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 156th ACRE meeting held on 21st July 2022

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 – online

Prof Andy Peters – online

Dr Ben Raymond – present

Prof Peter Lund – present

Prof Alan Raybould – present

Co-opted experts:

Prof Huw Jones (Aberystwyth) – present

Dr Huw Jones (SRUC) – online

Assessors

Anthony Hicks (Welsh Government) – online

Bill MacDonald (Welsh Government) – online

John McKillen (DAERA) – online

Laura Bowden (SASA) – present

Rosemary Anfield (Scottish Government) – online

Rhys Williams (FSA) – present

Hoa Chang (FSA) – online

Rob Wellens (HSE) – online

Susan Grogan-Johnson (HSE) – online

Keith Stephenson (HSE) – online

Gerard Kerins (GMI) – online

Iain Williams (GMI) – online

Defra attendees

Martin Cannell – present

Sean Simpkins – present

Solomy Nantege – present

Lucy Foster – online

Guests

Malcolm Burns – online

Jacob Malone – present

Apologies were received from Professor Kathy Bamford

1. **Minutes** for the 155th meeting, 14th May 2020. ACRE adopted these minutes, and they will be published as formal minutes on the gov.uk website.

2. **Matters arising**

   The Chair reminded members to notify the Secretariat of any new or updated conflicts of interest. Secretariat to confirm that co-opted members must declare and submit their interests too.

   Members were reminded to return their self-appraisals to the Secretariat as soon as possible in order that they can begin the reappointment process for those members who are eligible and wish to continue serving on the committee. To note also that the Secretariat is also working with the Public Appointments Team on the process of appointing a deputy chair from within the committee.

Regarding future meetings, there was a general preference for in-person meetings going forward but with the option for virtual attendance for flexibility. The Secretariat will discuss this further with the Chair including the optimum frequency and the issue of holding meetings elsewhere in the UK.

Expense forms and accompanying receipts to be submitted to the Secretariat via email going forward for ease on both parties.

Review section

3. ACRE/2022/P1 – review of ACRE work on GMO applications and consents since 155th meeting

The period between 2020 and 2022 saw ACRE assess a greater than usual number of release applications (field trials and clinical trials). To take stock and reflect on this busy period, the Secretariat gave an overview of the types of applications and scientific issues considered by the committee. Field trial applications included gene edited (GE) winter wheat, GM spring wheat, GM and GE spring barley and GM potato. Clinical trial applications included vaccines against *Salmonella paratyphi*, *Bordetella pertussis*, and Covid-19. ACRE had also been asked by Defra to consider risks to the environment relating to releasing two different non-native biological control agents into England.

There followed a short discussion about aspects such as existing provisions for GMO clinical trial inspections undertaken by the HSE and the legal and regulatory implications of the ERA derogation for covid19 research. The Chair noted that this paper demonstrates the range of topics that are within the scope of ACRE's remit and the diverse expertise held within the committee.

4. **ACRE/2022/P2 – review of ACRE work on genetic technologies / precision breeding regulation since 155th meeting**

The Secretariat highlighted that ACRE had been requested to provide Defra with scientific advice to assist with its development of policy on the regulation of organisms resulting from genetic technologies such as gene-editing. To help with this work ACRE had co-opted two additional independent experts in the fields of plant genetics and biotechnology, and animal genetics and biotechnology.

ACRE's advice on Defra's 2021 public consultation on the regulation of genetic technologies built on its previously published work in this area, including that which describes the dynamic nature of genetic material across the animal and plant kingdoms and the significance of this when considering whether targeted genetic changes could have occurred as a result of traditional breeding methods. The ACRE advice is published here:

https://www.gov.uk/government/publications/acre-advice-the-regulation-of-genetic-technologies/acre-advice-concerning-defras-consultation-on-the-regulation-of-genetic-technologies.

Following the publication of its advice on the consultation, ACRE was asked to develop precise criteria that could be used for assessing whether an organism produced by modern biotechnology could have been produced by traditional breeding methods. Subsequently new ACRE guidance was produced relating to the operation of the government's Statutory Instrument for field trials which amended the 2002 domestic GMO regulations for England. ACRE is very grateful to Professor Huw Jones (Aberystwyth) and Dr Huw Jones (Agri Innovation) for their continued expertise as co-opted experts.

Since coming into force of the SI on April 11th, 2022, Defra has received three notifications to grow Qualifying Higher Plants in accordance with stipulated measures. Currently, ACRE is gathering evidence to inform advice and guidance for the Genetic Technology (Precision Breeding) Bill.

It was noted that ACRE had been called upon to provide advice and guidance on a number of occasions, often to challenging deadlines. Furthermore, discussions frequently concerned highly technical and complex issues. There was general agreement that those members involved were content with the process followed and grateful to the Secretariat for its co-ordinating role.

5. Policy update on the Genetic Technology (Precision Breeding) Bill and wider GM reform

The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 helps to simplify the process for research done outside of the laboratory on Qualifying Higher Plants. The Genetic Technology (Precision Breeding) Bill will supersede this SI and introduce a new simpler regulatory regime for precision bred plants and animals to enable these organisms and derived products to be authorised and brought to market. The new regime will only apply in England. If approved, the act will first apply to plants, followed by animals once measures to safeguard animal welfare have been put in place. The intention is for ACRE to assess and confirm whether products fall under the precision breeding definition before they are brought to the market. If any precision bred animal or plant products are intended food or feed use, these will be authorised as being safe by the Food Standards Agency. The Bill team continues to work with stakeholders to understand any concerns and develop solutions.

There followed a short discussion about certain amendments to the Bill proposed in the House of Commons as well as some of the implications of the Bill concerning possible regulatory divergence both within the UK, and between England and the rest of the world. It was noted that the Bill team were very familiar with all the issues

raised and that they were the subject of significant ongoing evidence gathering, stakeholder engagement and discussion.

6. ACRE/2022/P3 – EU initiative on new genomic technologies

The Secretariat presented a paper that summarised the scope and methodology of a recent initiative concerning the future regulation of new genomic techniques (NGTs) in the EU. A key piece of work was an EU-commissioned desk study on the status of NGTs under Union law which included an overview of EFSA and MS opinions on the risk assessment of plants developed through NGTs plus an overview of non-EU legislation, a 'state-of-the-art' section on NGTs and a section on their safety.

More recently under this initiative the EU Commission has launched a public consultation to gather evidence about plants produced by certain NGTs which will inform new legislation in this area. Some of the key consultation questions were highlighted for the committee to consider.

There followed a short discussion on the implications of this initiative.

'Forward look' topics

7. ACRE/2022/P4 – Identification of GMOs and Precision Bred Organisms

The Secretariat introduced Paper 4 which summarised our current understanding of identifying GMOs and Precision Bred Organisms in food and feed. The paper gives an insight into current practice, and what is possible in terms of identification at present..

The Chair introduced Professor Malcolm Burns, Principal Scientist and Special Advisor at the Laboratory of the Government Chemist, who gave a presentation summarising approaches to and understanding of detection and identification of GMOs and precision bred organisms in food and feed. Professor Burns outlined the role of the LGC in safeguarding the quality of public science and ensuring accurate analytical measurement. The LGC is also the National Reference Laboratory for GMOs in food and feed providing advice and support to food and feed enforcement laboratories and competent authorities to ensure a harmonised approach.

DNA based methods are key for detecting and analysing GMOs and quantitative PCR (qPCR) is the current preferred DNA-based method for routine analysis. For authorised GMOs there are EURL validated protocols for event-specific detection which provide unequivocal target identification. Digital PCR is a relatively new technology that has the potential for much greater sensitivity of detection as well providing absolute as opposed to relative quantitation and is suited for the detection of minority targets in a high background of competing non-target DNA.

There are a number of challenges associated with detecting precision bred organisms. Whilst modern molecular biology methods (qPCR, dPCR, NGS, etc.) does allow the detection of specific single nucleotide polymorphisms (SNPs) they cannot, in isolation, necessarily tell us anything about the method used to generate the mutation. Thus, mutations obtained by GE (NGTs/Precision Breeding) cannot currently be distinguished from natural transformation (which can occur spontaneously) or those produced by traditional processes (e.g. induced through irradiation or exposure to chemical treatments). Therefore, the future analytical challenge will be to determine whether the genetic change exhibited in a PBO resulted from modern biotechnology or from traditional processes/natural transformation.

There followed a short exploratory discussion about some potential approaches that might be able to address issues around detection, labelling and tracing of PBOs.

8. ACRE/2022/P5 – Scientific and regulatory landscape of traditionally produced, gene edited and genetically modified microorganisms

The Secretariat introduced this paper which provides an overview of the scope, evidence and rationale for ACRE's advice relating to the environmental release of micro-organisms (provided as part of its response to Defra's consultation on genetic technologies). The advice was used by the Government to inform decisions about regulating GM and gene-edited micro-organisms. The paper touches on the relatively minimal regulatory landscape controlling the commercial release of conventionally developed (non-GMO) micro-organisms for environmental applications (such as biofertilizers, biocontrol and bioremediation).

Defra's stakeholder engagement in this area suggests that currently there is no reason to expect a product marketing application in the short to medium term. However, given the rapid developments in the field of microbial genomics it is timely for ACRE to increase its awareness of emerging and novel applications in the area, as well as its understanding of a changing regulatory landscape and associated implications.

The Chair introduced Dr Jacob Malone, a Principal Investigator from the John Innes Centre who gave a presentation on research into, and applications of, genetic technologies in environmental microbiology. Dr Malone began by outlining some potential applications of GM/GE microbes such as combating different plant pathogens through competitive interactions with genetically 'attenuated' versions, plant growth promotion, biocontrol and bioremediation. He then described some key advances in technologies for altering bacterial genomes, including sequencing capability, DNA synthesis and cloning. Complementing this was an overview of recent advances in bioinformatics capability for determining the structure of soil microbiome communities, the genetic basis of pathogenicity within a genus and the significance of relationships between different microbial genomes within environmental samples.

Also, characterising microbial collections and synthetic communities is leading to a much greater understanding of how microbial communities interact with plants. The ability to modify any micro-organism for a specific purpose is within the grasp of scientists in the area.

There followed a detailed discussion on many aspects of this topic. It was noted that a potential area for early products might be the removal of antimicrobial resistance genes from a conventionally developed microbe (ie through targeted evolution or random mutagenesis approaches) that is otherwise perfectly designed to perform a function. Members discussed the ability to predict the exact biological effect on microbial communities following the introduction of a microbe with an altered function. This included the extent to which it might be possible to predict / manage any increase in capacity of the modified microbe to proliferate/disseminate in the environment.

It was noted that, for most developers, under the current regulatory landscape it is not economically feasible to submit applications for marketing authorisations. However, it will be important for ACRE to maintain a high level of understanding of new developments in the area.

9. AOB

Another field trial application is pending

10. Future meeting arrangements

Secretariat unable to give a timing but will communicate the date of the next meeting as soon as possible. It may be necessary to link this to the timing of the progression of the GT(PB) Bill through Parliament.