renew existing marketing authorisations related to the following GM crops: maize, soybean and cotton. The Secretariat had shared information relating to these applications with ACRE and summarised the relevant details relating to the inserted genetic material, the trait and the crop species.

Because the four applications in this case were marketing authorisation renewals, ACRE confirmed that it was content to apply its generic advice, as it had already assessed them and was familiar with the environmental risks. For future applications ACRE suggested that applying its generic advice to individual cases will be dependent on, for example, whether ACRE has already assessed the GMO (i.e. most renewals will come into this category), whether an EFSA opinion exists, the specific crop (non-crop foods are likely to be of particular interest) and the existence of environmental risk not considered in ACRE's generic advice.

ACRE's generic advice relating to GMO food/feed crops is currently divided into three types. Concerning the four new applications, the Secretariat agreed to list each one in a separate table relating to the relevant generic advice. These tables and the associated generic advice will be published on the ACRE web pages and updated each time ACRE assesses a new application.

8. ACRE/APR2023/INF1 – Environmental principles policy statement

The Secretariat presented an information paper relating to a new legislative duty coming into force from 1st November 2023: the Environmental Principles Policy Statement (EPPS). This was introduced to the Environment Act 2021 which places a legal duty on Ministers to undertake 'due regard' to the Environmental Principles in the policy statement during the process of developing any new policy, but not individual decisions. The statement consists of five principles towards supporting Environmental Improvement Plans, delivering on Defra's net zero commitment to tackle climate change and to build resilience to biodiversity loss:

- **The integration principle** environmental protection should be integrated into the making of policies
- **The prevention principle** means that government policy should aim to prevent environmental harm.
- **The rectification at source principle** states that environmental damage should, as a priority, be addressed at its origin to avoid the need to remedy its effects later.
- **The polluter pays principle** means that, where possible, the costs of pollution should be borne by those causing it, rather than the person who suffers the effects of the resulting environmental damage, or the wider community.
- **The precautionary principle** assists the decision-making process in the face of a lack of scientific certainty. The principle helps policy-makers deal with risks which may not be precisely calculable in advance.

The ACRE Secretariat were asked to share this information to raise awareness within the committee. The Committee noted the EPPS and that it probably would not be directly relevant to its core work (responsible for providing advice for individual decisions on risk assessments). However, there may be occasions where its advice is supporting policy development and therefore ACRE would need to acknowledge this.

9. **AOB**

The Secretariat gave an update on the public appointments of four members to ACRE. Applications closed on Wednesday 19th April. A public announcement is expected in July following the appointment of the candidates.

10. **Future meeting arrangements**

The Secretariat will communicate the date of the next meeting as soon as possible. The Committee passed on their location preferences for future meetings.