

Advisory Committee on Releases to the Environment

Annual Report 2013

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Foreword by the Chair, Professor Rosie Hails

This report covers ACRE's activities in 2013. Through the year ACRE held five full committee meetings, a number of subgroup meetings and an evidence gathering session which was open to the public. In total eleven reports or pieces of written advice were published. ACRE's website previously hosted by Defra migrated to gov.uk which covers most government-related functions in one place.

Advice on commercial applications

As usual the majority of our work on applications for commercial release or import of GM crops has been carried out under Regulation (EC) No. 1829/2003 with EFSA taking the lead role. ACRE considered in detail the cultivation applications for Bt11 maize; MON810 maize and 59122 maize. For 59122 maize it also commented on an EFSA statement which reviewed studies on honeybees and ladybirds submitted by the applicant. In addition it considered 1507 maize under Directive 2001/18/EC.

In February ACRE published advice on MON87705 soybean and MON87460 maize, which the committee had discussed in detail during 2012. Through the course of 2013, six further applications which excluded cultivation were considered in detail under the food and feed regulations, including oilseed rape, cotton and soybean, as well as further maize GM varieties.

ACRE also considered a marketing application under Part C of Directive 2001/18/EC to import and distribute cut flowers from carnation SHD-27531-4, which has been modified for altered flower colour. The Dutch Competent Authority led on assessing this application for EFSA. ACRE agreed with the Dutch assessment that there was no greater risk with this variety than from conventional varieties. ACRE's advice was published on 3rd December and used to inform the UK opinion sent to the Commission in November.

ACRE advised on two applications to market veterinary medicinal products under Regulation (EC) No. 726/2004. Under this regulation information on the assessment can only be made available following the Commission's decision at the end of the process.

Advice on research trials

ACRE also considered one new research trial application and consent variation for two previously considered trial applications. The first of these was a new application from Celladon for trials using a GM adeno-associated viral vector expressing a heart calcium transporter gene. The aim is to correct for calcium deficiency in heart tissue, which is an important determinant of heart failure. ACRE concluded that recombination involving the vector and replication of the vector were unlikely, and risks from shedding were low. ACRE's advice was published on 25th March 2013 and consents were issued in April for trials in England and Scotland.

ACRE also agreed two consent variations on a trial of aphid-repellent wheat at Rothamsted Research. The first variation requested was for the density of seeds sown to be increased, and this consent variation was issued on 16th March. The second was for an additional planting in 2013 to take advantage of any autumn flush of aphids, and this was agreed and issued on 8th June.

ACRE also considered and agreed a variation to the prostate cancer vaccine trial. Bavarian Nordic asked for an extension of the patient enrolment period, and ACRE confirmed that this did not affect the risk assessment. Consent variations were issued in England on 16th November and subsequently by devolved administrations. The application for a trial in Northern Ireland was submitted later than applications for the rest of the UK so ACRE advice for the Northern Ireland trial was not published until 4th January 2013.

Reviews of research

As part of its usual work programme ACRE reviewed research reports and papers as relevant through the year. These included a Defra funded systematic review of the impacts of the global cultivation of GM crops. While ACRE recommended that this should be published, ACRE also recommended that the weaknesses and limitations of this study should be acknowledged. ACRE considered a paper on the use of the cauliflower mosaic promoter in GM crops and disagreed with a review suggesting that this had significant regulatory impact. Three papers on the indirect impacts of GM herbicide tolerant (GMHT) crops on monarch butterfly populations in the US were considered by ACRE. ACRE found that the results were insufficiently robust or representative to draw conclusions. Another research paper on the influence of a gene for glyphosate resistance on growth and fecundity of weedy rice had limitations, and ACRE concluded that there were no immediate implications for the risk assessment of glyphosate-tolerant crops.

Post-market monitoring

The work of the ACRE subgroup to provide advice on post-market monitoring published its report on 12th March 2013. Most of this work had been carried out during 2012, and in particular the subgroup had examined the utility of our existing environmental surveillance networks for informing post-market monitoring.

New techniques

The work of the ACRE subgroup on whether certain new techniques in plant breeding are captured by the EU's legislation on GMOs was published on 18th July 2013. This also fed into the subsequent work on the EU regulatory system described below.

The EU Regulatory System: is it fit for purpose?

ACRE first registered concern about fundamental principles of the legislation in its 2007 report: 'Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems'¹. This report was designed to place the advice ACRE issued on the UK's farm-scale trials of herbicide-tolerant crops into a wider context; it highlighted inconsistencies in the approach to GMO regulation. During the course of 2013 ACRE members returned to this subject through three work packages on the EU regulatory framework. These were focused around answering the following three questions:

- 1) Can the current limitations of the regulatory system be addressed piecemeal, or only by a fundamentally new framework? If the latter, what would be the essential elements of that framework?
- 2) Is there scientific justification for basing a regulatory system on the techniques by which organisms were produced rather than on their properties and behaviour?
- 3) Are there more effective ways of working within the existing regulatory framework?

¹

<http://webarchive.nationalarchives.gov.uk/20080727101330/http://www.defra.gov.uk/environment/acre/fsewiderissues/pdf/acre-wi-final.pdf>

The work packages were informed by an evidence gathering meeting held in March 2013, in which ACRE learned from experience in other countries and other regulatory systems (e.g. pesticides). This meeting was followed by a number of subgroup meetings through 2013, leading to the production of three reports. The first report, 'Towards an evidence-based regulatory system for GMOs', discusses what a science based regulatory framework may look like. The second report 'Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs' discusses why new breeding techniques create difficulties with the way in which the current regulatory system is prescribed. The third report 'Towards a more effective approach to environmental risk assessment under current GMO legislation' focuses on how evidence could be used more effectively to inform regulatory decisions within the constraints of current legislation.

Together the new reports reflect ACRE's concern that the operation of the current regulatory system is becoming increasingly untenable. The reports were peer reviewed prior to their publication on August 27. ACRE also agreed to provide an over-arching paper that would tie the three reports together, which has now been published in Trends in Biotechnology². I was invited to present the reports to the Irish Environmental Agency's GMO Technology Conference in Dublin (October 2013).

Membership

During 2013 Mike Bonsall was reappointed for a further three years. Keith Lindsey and Chris Pollock retired as they came to the end of their term – Keith as a member and Chris as chair for the last ten years. The committee owes a huge debt of gratitude to them for their service over that time. I was appointed as the new chair in September 2013.

Looking forward to 2014

ACRE aims to promote openness and transparency through having all committee meetings open to the public to attend as observers (retaining the option to discuss some items in private where appropriate, for example if there are items that are commercial in confidence). The role and function of ACRE will be the subject of a triennial review over the coming year, a commitment emerging from the review of public bodies in 2010. This is expected to take

² Pollock C.J. and Hails R.S. The case for reforming the EU regulatory system for GMOs. Trends in Biotechnology, February 2014, Vol 32 No 2: 63-64.

three months from March 2014, and will examine whether ACRE's functions are still needed and what would be the best form for delivery. ACRE members, secretariat and stakeholders will have the opportunity to contribute. The results will be published and announced to Parliament.

Early discussions within ACRE have identified three areas of work for the coming year:

- Following from publication of the three reports on the EU regulatory system, ACRE plans to discuss with EFSA views on how unintended effects on non-target organisms should be dealt with in environmental risk assessments. Following up a specific commitment in Report 3, ACRE also aims to consider in more detail what constitutes environmental harm.
- Discussions between Defra and researchers have indicated that there is difficulty in interpreting information they are required to supply for research applications, and a lack of knowledge about the application process. ACRE will consider how to address this to ensure a good understanding of the risk assessment process.
- Synthetic biology is likely to be an area of interest to ACRE in the future. Most synthetic biology products currently fall within the definition of genetic modification set out in the contained use and deliberate release directives but future products may increasingly challenge current risk assessment methodologies particularly with regard to deliberate releases. The Convention on Biological Diversity is gathering evidence to inform decision making in this area and its scientific body is due to present recommendations in October 2014.

I am grateful to all members and assessors for their expertise and commitment to ACRE. Finally, I would like to re-iterate my thanks to my predecessor, Chris Pollock, for his dedication to ACRE over the last decade and more. I am aware that Chris's shoes will be very difficult to fill, and I am extremely grateful to him for all that I have learnt over the last few years.

Rosie Hails

April 2014.

Chapter 1

Introduction

This is the twentieth annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2013. Our main function is to give statutory advice on the risks to human health and the environment from the release and marketing of genetically modified organisms (GMOs). Occasionally we also advise on the release of certain non-GM species which are not native to Great Britain but are proposed for use as bio-control agents. The full terms of reference for ACRE are set out in Appendix I.

ACRE advises the UK Government and Devolved Administrations of Scotland, Wales and Northern Ireland. Our advice is given, in England, to the Secretary of State for Environment, Food and Rural Affairs who acts in matters concerning the environment and agriculture. In the Devolved Administrations we advise the appropriate ministers.

ACRE held five regular committee meetings during 2013 as well as an evidence-gathering meeting and there was also a significant amount of consultation by e-mail. Through the year we have dealt with many issues summarised below.

Much of our effort this year was devoted to an assessment of the current regulatory framework and how this could be implemented in a more evidence-based and consistent manner. ACRE held a useful evidence-gathering meeting in March and published three reports in August. ACRE first registered concern about fundamental principles of the legislation in our 2007 report: 'Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems'. The new reports reflected ACRE's concern that the operation of this regulatory system is becoming increasingly untenable.

We considered and published advice on a gene therapy trial for heart patients, which aims to correct calcium deficiency in heart tissue, which is an important determinant of heart failure. We also published advice on a GM research trial in Northern Ireland for prostate cancer vaccines using modified vaccinia and fowlpox viruses, and published advice on an extension of the trial of aphid-repellant wheat at Rothamsted.

We also considered an application to market GM carnation flowers, modified for petal colour and herbicide tolerance and our advice informed the UK opinion forwarded to the Commission.

We published advice on MON87705 soybean and MON87460 maize, applications to market these products for uses excluding cultivation.

We considered in detail applications to cultivate four varieties of maize, and to import and process two varieties of maize, two oilseed rape varieties, one cotton and one soybean. This included final consideration of 1507 maize and commenting on an EFSA statement on 59122 maize which assessed new information following studies of honeybees and ladybirds. We carried out a further assessment of Bt11 and MON810 maize in the light of EFSA reviews and a Greek safeguard action against MON810. We completed and published our report on new techniques in plant breeding, analysing whether certain techniques are captured by EU legislation on GMOs. Our report on post-market environmental monitoring was published in March. The sub-group which put this together had provided scientific advice on monitoring of GM crops and in particular it examined whether existing environmental surveillance networks in the UK could be used for general surveillance.

1.1 Membership of the committee

ACRE members are appointed through open competition and are regulated by the Office of the Commissioner for Public Appointments. Members are independent and selected purely for their scientific and technical expertise, and do not represent stakeholders such as the biotechnology industry or environmental pressure groups. The range of expertise on ACRE allows the committee to advise competently on the risk of releasing GMOs, particularly on the potential wider impact on biodiversity and farmland ecology.

During 2013 ministers appointed Rosemary Hails as chair of the committee, following the retirement of Chris Pollock in August. Keith Lindsey also retired in August and Mike Bonsall was reappointed for a further term in December. Biographical details of all the members who served on the committee in 2013 are given in Appendix IV.

Representatives from Government departments and agencies received the appropriate briefing papers, were consulted on ACRE business and in some cases attended meetings. These bodies include the Food Standards Agency, the Health and Safety Executive, the Scottish Government, the Welsh Government, DoE Northern Ireland, Natural England (on behalf of the joint

nature conservation agencies) and the GM Inspectorate at the Food and Environment Research Agency (Fera).

The secretary to the committee was Louise Ball. The secretariat also included Kath Bainbridge, Martin Cannell, Ellen Colebrook and David Sherlock. Katherine Bainbridge left the secretariat during the year and Ellen Colebrook joined it. All staff members making up the secretariat are from the GMO Team in Defra. The committee is grateful to the secretariat for its hard work and support over the period of this report.

1.2 ACRE sub-groups

As a committee, our terms of reference³ are centred on our statutory duty to advise ministers on the risk to human health and the environment from the release of genetically modified organisms (GMOs). The casework that we have dealt with in the past year is described in Chapter 2. However, our remit extends further than case-by-case advice on applications to release or market GMOs; we also have a key role in advising ministers on any science-based GM matter.

During the year the final reports on post-market environmental monitoring, new techniques and the operation of the EU regulatory system were published.

1.2.1 Post-market Environmental Monitoring Sub-group

This sub-group was set up in March 2011 to advise ACRE on implementation of post-market environment monitoring according to EU legislation. The sub-group aimed to provide advice on robust and proportionate monitoring measures needed to identify any anticipated or unanticipated adverse effects resulting from the commercial cultivation of GM crops. It also provided specific advice on the post-market monitoring of GM herbicide-tolerant crops and how mitigation measures might influence monitoring requirements. The sub-group advised on farmer questionnaires as designed by GM consent holders and the likelihood of this approach detecting different types and levels of change. It also investigated what information might be derived from existing environmental surveillance networks, which ones were the most suitable for GM monitoring purposes, and identified gaps in the networks. It

³ See Appendix I for the full terms of reference

aimed to provide ACRE with advice setting out a range of options which could be adopted for post-market monitoring in England.

The ACRE sub-group looked at all aspects of monitoring, but particularly at the potential for using environmental surveillance networks for general surveillance, and provided a detailed statistical power analysis which looks at the effects which could be detected with analysis of the data collected by existing networks. These networks can be used to detect large effects on relatively abundant species. The final report was published on 12 March 2013⁴.

1.2.2 New Techniques Sub-group

The sub-group was established in 2009 to consider the regulatory status of organisms generated by 'new techniques.' In general, the 'new techniques' referred to have been developed since the GM legislation was drafted. There is ambiguity as to whether organisms generated using these techniques meet the definitions of a GMO as set out in the GM legislation. In many cases these techniques result in changes which are indistinguishable from changes which occur naturally or could be produced by conventional breeding methods. In 2007 the European Commission set up a working group to consider these issues and ACRE considered this report before it finalised its own advice.

ACRE's report on new techniques was published on 18 July 2013⁵.

1.2.3 Sub-group on the regulatory framework

ACRE set up a sub-group in 2013 to consider how the current regulatory framework could be implemented in a more evidence-based and consistent manner and where potential challenges might lie in terms of implementing a consistent and proportionate process against a background of constantly changing technology, both GM and conventional. It drafted the three reports described below.

⁴ <https://www.gov.uk/government/publications/genetically-modified-crops-post-market-monitoring>

⁵ <https://www.gov.uk/government/publications/genetically-modified-organisms-new-plant-growing-methods>

1.3 Operation of the regulatory framework

Much of ACRE's effort in 2013 was devoted to an assessment of the current regulatory framework and how this could be implemented in a more evidence-based and consistent manner. This followed up the 2007 ACRE report: 'Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems'⁶ where ACRE first registered concern about fundamental principles of the EU legislation on GMOs.

As part of this process, ACRE held in March 2013 an evidence-gathering meeting at which guest speakers covered the following topics:

Ecological risk assessment and decision-making: making effective use of data to reduce uncertainty

Putting ecological change into perspective

Environmental risk assessment of chemicals

Environmental risk assessment of GMOs: a weediness perspective

ACRE found this provided a very useful contribution to its subsequent deliberations. It considered the relevant issues in three work packages which resulted in three reports published in August 2013. The first report, 'Towards an evidence-based regulatory system for GMOs'⁷ discusses what a science based regulatory framework may look like. The second report 'Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs'⁸ discusses why new breeding techniques create difficulties with the way in which the current regulatory system is prescribed. The third report 'Towards a more effective approach to environmental risk assessment

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<http://webarchive.nationalarchives.gov.uk/20080727101330/http://www.defra.gov.uk/environment/acre/fsewiderissues/pdf/acre-wi-final.pdf>

⁷ <https://www.gov.uk/government/publications/genetically-modified-organisms-review-of-current-eu-regulations>

⁸ <https://www.gov.uk/government/publications/genetically-modified-organisms-the-case-for-new-regulations>

under current GMO legislation⁹ focuses on how evidence could be used more effectively to inform regulatory decisions within the constraints of current legislation. All three reports were subjected to independent peer-review prior to publication. The most challenging issue was the coverage of 'harm' and ACRE discussed how to frame and contextualise this within the wider debate.

The three published reports were circulated to the European Commission, other EU member states and EFSA. The chair presented the reports at the Irish Environmental Protection Agency's GMO Technology Conference on 11 October.

A summary paper covering all three reports was published by the journal 'Trends in Biotechnology'¹⁰.

1.4 Work plan over the next year

1.4.1 Impacts on non-target organisms

In its report 'Towards a more effective approach to environmental risk assessment under current GMO legislation' ACRE highlighted different approaches for assessing potential impacts on non-target organisms resulting from unintended changes to the GM crop. ACRE proposes to take this issue forward in 2014.

1.4.2 Harm

In the course of its 2013 work examining the most effective approach to environmental risk assessment of GMOs under the current regulatory framework, ACRE committed to considering issues around 'defining environmental harm' in more detail in 2014. This was in response to the finding that there is a need for greater clarity for risk assessors in defining what kind of environmental impacts or changes resulting from the release of a GMO should be considered harmful, and the need for environmental impacts to be considered in a broader agro-ecological context. A 'harm' sub-group will be established in 2014 to consider these issues in more detail. The sub-group

⁹ <https://www.gov.uk/government/publications/genetically-modified-organisms-improving-risk-assessments>

¹⁰ Pollock C.J. and Hails R.S. The case for reforming the EU regulatory system for GMOs. Trends in Biotechnology, February 2014, Vol 32 No 2: 63-64.

will complete its work by the end of 2014 and will produce a paper as well as updated guidance to risk assessors.

1.4.3 Public engagement

ACRE is committed to transparency and openness in the way it conducts its business and has therefore agreed to hold its full committee meetings in public from the beginning of 2014. Members of the public would be able to attend as observers but not take part in the meetings. However there might be an occasional need for some parts of some meetings to be held in private, to allow ACRE to discuss commercially confidential or other sensitive issues.

1.4.4 Triennial review

Following the review of public bodies in 2010, which concluded that ACRE should be retained as an independent arms-length advisory body, there was a commitment to carry out regular triennial reviews of these bodies. The review of ACRE will be launched in March 2014, should take no longer than three months and will be proportionate to the small scale of ACRE's activities. The review will examine whether ACRE's functions are still needed and what the best form of delivery for that function is. Assuming the conclusion is that ACRE should continue to perform its functions as an NDPB, Defra will review the control and governance arrangements and the effectiveness of the sponsorship relationship. ACRE members and its stakeholders will be consulted and have the opportunity to contribute. The results of the review will be published and announced to Parliament.

1.4.5 Convention on Biological Diversity and synthetic biology

The Convention on Biological Diversity (CBD) has identified synthetic biology as requiring special consideration with regard to the impacts that its products and activities may have on biodiversity. Whilst existing regulatory frameworks governing GMOs are currently adequate for ensuring the safe use of products associated with synthetic biology, future products and applications may increasingly challenge current risk assessment methodologies especially with regard to deliberate release uses (which are expected to increase as the area develops). The CBD will consider adopting recommendations from their scientific body in October 2014. The outcomes could include adding to CBD provisions for controlling living modified organisms. The secretariat consulted ACRE members on a paper produced by the CBD in September 2013 and will continue to consult or inform ACRE about activities in this area, particularly on

the robustness of the evidence relating to risks to the conservation and sustainable use of biodiversity.

1.5 Interactions with other advisory committees

A number of other Government advisory committees give advice on different aspects of GMOs and their work is complementary to our own. The main ones are:

the Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM(CU))

the Advisory Committee on Novel Foods and Processes (ACNFP)

the Advisory Committee on Animal Feedingstuffs (ACAF)

The ACRE secretariat maintains strong links with the secretariats of the above committees (especially SACGM (CU) and ACNFP) facilitating initiatives such as joint responses to EFSA consultation documents.

We are keen to ensure that ACRE does not duplicate the work of other advisory committees but that we work together to carry out our statutory duties.

Chapter 2

Casework

ACRE's main function is to give advice to ministers on the risks to human health and the environment from the release of GMOs. We undertake critical reviews of applications to release GMOs under the UK and European regulatory framework (Directive 2001/18/EC). Release applications received are of two types depending on their intended purpose. Applications under Part B of this Directive, for research and development trials, are submitted within the UK and consent is given at a national level. Applications under part C (more correctly called 'notifications') are for placing a GMO on the European Union market. Part C applications are initially assessed by one (lead) Member State in Europe which then forwards a summary to the Commission and other Member States for assessment.

Nearly all the marketing applications the committee sees are processed through Regulation (EC) No. 1829/2003 on the authorisation of genetically modified food and feed. The scope of 1829/2003 is the marketing of any GMO that is intended for use as food or feed, including the cultivation of crop plants that are intended for these uses. The regulation provides a single unified approval process for food and feed uses, which will not then require approval under Part C of Directive 2001/18/EC. The initial application is made through the competent authority of a Member State but lead responsibility for processing the application rests with a central body, the European Food Safety Authority (EFSA). For applications including cultivation an environmental risk assessment in keeping with the requirements of 2001/18/EC is required, and EFSA is obliged to consult the 2001/18 competent authorities concerning environmental risk assessments. The Food Standards Agency leads on these applications in the UK while the role of ACRE is to advise on the environmental risk assessments provided with applications for import and processing and for cultivation, where a live GMO is involved.

Marketing applications for uses other than food and feed, e.g. industrial uses or bioremediation, continue to be processed under Part C of 2001/18/EC. The committee saw one new application follow this route in 2013, which was for cut carnation flowers. ACRE also provided its final advice on an application for

1507 maize which was originally submitted in 2001 when there was no alternative to the Part C procedure.

In reviewing applications, we give advice on whether or not the proposed release activities, as specified in the application, pose a significant risk to human health and the environment. We pay particular attention to the environmental risk assessment and any risk management and monitoring conditions attached to proposed releases. If these are not sufficient, we indicate what is required to ensure adequate risk management. Further information or clarification on particular points is often requested from applicants.

ACRE is also asked on occasions to advise on the environmental risk assessment aspects of marketing applications for human and veterinary medicinal products containing or consisting of a GMO, submitted to the European Medicines Agency under Regulation (EC) No. 726/2004.

2.1 Release applications for research and development purposes under Part B of Directive 2001/18/EC

In 2013 we advised on one new application for a release under Part B of Directive 2001/18/EC and advised on variations to two other consents. ACRE recommended that the new trial should be granted with specific conditions attached and that the variations were safe to go ahead. The total number of UK applications for releases now stands at 239 since the original Deliberate Release Regulations came into force in February 1993¹¹.

Summary details of the applications reviewed by ACRE this year are presented below.

¹¹ 214 applications under the 1993 regulations, 25 applications under the 2002 regulations.

2.1.1 Applications from Celladon under Part B of Directive 2001/18/EC for gene therapy trials using a GM adeno-associated viral vector (AAV1/SERCA2A) expressing a heart calcium transporter gene. Ref. 13/R46/01 and 13/R46/01/S

ACRE considered two applications in February from the Celladon Corporation to undertake a gene therapy trial involving patients with heart failure. The trial was proposed for three sites in England and one in Scotland. The aim was to determine the safety and efficacy of using a genetically modified, replication defective virus to deliver a gene for calcium transport into cardiac tissue, thereby correcting for this deficiency which is an important determinant in heart failure.

ACRE agreed that the genetic composition of the viral product was well characterised and the methods used to produce the inoculant were such that the GMO, as described in the application, would be delivered to the patients. ACRE noted that, although low levels of the antibiotic resistance genes used in the intermediates of production of the gene therapy agent could be detected by PCR, this did not present any significant risk.

ACRE concluded that the likelihood of replication and recombination of the GM virus was negligible. This was on the basis that the viral genome has had its virulence genes and other genetic elements removed (leaving only 6% of the original genome present in the GMO) and can only be propagated in the presence of a 'helper' virus.

The risks presented by shedding of the GMO were discussed. ACRE noted that data on the timing of shedding were limited to studies in which the same or a very similar vector was used to carry different human genes. ACRE agreed that the lack of data on shedding would normally be a significant issue for discussion, but as the GMO is a non-pathogenic, non-replicating entity, encoding a human gene, ACRE agreed that the risk from shedding was negligible. This is because even if small amounts of vector were shed (as expected), the biological containment inherent to it would make this essentially an environmental dead-end.

Overall ACRE was satisfied that all potential risks to the environment and non-patient humans had been sufficiently considered and that the appropriate management procedures had been described. ACRE's advice was published on 25 March.

Consent for this trial was issued on 14 April 2013 in England and 22 April in Scotland.

2.1.2 Request from Rothamsted Research to carry out an additional sowing of its GM wheat as part of its existing trial ref. 11/R8/01

ACRE considered this request at its May meeting. Following ACRE advice in 2011, Defra authorised a small trial of GM wheat at Rothamsted Research, which had been modified to produce a pheromone that repels aphids. The application was for two sowings; one in spring 2012 and the other in spring 2013. Rothamsted submitted a request to extend the consent so that it can carry out an additional sowing in autumn 2013 to take advantage of any autumn flush of aphids. In contrast to the previous sowings, Rothamsted proposed to destroy the autumn-sown plants before they reach maturity.

ACRE concluded that the additional planting would not increase the risk posed by this trial, which is negligible. It noted that environmental exposure would be reduced further as the GM wheat is extremely unlikely to flower and set seed. ACRE discussed the timing of herbicide treatment (to kill the plants) and monitoring and management practices to prevent re-growth.

A variation to the consent to allow the autumn planting to go ahead was issued on 8 June 2103.

ACRE advised in March on an earlier request by Rothamsted, to increase the allowable seed density per square metre in the wheat trial. ACRE considered this would not affect its assessment of the trial. A variation to the consent to allow an increase in seed density was issued on 16 March 2013.

2.1.3 PROSTVAC prostate cancer vaccine application ref. 11/R44/01, 11/R44/01/W, 12/R44/01, 12/R44/01/S/ and 12/R44/01/NI

ACRE advice was published on 4 January on an application from Bavarian Nordic Inc. (formerly BN ImmunoTherapeutics, Inc) to carry out a trial of GM vaccines against prostate cancer (PROSTVAC V/F) in Northern Ireland. ACRE has previously published advice on the applications for the rest of the UK. PROSTVAC V/F is designed to eradicate prostate serum antigen-expressing tumour cells in men with prostate cancer. The vaccine comprises two live attenuated GM viral vectors. PROSTVAC- V is a modified, attenuated vaccinia virus whereas PROSTVAC- F is a modified, attenuated fowl pox virus. Both GMOs contain the same transgenes - a PSA gene and genes encoding three immunological co-stimulatory molecules (referred to as TRICOM).

Northern Ireland ministers issued a consent on 17 January.

In considering the Northern Ireland application ACRE noted a point arising from the public consultations on these trials. This raised concerns about volunteers involved in the trial handling cattle because of the possibility that the GM vaccinia vaccine could be transmitted.

ACRE re-iterated its previous conclusion, which was that the likelihood of secondary transmission (to humans and other susceptible animals) was unlikely and that the consequences if transmission were to occur would be minimal. In coming to this conclusion, ACRE discussed the attenuated nature of the GMO and the procedures set out in the application to minimise environmental exposure. These include subcutaneous vaccination, hygiene measures and dressing the wound site until the scab falls off. ACRE's conclusion (about transmission, persistence and impact) was also informed by a discussion on world-wide human vaccination programmes to eradicate smallpox and the presence of wild type vaccinia-like organisms in the environment.

Defra subsequently received a request for an extension of the patient enrolment period to December 2014 for the PROSTVAC trials. ACRE was consulted in September and confirmed that extending this date did not affect its previous advice on this trial. Revisions to the two English consents were issued on 16 November and the Devolved Administrations agreed to issue revisions to their consents.

2.2 Applications to market GMOs under Part C of Directive 2001/18/EC

2.2.1 Application from Suntory Holdings Ltd to import, distribute and retail SHD-27531-4 cut carnation flowers ref. C/NL/13/01

In October ACRE reviewed the application from Suntory Holdings Ltd to import, distribute and retail SHD-27531-4 GM carnations on the EU cut flower market. The application does not include cultivation. ACRE had reviewed similar applications previously. The Dutch Competent Authority is leading on this application and had concluded that there were no problems with granting consent to market these carnations.

This carnation has been genetically modified to express two enzymes in the anthocyanin biosynthesis pathway [i.e. dihydroflavonol-4-reductase (DFR) and flavonoid 3'5'-hydroxylase (F3'5'H)]. The genes encoding these proteins were derived from petunia and viola (pansy) respectively. Simultaneous expression of both of these proteins in carnation results in modified flavonoid synthesis and formation of the blue/violet pigment delphinidin in the flowers. In addition, SHD-27531-4 plants have been modified to contain SuRB gene from tobacco encoding acetolactate synthetase (ALS). This enzyme was modified to confer resistance to the herbicide chlorsulfuron. Chlorsulfuron was used to select transformed plants in the genetic transformation process.

ACRE concluded that the import and distribution of this carnation line does not pose an increased risk to human health or the environment as compared with non-GM carnation varieties. ACRE's advice was used to inform the opinion, which was sent to the Commission in early November as the UK's contribution to the EU-wide assessment of the application. The ACRE advice was published on 3 December 2013.

2.2.2. Application from Pioneer Hi-Bred International Inc. and Mycogen Seeds to market insect-resistant and herbicide tolerant 1507 maize for uses including cultivation ref. ES/01/01

ACRE has issued advice at the various stages required in the assessment of this notification, which because of its age had been processed via Part C of Directive 2001/18/EC. These steps related to the EU-wide assessment of the notification, the responses from the applicant to questions/ concerns raised during this assessment and finally EFSA's opinion on the issues that remain unresolved. As notification ES/01/01 has been in the regulatory system since 2001, the EU Commission requested a number of additional updates from EFSA. These took new information in the peer-reviewed literature into account and provided further clarification on key issues. ACRE therefore reviewed its advice, building on its previous views and focussing on the key issues.

ACRE previously advised that 1507 maize is very unlikely to be cultivated in the UK because the pest it targets is not a problem here. In addition to the pest-resistance trait, 1507 maize was modified for tolerance to glufosinate ammonium herbicides. This latter trait was used in the development of 1507 maize but any authorisation to cultivate this GMO would not include the use of glufosinate ammonium as a novel system for weed control in the commercial crop.

Since ACRE issued its advice in 2005, the EU Commission requested that EFSA update its scientific opinion on six occasions. These updates focussed on two areas of the environmental risk assessment where EFSA had previously identified significant uncertainty (and recommended management options for addressing this). The uncertainty is associated with the potential for 1507 maize to (i) have an adverse effect on non-target butterflies and moths (Lepidoptera) and (ii) for target pests to develop resistance to 1507 maize.

EFSA concluded that there was no new evidence that invalidated its existing assessment of the environmental risks. This assessment concluded that 1507 maize is unlikely to raise a safety concern for the environment as long as appropriate management measures are implemented during cultivation. To this end, EFSA recommended measures to address possible resistance in target pests to the insecticidal protein found in maize 1507 and to reduce the risk of exposure to the plant's pollen for certain highly sensitive species of non-target butterflies and moths.

ACRE's previous advice concluded that this 'GMO is unlikely to have adverse effects on human health or the environment in the context of its proposed uses as compared with its non-GM counterparts'. This was on the basis that the likely comparator would be conventional maize sprayed with foliar insecticides and that, even if insect resistance evolved, it would be unlikely to result in environmental harm. However, there is uncertainty about whether non-target butterflies and moths could be exposed to 1507 maize pollen such that the ecological impact of this interaction is greater than the consequences of applying foliar insecticides. In order to address this uncertainty, ACRE supported the applicant's proposal to carry out post-market monitoring involving experts from Spain.

In this advice, ACRE considered an alternative approach to addressing the uncertainty about the hazard posed to non-target butterflies and moths by 1507 maize pollen.

Member States could implement measures that reduce exposure to 1507 maize pollen (e.g. through the use of non-Bt maize border rows or separation distances) in regions in which adoption rates of 1507 maize are likely to be moderate or high and where significant populations of non-target butterfly and moth species are to be found in and around maize fields. ACRE however agreed with EFSA that such measures are likely to be overly precautionary for hypothetical hazards, and considered it important to determine whether there is a more informed basis for predicting hazard. Further desk studies could be

devised by Member States that predict whether non-target butterfly and moth species would be exposed to the pollen of 1507 maize to a significant degree by drawing together data on distribution and phenology as far as it is known. EFSA's model could provide a framework for estimating the consequences of exposure noting that any butterfly or moth species that were identified would not necessarily be highly sensitive to the Cry1F protein in 1507 maize. If significant uncertainties remain after this exercise, then this would support the implementation of management measures.

In its 2012 opinions, EFSA revisited its advice on insect resistance management (IRM). The evolution of resistance to pests and diseases is not a phenomenon that is specific to GM crops and ACRE is not convinced that this necessarily results in environmental harm. However in general, ACRE considers it important to implement measures that prevent or slow down the evolution of field resistance in pest species. To achieve this, ACRE agreed with EFSA's recommendations for IRM and with its advice that IRM needs to be updated periodically in the light of new information and technological advances.

ACRE's updated advice was published on 3 December 2013.

2.3. Applications to market GM food and feed under Regulation (EC) No. 1829/2003

ACRE was kept informed of marketing applications submitted under Regulation (EC) No. 1829/2003, many of which were within the committee's remit because they were for the import and/or the cultivation of live GMOs. ACRE considered the environmental risks of the following cases in detail:

2.3.1. 73496 oilseed rape ref. EFSA-GMO-DE-2012-109

ACRE considered in February an application from Pioneer for 73496 oilseed rape for food and feed, import and processing. Pioneer has developed 73496 oilseed rape to express GAT4621 protein which confers glyphosate tolerance. In July 2012 ACRE had asked for detailed information on the molecular characteristics of 73496 oilseed rape in addition to information relating to the potential for grain to be spilled during import and the environmental consequences if this were to happen. Members considered the details supplied but considered they raised no new issues so they agreed to wait until EFSA's opinion is published before commenting further. Once EFSA's opinion is available ACRE will confirm whether its general advice on GM herbicide-tolerant oilseed rape applies in this case.

2.3.2. MON87460 maize ref. EFSA-GMO-NL-2009-70

In February ACRE considered the EFSA opinion on this drought-tolerant maize application, submitted by Monsanto for food and feed uses, import and processing. When this application was submitted under the GM food and feed regulation, ACRE asked that the secretariat provide it with an opportunity to discuss drought resistant maize. ACRE noted that the scope of the application does not include cultivation. However, the committee thought it useful to consider what the environmental risk assessment of this crop/ trait combination might look like, taking into consideration that bodies such as the Ad Hoc Technical Expert Group under the Cartagena Protocol has issued guidance on the environment risk assessment of abiotic stress tolerant GM crops.

ACRE considered that the molecular characterisation of the GMO was effective. The committee then discussed the function of the transgene, which is associated with common stress signalling pathways (including those associated with cold and drought). As would be predicted from plants with natural stress tolerance, five years of field trials involving this GMO have demonstrated that there is a complex environmental interaction with a variable, marginal cost accrued under non-stress conditions. The genetic modification facilitates recovery of the plants after exposure to stress.

ACRE considered that the applicant had measured appropriate physiological parameters associated with fitness, persistence and invasiveness in its assessment. From the characteristics measured, ACRE concluded that there was no reason to expect that this GMO would present a greater risk to the environment than its non-GM counterparts if live grain were spilled during transportation. ACRE concluded that its advice on GMOs that have limited potential to grow and flower in the UK is appropriate for this application to import MON 87460 maize. Advice was published on 18 February.

2.3.3. MON87705 soybean – ref EFSA-GMO-NL-2010-78

ACRE considered in 2012 an application from Monsanto for MON87705 soybean, for uses excluding cultivation. This has been developed with an improved fatty acid profile to enhance the suitability of soybean oil for food and industrial uses. The improved profile is expected to increase oxidative stability and enable formulation of foods with lower saturated fat content, and provide industrial oil with improved stability that could serve as a lubricant without needing hydrogenation. MON 87705 contains the soybean FAD2-1A/FATB1-A gene fragments down-regulating endogenous FAD2 and FATB

enzymes and the CP4 epsps gene cassette conferring tolerance to glyphosate-containing herbicides. ACRE concluded that its advice on GMOs that have limited potential to grow and flower in the UK is appropriate for this application. ACRE's advice was published on 18 February.

2.3.4 Draft ACRE advice on the environmental risk assessment and risk management of two Bt maize events: Bt11 and MON810.

ACRE was asked in February to consider issuing final advice on two applications to cultivate Bt maize events (Bt11 and MON810). It was asked to take into consideration (i) previous iterations of its advice on these applications (ii) EFSA's latest reviews of the relevant literature (iii) a safeguard action against MON810 maize taken by Greece and (iv) ACRE's advice on 1507 maize. In the case of the latter, ACRE was asked to consider specifically whether the risks posed to non-target Lepidoptera by Bt11 and MON810 maize pollen were different from 1507 maize pollen and the implications for any consent conditions. ACRE was also asked to consider a paper by Holst et al.¹² that questioned the parameterisation of the model developed by Perry (which underpins EFSA's opinion) – specifically on what a 'worst case scenario' should look like.

ACRE concluded that the information in EFSA's literature reviews and in the Greek safeguard action (which pertained largely to potential impacts on non-target Lepidoptera) did not raise any additional issues/ concerns. ACRE noted that the Greek authorities had included non-published research, including verbal discussions in its evidence.

ACRE considered that the introduction to the paper by Holst et al. included useful references to the sort of desk studies that ACRE had recommended in its advice on 1507 maize. It also welcomed the way that the authors had explored the mechanisms between pollen shed and butterfly feeding phenology. The focus of the paper is on peacock butterflies as there is information available for parameterizing the model. In addition, this butterfly is widespread and, in relation to latitude, has different number of generations per year. The study found that exposure of peacock butterflies to maize pollen would be greater at latitudes where there were two generations per year rather one. However, ACRE had concerns about the model's parameterisation.

¹² Holst N., Lang A., Lovei L and Otto M. (2013). Increased mortality is predicted of *Inachis io* larvae caused by Bt maize pollen in European farmland. *Ecological Modelling* 250: 126 – 133.

ACRE noted that the Holst paper does not include a spatial component (unlike the Perry model). Holst et al. consider the potential impact of Bt maize pollen on Lepidoptera within maize fields (living on nettles); they do not take decreasing exposure with distance from Bt maize fields into account nor did they consider the proportion of butterflies that are likely to be in the vicinity of these fields.

ACRE was concerned with how Holst et al. deal with uncertainty. Whereas Perry proposes a normal curve of LD50 values, Holst et al. plot data from the literature but then do not fit a mean. Instead, they draw the probit line to left of the graph, ensuring that all data points are to the right of this line, and justify this by referring to it as a worst case solution for dealing with uncertainty. The result is that the probit line is fitted to two data points only, both with low mortality values. ACRE advised that this is not a credible way of dealing with uncertainty. The result is that this study inflates the risk significantly. ACRE concluded that Holst et al. have not demonstrated flaws in the conclusions of the Perry model as implied.

ACRE reiterated that both models reflect the real world in a very simplistic way (i.e. in ignoring other mortality factors/ huge fluctuations in natural populations). The challenge in how to extrapolate from a small percentage mortality to population level impacts remains.

ACRE then considered the outputs of the Perry model, as described in the EFSA opinion for Bt11/ MON810 maize, with respect to the potential impact of Bt11/ MON810 maize pollen on non-target Lepidoptera.

ACRE emphasised that the outputs of the model provide no evidence of harm. ACRE noted that this approach assumes that there is an effect and attempts to estimate the magnitude of the effect. ACRE considered it preferable to start with a null hypothesis and thereafter determine the direction of any effect. This should be informed by what regulators consider to be harmful although ACRE considered it challenging to set a mortality threshold. This would require more data in order to translate percentage mortality into impact on lepidopteran populations.

ACRE concluded that, in effect, there is a continuum of potential impacts and regulators are attempting to draw a line where management measures to reduce exposure of non-target Lepidoptera to pollen are triggered (noting that this point does not equate to harm). As the concentration of Cry1 protein in MON810/ Bt11 maize pollen is approximately 350 times lower than that of 1507 maize pollen, ACRE considered whether positioning MON810/ Bt11

maize further down the 'impact continuum' had regulatory significance. As hazard could not be ruled out in every conceivable scenario, ACRE thought it appropriate that EU member states should be able to require management measures where these are required. However, these should be the exception rather than the rule.

2.3.5 59122 maize for uses including cultivation ref. EFSA-GMO-NL-2005-23

ACRE discussed EFSA's opinion on 59122 maize at its May meeting. This GMO has been notified by Pioneer Hi-Bred International and Mycogen seeds for cultivation in the EU. 59122 maize expresses binary Cry proteins (Cry34Ab1 and Cry35Ab1) that act synergistically to control corn rootworms (*Diabrotica* species). It also contains a pat gene that confers tolerance to glufosinate ammonium herbicides. Herbicide tolerance was used as a selectable marker in the development of the GM event but this trait will not be used in the commercial cultivation of the crop. ACRE discussed the possibility that farmers would use glufosinate ammonium with 59122 maize. ACRE considered the potential indirect impacts of using altered herbicide regimes in maize when assessing GM herbicide tolerant maize events such as T25. It assessed the potential for harm to biodiversity (through more effective weed control) in the context of the biodiversity value of maize more generally. In general, the biodiversity value of maize is low and as such, ACRE considered it appropriate to monitor herbicide use and weed profiles through the farm questionnaire. The farm questionnaire for 59122 maize is therefore, the appropriate tool to address this possibility.

ACRE considered the application to authorise 59122 maize in detail in 2007; in 2008 it considered further information submitted by the applicant, which addressed the questions ACRE raised in 2007. At this meeting, ACRE discussed whether EFSA's opinion was consistent with its conclusions. ACRE agreed with EFSA that this GMO is unlikely to have a greater impact on the environment than its non-GM counterparts and it agreed with EFSA's reasoning. ACRE also noted the amount of evidence presented in the application and discussed/cited in EFSA's opinion. ACRE's discussion focused on the key elements of the environmental risk assessment.

Whilst ACRE supports the effective use of existing data, it questions some of the requirements for new data in order to assess the potential risks to non-target organisms. In this case, ACRE noted that studies using plant material led to the conclusion that 59122 maize is unlikely to be toxic to butterflies and moths (Lepidoptera) at biologically-relevant concentrations. The next section

of the opinion then discusses tests on Lepidoptera using purified protein, which comes to the same conclusion. ACRE also questioned the range of non-target organisms that were studied. It noted that this approach was consistent with EFSA's guidance but considered it important to focus on organisms taxonomically related to the target organisms (Chrysomelidae) in the first instance and to widen the net as appropriate. In this case, because one of the binary proteins (Cry35Ab1) has some evolutionary relatedness to a toxin that binds to mosquito larval mid gut membranes, dipteran species were also tested. ACRE was not convinced that testing species representing a range of functional groups should be required when there is no scientific theory linking these binary proteins with toxicity in these species.

ACRE did not agree with EFSA that case-specific monitoring is required for the accumulation/ persistence of the binary proteins in soils where 59122 maize is grown continuously. ACRE agreed with EFSA's analysis and conclusion that the Cry proteins are unlikely to be toxic to soil organisms. Given this conclusion, ACRE was not convinced that data on the presence of these proteins would improve the risk assessment. At best, these would provide additional information on environmental exposure. ACRE discussed the likelihood that any protein that was stabilised (e.g. through absorption on to clay particles) would persist in its active form.

In its discussions of other applications to cultivate Bt maize events, ACRE has questioned whether the evolution of pest resistance results in environmental harm (noting that the baseline for comparison is the agronomic impact associated with non-GM maize). Nonetheless, ACRE considers it important to preserve traits that provide plants with protection against pests or disease. Due to the characteristics of 59122 maize and that of its target pest, EFSA has recommended approaches in addition to the non-Bt maize refugia strategy proposed by the applicant. ACRE agreed with the development of more robust approaches to protect the longer-term durability of the Bt trait. However, the committee considered that as it was in the interest of the companies to protect their technology and as such, it is important to facilitate their innovation and not limit this by being too prescriptive.

At its December meeting ACRE considered an EFSA statement supplementing its conclusions and risk management recommendations on 59122, in the light of new scientific information on non-target organisms and regionally sensitive areas.

ACRE noted that EFSA's previous opinion was that there was sufficient evidence to base a conclusion on the risks posed to non-target organisms

(NTOs) by intended and unintended effects of the genetic modification. In this statement, EFSA revisited its conclusion after reviewing two studies included in the application on honeybees and ladybirds.

As the study involving honeybees was required to support the applicants' conclusion that there are unlikely to be unintended adverse effects on pollinators it should have involved plant material from 59122 maize rather than a non-commercial line that contains the same Cry genes. Consequently EFSA has requested new data. ACRE has previously discussed in more detail the value that such studies add to the weight of evidence on whether unintended effects associated with a GM crop are likely to have adverse effects on NTOs. It therefore, did not agree that a new study would inform the risk assessment significantly.

EFSA has concluded that laboratory studies involving the ladybird *Coccinella septempunctata* were of limited value to the risk assessment because the levels of exposure to Cry34Ab1 and Cry35Ab1 proteins were either too low or unknown. It also considered that there were too few ladybirds in the field trials carried out in the EU and USA to draw conclusions about the impact of the GMO. ACRE concluded that the specificity of the binary protein at biologically relevant concentrations and the likely exposure ladybird populations (which are from a different taxonomic family to the target pests), indicate that the GMO is unlikely to have an adverse effect on this NTO. If a new study is required by EFSA, ACRE concluded that there is no reason per se. why a study that included 59122 in a stacked GM event would not be appropriate.

2.3.6 T304-40 cotton – ref. EFSA-GMO-NL-2011-97

ACRE was asked to in June to consider the EFSA opinion on an application from Bayer CropScience to market GM T304-40 insect-resistant and herbicide-tolerant cotton. This is an application for import, processing and used as food and feed; it does not include cultivation in its scope. T304-40 contains a single insert consisting of the Cry1Ab and the bar expression cassettes, providing insect resistance and tolerance to glufosinate herbicides respectively. ACRE agreed that its current advice on GM crops that will not grow under UK conditions applied in this case.

2.3.7 GT73 oilseed rape – ref. EFSA-GMO-NL-2010-87

ACRE considered in December the EFSA opinion on an application from Monsanto to import GT73 glyphosate-tolerant oilseed rape into the EU, for uses excluding cultivation. GT73 contains a single insert consisting of the

goxv247 and CP4 epsps expression cassettes. Both proteins confer tolerance against glyphosate-based-herbicides. GT73 oilseed rape was authorised previously for import and food uses in 2005; Monsanto has applied for this authorisation to be renewed. ACRE considered this in 2011 and agreed to produce advice for herbicide-tolerant oilseed rape. This text was agreed in July 2012. ACRE confirmed in October that this advice applied to GT73 oilseed rape after considering EFSA's latest opinion. This concluded that there are no safety concerns in the context of its proposed uses.

2.3.8 T25 maize – ref. EFSA-GMO-NL-2007-46

ACRE led on the environmental risk assessment of an application from Bayer to market GM herbicide-tolerant T25 maize that included cultivation in its scope. T25 contains a single insertion locus containing a pat cassette conferring tolerance to glufosinate-based herbicides. In February, the secretariat informed ACRE that the scope of the application had been altered so that it no-longer included cultivation. EFSA issued an opinion on the revised application in October and ACRE confirmed that T25 maize poses no greater risk to the environment than its conventional counterpart in the context of its purposed use. ACRE also agreed that instead of issuing its previous draft advice that related to cultivation of this GMO, it would now add T25 to its generic advice on GM crops that have a limited potential to grow or flower outside agricultural conditions.

2.3.9 MON87708 soybean – ref. EFSA/GMO/NL/2011/93

In October, ACRE considered EFSA's opinion on an application from Monsanto to market GM herbicide-tolerant MON87708 soybean for food and feed uses, import and processing but excluding cultivation. ACRE agreed with EFSA's conclusion that MON87708 is as safe as its conventional counterpart and non-GM soybean reference varieties with respect to potential effects on human and animal health or the environment. ACRE recommended this could be included in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK.

2.4 Other Advisory Duties

ACRE may be called upon to assess the environmental risk assessment aspects of marketing applications for human or veterinary medicinal products containing or consisting of a GMO, submitted to the European Medicines Agency in accordance with Regulation (EC) No. 726/2004. The committee commented on two of these applications in 2013. Under this legislation

information on the assessment of the application may only be made available as part of the European Public Assessment Report following the Commission decision at the end of the assessment process.

Ministers can also call upon ACRE to advise on any scientific issue relating to GMOs. In addition to deliberate release and marketing applications ACRE examines advice issued by EFSA and comment on research papers.

ACRE may be asked to consider and advise on the possible impact of releasing certain non-native plants and animals under the Wildlife and Countryside Act 1981. This Act prohibits, except where licensed by the Secretary of State, the release of animals that are not present in Great Britain or any species in Schedule 9 of the Act. Schedule 9 is a list of non-native animals that are already present in Great Britain that we wish to discourage from spreading, and plants and algae that may or may not be present, but that are considered undesirable. ACRE may be consulted on certain applications to introduce non-native biocontrol agents, where its expertise is considered to add value to the advice that is routinely sought from the Statutory Conservation Agencies and others, but it was not asked to advise on any new licence applications during the year.

Members of the secretariat are involved day to day in advising HSE on the environmental risks of GMO contained use notifications and processed 192 cases in 2013.

2.4.1 Review of the environmental impacts of GM crops

ACRE was asked in February to provide a critical appraisal of a Defra-funded review of the environmental impacts of global cultivation of GM crops¹³. The study was one of a pair, commissioned to systematically review the impacts of cultivating GM crops. The other study focuses on the economic impacts, but ACRE did not consider this report in detail as economic impacts are beyond the committee's remit. ACRE welcomed the initiative taken by Defra in commissioning systematic reviews of the literature in these important areas.

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<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=17402&FromSearch=Y&Publisher=1&SearchText=GM crops&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description>

ACRE noted that systematic reviews are a relatively new discipline in the field of environmental science. ACRE highlighted the important role played by organisations such as the Collaboration for Environmental Evidence (CEE) in quality control for systematic reviews and in providing guidance and support to authors. The environmental review had not met the standards required by CEE. ACRE agreed with this assessment but noted that the review process represented an important step towards developing a systematic approach for reviewing the literature on the environmental impacts of cultivating GM crops and that lessons could be learnt for future analyses. The committee recommended that Defra publish the report, but that the weaknesses in the methodology and the limitations of the data used should be clearly acknowledged and the results interpreted with caution.

2.4.2. Research paper: Possible consequences of the overlap between the CaMV 35S promoter regions in plant transformation vectors used in the viral gene VI in transgenic plants

In February the Welsh competent authority asked ACRE to consider a recently published paper by Podevin and du Jardin that discusses the use of the cauliflower mosaic promoter in GM crops¹⁴. The secretariat informed the committee that it had sought advice from specialists on ACRE when media articles interpreting this desk study were published. These ACRE members explained the background to the paper and the implications for regulators.

ACRE explained that the cauliflower mosaic virus is common in the environment (as it infects Brassica crops) and as such the protein encoded by gene VI (which overlaps with the cauliflower mosaic virus promoter region) is eaten in human diets. ACRE noted that the bioinformatic analyses carried out by Podevin and du Jardin confirmed that the insertion of DNA, including that derived from the cauliflower mosaic virus, is unlikely to generate products that are toxic or allergenic.

ACRE discussed the function of gene VI and noted that because it is multi-functional, it may have unintended effects such as altering the plant's susceptibility to disease. However, ACRE considered it important to put this in context i.e. plant breeders discard plants that have unwanted unintended effects during the breeding process and in the case of GM crops they then

¹⁴ https://www.landesbioscience.com/journals/gmcrops/article/21406/?show_full_text=true&

undergo a detailed risk assessment which includes an examination of their physical and agronomic characteristics (e.g. susceptibility to pests and disease).

ACRE also noted that GM crops containing fragments of the gene have been grown on a widespread basis outside the EU with no indication of any untoward effects. This discussion was consistent with the initial view provided by ACRE experts and supports their conclusion that this paper has no regulatory impact.

2.4.3. Indirect impacts of GMHT crops on monarch butterfly populations in the USA

ACRE considered at its December meeting three research papers on monarch butterflies¹⁵ and how these contributed to the understanding of the dynamics of Eastern North American migratory populations of these butterflies. The papers identify a number of drivers that may affect this population including degradation of forest in its over-wintering habitat in Mexico, extreme weather and loss of breeding habitat in Eastern North America, including loss of common milkweed (which the monarch larvae feed on) from arable fields. ACRE concluded that the papers present a plausible hypothesis (i.e. reduced habitat resulting in fewer butterflies). However, the results presented are not sufficiently robust or representative to allow conclusions about the relative impact of the key drivers on population persistence to be drawn. Lack of information on resilience and a lack of data on different parts of the life cycle are particularly significant. ACRE noted the difficulty of working on continental scales (necessary due to the life history of this species) and that significant resources would be required to carry out a study that would provide sufficient power to detect subtle effects.

¹⁵ Brower L P et al, Decline of monarch butterflies overwintering in Mexico, *Insect Conservation and Diversity* (2012) 5, 95-100.

Davis A K, Are migratory monarchs really declining in eastern North America? Examining evidence from two fall census programs, *Insect Conservation and Diversity* (2012) 5, 101-105

Pleasants J M and Oberhauser K S, Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population, *Insect Conservation and Diversity* (2012) doi: 10.1111/j.1752-4598.2012.00196.x

2.4.4. Research paper – a novel epsps transgene for glyphosate resistance stimulates growth and fecundity in weedy rice without herbicide

Defra asked ACRE to consider this paper¹⁶, particularly with respect to the quality of the science and any implications for risk assessment of glyphosate tolerant crops. ACRE highlighted a number of limitations to the study, in particular the failure to carry out repeats of field experiments in different years, and a failure to demonstrate specific and linked segregation of the GM trait and observed phenotype. ACRE also noted that detecting differences in 'fitness' requires a whole life cycle approach, and results cannot be extrapolated from tests carried out in controlled conditions. As such, ACRE felt that there were no immediate implications of this study for risk assessment of glyphosate-tolerant crops.

¹⁶ Wang W et al, A novel 5-enolpyruvylshikimate-3-phosphate (EPSP) synthase transgene for glyphosate resistance stimulates growth and fecundity in weedy rice (*Oryza sativa*) without herbicide, *New Phytologist* (2013)

Appendix 1

ACRE's terms of reference

ACRE is a statutory advisory committee appointed under section 124 of the Environmental Protection Act 1990 (the EPA) to provide advice to Government regarding the release and marketing of genetically modified organisms. The committee works within the legislative framework set out by Part VI of the EPA and the GMO Deliberate Release Regulations 2002 which together implement Directive 2001/18/EC. The committee's terms of reference are as follows:

1. To advise the Secretary of State for Environment, Food and Rural Affairs, Scottish and Welsh ministers (hereafter collectively known as 'the ministers') and other bodies as appropriate on the exercise of powers under Part VI of the Environmental Protection Act 1990.
2. To advise the ministers and other bodies as appropriate on releases into the environment of Great Britain of animals and plants covered by sections 14 and 16 of the Wildlife and Countryside Act 1981.
3. To advise ministers in Northern Ireland as appropriate on the exercise of powers under the Genetically Modified Organisms (Northern Ireland) Order 1991.
4. To provide to the ministers on request scientific advice on GMOs, including advice to the Health and Safety Executive in respect of the human health aspects of releases to the environment.
5. To advise the ministers and other bodies as appropriate on research needs.

In practice this means that ACRE's remit, as set out by the legislation, is to provide advice on:

whether consents to release or market GMOs should be issued and any conditions which should be attached to consents

the limitations and conditions of consents issued to release or market GMOs, this covers post-release monitoring and provision to make amendments to consents

fees and charges relating to the cost of issuing consents and in respect of maintaining inspection and enforcement regimes

the making of regulations under Part VI of the EPA 1990 and the deliberate release directive

In addition ACRE also provides advice on:

the evaluation of new GM research findings

any science-based GM matter

research needs in the area of risk assessment of GMOs

releases into the environment of non-indigenous animals and plants

Further information on the regulatory regime for the release and marketing of GMOs is available at <https://www.gov.uk/government/policies/making-the-food-and-farming-industry-more-competitive-while-protecting-the-environment/supporting-pages/genetic-modification>

Appendix II

Openness and transparency

We have a continuing commitment to openness and transparency in the working of our committee and its sub-groups. We publish meeting agendas on the Gov.UK website¹ in advance of each meeting and invite comments. The minutes of our meetings are also published on the website, and the secretariat aims to do this within a target period of 15 working days after each meeting. Meeting minutes are supported by detailed advice on individual deliberate release applications which are produced once the assessment process has been completed. We advise on other specific issues when required. Our advice to ministers is published on the web or is available on request from the secretariat, and for deliberate release applications it is also placed on the GMO statutory public register. We have a programme of increased public engagement which includes holding some of our standard committee meetings in public, holding open meetings on topics where we need to gather evidence to inform our advice to ministers, and participation in outside events where relevant to ACRE's remit. From 2014 all the standard committee meetings will be open to the public.

As a committee, we publish guidance and, of course, annual reports of our business. All members are required to declare interests that may conflict with their role on ACRE. Details of members' interests are publicly available and reproduced each year in our annual report (Appendix V). We also have transparent working practices that allow us to deal openly with the infrequent conflicts of interest that arise at ACRE meetings. If a member's interests conflict with an item of ACRE business, for example where release applications are received from institutes or companies with whom a member is involved, the member is required to inform the committee. The committee then decides whether the link requires the member to be absent from discussions. The decision of the committee and its reasons for including or excluding the individual is minuted and published on the web site.

¹ <https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment>

As part of our commitment to openness and transparency, and to fulfil our obligations under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004, we have placed an ACRE publication scheme on the web at http://archive.defra.gov.uk/acre/pdf/acre_pub_scheme.pdf. The scheme sets out the classes of information that ACRE publishes, the manner in which the information is published and whether the material is free of charge or payment is required.

Appendix III

ACRE membership in 2013

Members	Main Expertise
Professor Christopher Pollock (chair until 31 August)	Plant breeding, plant physiology, agronomy
Professor Rosie Hails (chair from 1 September)	Ecology, entomology
Professor Kathy Bamford Dr Mike Bonsall	Medical microbiology and human infection Entomology, evolutionary ecology, ecology and mathematical biology
Dr Rosemary Collier Professor Jim Dunwell Professor Les Firbank Dr Matthew Heard	Applied entomology, horticultural crops Plant biotechnology Agri-ecosystems Community ecology, plant population ecology, agricultural ecology, conservation science
Professor David Hopkins Dr Ieuan Joyce	Soil biology and biochemistry Farming practice

Simon Kerr

Agronomy

Professor Keith Lindsey

Plant molecular biology

(until 31 August)

Professor Andy Peters

Clinical development and regulation of
vaccines

Sub-group on the EU regulatory framework

Professor Rosie Hails

Professor Les Firbank

Dr Ieuan Joyce

Professor Chris Pollock

Dr Matthew Heard

Dr Mike Bonsall

Appendix IV

Biographies of ACRE members

Professor Rosemary Hails MBE (chair from 1 September 2013)

Centre for Ecology and Hydrology, Wallingford

Expertise: Ecology, entomology

Prof Hails is the Science Director for Biodiversity and Ecosystem Science at the Centre for Ecology and Hydrology, and a visiting professor at Oxford Brookes University. She was a member of the Agriculture and Environment Biotechnology Commission 2000 – 2005. Her research interests include biological invasions of insects, plants and pathogens, how these invasions may affect the native communities, and the risk assessment of genetically modified plants and viruses. She is chair of the Natural Capital Initiative and sits on the Council for the Society of Biology and the British Ecological Society. She is also a member of the Natural Capital Committee, which reports to the Economic Affairs Committee. She was awarded an MBE for services to environmental research in June 2000. First appointed to ACRE on 9 October 2006. Current term runs from 1 September 2013 to 31 August 2016.

Dr Kathy Bamford

Imperial College

Expertise: Medical microbiology and human infection

Kathy Bamford is a consultant medical microbiologist at Imperial College Healthcare NHS Trust (ICHT) and Visiting Professor in the Dept. of Infectious Diseases and Immunity at Imperial College. Her expertise is in the aetiology diagnosis and management of human infection with research interests in the immunopathology, prevention and management of infection. She is medical microbiology lead in the development of the Centre for Infection Prevention and Management at ICHT, a Fellow and examiner for the Royal College of Pathologists. First appointed to ACRE on 12 March 2009. Current term runs from 12 March 2012 to 11 March 2015.

Dr Michael Bonsall

Department of Zoology, University of Oxford

Expertise: Entomology, evolutionary ecology, ecology and mathematical biology

Dr Michael Bonsall is a University Lecturer (Reader) in Mathematical Biology (Zoology) at the University of Oxford and a Fellow of St. Peters College, Oxford. He has expertise in insect ecology and evolutionary biology. His work involves the application of mathematical methods to population biology and his research interests cover the areas of population dynamics, community ecology and evolutionary ecology. He is a Fellow of the Royal Entomological Society, the Royal Statistical Society, and has served on the Council of the British Ecological Society (2005-2008) and as a member of the NERC Peer Review College (2005-2009). He is on the editorial boards of *Proceedings B*, *Ecology Letters*, *Theoretical Ecology* and *Ecological Entomology*. First appointed to ACRE on 1 December 2007. Current term runs from 1 December 2013 to 30 November 2016.

Dr Rosemary Collier

University of Warwick

Expertise: Applied entomology, horticultural crops

Rosemary Collier is Director of the Warwick Crop Centre, which is part of the School of Life Sciences at the University of Warwick, and a visiting professor at Harper Adams University College. She is an applied entomologist and her main research interests are modelling interactions between insects and the environment, the host-plant finding behaviour of plant-feeding insects and the development of Integrated Pest Management systems for the pests of field vegetable and bulb crops. She is Course Leader for MSc courses on Sustainable Crop Production and Food Security. She is a Fellow of the Royal Entomological Society and, a member of the UK Insecticide Resistance Action Group, and a member of the Royal Horticultural Society Science Committee and the IOBC-WPRS Council. First appointed to ACRE on 1 September 2012 and this term runs until 31 August 2015.

Professor Jim Dunwell

University of Reading

Expertise: Plant biotechnology

Professor of Plant Biotechnology in the School of Agriculture, Policy and Development at the University of Reading. He has expertise in plant cell biology, and the production and utilisation of transgenic crops. His present research interests include studies of plant gene expression and the evolution of plant proteins. Joined ACRE in September 2003 as the ex-officio representative of ACNFP. Appointed as an ACRE member in his own right from 9 October 2006. Current term runs from 9 October 2012 to 8 October 2016.

Professor Les Firbank

University of Leeds

Expertise: agri-ecosystems

Les Firbank is Professor of Sustainable Agriculture in the School of Biology at the University of Leeds. He is researching into the joint delivery of food and other ecosystem services from rural land, partly through the developing of multifunctional farming systems and partly through the standardisation of ecosystem monitoring data across Europe. He is an Independent Director the Red Tractor food assurance scheme. His research background is in quantifying interactions between farming and the environment, and led the UK farm-scale evaluations of genetically modified herbicide-tolerant crops. He is a member of the editorial boards of Agriculture, Ecosystems and Environment, International Journal of Agricultural Sustainability and Journal of Environmental Management, and was Co-ordinating Lead Author for the Enclosed Farmland chapter of the UK National Ecosystem Assessment. First appointed to ACRE on 26 October 2009. Current term runs from 26 October 2012 to 25 October 2015.

Dr Matthew Heard

NERC Centre for Ecology and Hydrology, Wallingford

Expertise: community ecology, plant population ecology, agricultural ecology, conservation science

Dr Heard is a research scientist at the NERC Centre for Ecology and Hydrology where he leads the community ecology group. His work involves both community and population ecology and he is particularly interested in understanding interactions between plants and invertebrates. His research has been applied to species and habitat conservation, risk assessment of genetically modified plants and ecosystem restoration. He is particularly interested in interactions between farming and the environment. He was a co-ordinator of the UK farm-scale evaluations of genetically modified herbicide-tolerant crops, is a member of the NERC Peer Review College and an advisor to the Knepp Rewilding Project. He is on the editorial boards of the Journal of Ecology and Insect Conservation and Diversity. First appointed to ACRE on 26 October 2012 and this term runs until 25 October 2015.

Professor David Hopkins

Heriot-Watt University

Expertise: soil biology and biochemistry

David Hopkins is Professor of Environmental Biology and Head of the School of Life Sciences at Heriot-Watt University, Edinburgh. He is a specialist in soil biology and biochemistry with major interests in nutrient cycling, soil management in agricultural systems, and the decomposition of residues from plants with genetic modifications, having worked in two plant systems – plants with genetic modifications to lignin biosynthesis and plants with the insecticidal Bt modification. He also has a long-standing interest in the ecology of polar regions including 10 summer seasons undertaking field work in Antarctica. He is a former President of the British Society of Soil Science, Royal Society of Edinburgh Research Fellow, and he has also enjoyed enduring research collaborations with Agriculture and Agri-Food Canada, the British Antarctic Survey and Antarctica New Zealand. He studied at Manchester Polytechnic and the University of Newcastle upon Tyne where he also undertook postdoctoral research, and he has held academic positions in the Universities of Dundee, Stirling and Canterbury (Christchurch, New Zealand). Until 2010, he was Director of Science at the Scottish Crop

Research Institute (SCRI) in Dundee, now part of the James Hutton Institute. First appointed to ACRE on 11 April 2011. Current term runs from 11 April 2014 until 10 April 2017.

Dr Ieuan Joyce

Farmer, Ceredigion and Herefordshire

Expertise: Farming practice

Ieuan Joyce manages in partnership a mixed farm integrating nature conservation and food production objectives. He was a board member of the Countryside Council for Wales and the Joint Nature Conservation Committee until April 2013, and is a former lecturer in animal science at the University of Leeds with research interests in mammalian reproductive genetics. He is a member of the Upland Forum, advising the Welsh Assembly Government on rural issues, and a trustee of the Elan Valley Trust which manages the 40,000 acre Elan Valley estate on behalf of Dwr Cymru. First appointed to ACRE on 26 October 2009. Current term runs from 26 October 2012 to 25 October 2015

Simon Kerr

National Institute of Agricultural Botany (NIAB)

Expertise: Agronomy

Simon Kerr is Head of Regional Trials at NIAB, where he has responsibility for NIAB's field trials across 10 regional centres with a range of arable, vegetable and forage crops. He has direct experience of supervising GM crop trials and serves as a technical expert for Fera for combinable crop, sugar beet and potato variety decisions for the purposes of National Listing. First appointed to ACRE on 1 September 2012 and this term runs until 31 August 2015.

Professor Keith Lindsey – retired 31 August 2013

Durham University

Expertise: Plant molecular biology

Professor Lindsey is Director of Research and Professor of Plant Molecular Biology in the School of Biological and Biomedical Sciences at Durham University. He has expertise in the mechanisms of gene function, particularly in relation to how plants grow and develop. He is President of the Society for

Experimental Biology and a Fellow of the Society of Biology. He was appointed as a member of the council of the BBSRC for four years from 1 April 2010. ACRE member from 1 September 2003 until 31 August 2013.

Professor Andrew Peters

Scotland's Rural College (SRUC)

Expertise: clinical development and regulation of vaccines

Professor Peters is Assistant Principal, International Development at SRUC Edinburgh and also owns the consultancy business Arpexas Ltd. specialising in vaccine research, development regulation and knowledge transfer. He also has considerable experience in reproductive biology with a current research interest in immunocontraceptive vaccines. He also holds a special professorship in animal science at the University of Nottingham. First appointed to ACRE on 9 October 2006. Current term runs from 9 October 2012 until 8 October 2016.

Professor Christopher Pollock CBE (former chair) – retired 31 August 2013

Expertise: Plant physiology, biochemistry and plant breeding

Professor Pollock is the former Research Director of the Institute of Grassland and Environmental Research. His research interests include plant primary metabolism and response to environmental stress. He is an Honorary Professor at Aberystwyth University and is involved in a number of activities relating to agricultural research and policy. He is a member of the BBSRC Council and a non-executive director of the National Non-food Crops Centre. He was acting chief scientific advisor to the First Minister of the Welsh Government and chair of the 2008 Research Assessment Exercise Sub-panel for Agriculture, Veterinary and Food Science. First appointed to ACRE as a member on 18 June 1999. ACRE Chair from 1 September 2003 to 31 August 2013.

Appendix V

ACRE members' interests

ACRE members are required to declare their interests to identify areas that might conflict with the business of the committee. ACRE has open and transparent working practices to deal with the infrequent conflicts of interest that do arise (Appendix I). Members' interests are outlined below. They include things such as involvement in companies, partnerships, trusts or other bodies of which the member is the paid employee, partner or proprietor; directorships of companies; membership of local authorities, health authorities and trusts, training and enterprise councils, and the magistrate's bench; and where they might be affected by the work and advice of the body.

Register of members' interests – 31 December 2013

ACRE MEMBER	COMMERCIAL INTERESTS		NON-COMMERCIAL INTERESTS		PARTNER'S INTERESTS	
	Name of Organisation	Nature of Interest	Name of Organisation	Nature of Interest	Name of Organisation	Nature of Interest
Dr Kathy Bamford	Pfizer, Pharmacia, Wyeth, Gilead, Baxter, Bayer, Astellas	Advisory boards, expert panel, review	Royal College of Pathologists	Examiner Member of National Quality Assurance Advisory Panels for Microbiology	None	
	Pharmacia, Pfizer, Baxter					
	Pharmacia, Baxter	Research funding (investigator lead)	UK-CRC, Wrexham GI Society, HHTRC	Research funding		

			Society for General Microbiology	Member Representative on National Quality Assurance Advisory Panels for Microbiology		
			Imperial College Healthcare NHS Trust	Employee		
			Imperial College	Visiting Professor		
			NIHR HTA	Panel member		
Dr Michael Bonsall	Oxitec Ltd	BBSRC – iCASE studentship	University of Oxford	Employee	Academy of Medical Sciences	Director of Medical Policy
		BBSRC - LINK Grant	St Peter's College, Oxford	Fellow, employee		

		2014-17	BBSRC, NERC, Royal Society	Funding for research		
			EFSA	Member of working groups on protection goals and endangered species		

Dr Rosemary Collier	Rijk Zwaan	Funding for research	University of Warwick	Employee	Fraser Associates UK	Sole trader; innovation and resilience in the agri-food supply chain.
	DuPont	Funding for research	NERC EPSRC Defra AHDB	Funding for research	Warwickshire Rural Hub	Director
	Syngenta	Funding for research	RHS Science Committee	Member (unpaid)	Awards Council, Fruiterers Company	Chairman
			Insecticide Resistance Action Group	Member (unpaid)	Agri-food Group, Institute of Food Science and Technology	Chairman
			IOBC-WRPS Council	Member (unpaid)		

Professor Jim Dunwell	None		University of Reading	Employee	None	
			EU, Defra and HGCA	Funding for research		
			Rothamsted Research	Rothamsted Fellow		
			University of Nottingham	Special lecturer		

Professor Les Firbank	Firbank Ecosystems Ltd	Director Consultancy to the Land Use Policy Group (LUPG), ADAS and Cambridge Programme for Sustainability Leadership	University of Leeds	Employee	University of Leeds Marks & Spencers companies involved in pig nutrition	Employee Research/consultancy
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	Assured Food Standards Ltd (Red Tractor Scheme) – not for profit	Independent Director	Defra	Member, Demonstration Catchments Research Advisory Group		
			WCMC	Contributing researcher, UK National Ecosystem Assessment (Phase 2)		
			EU Framework 7	Funding for research		

Professor Rosemary Hails	None		NERC Centre for Ecology and Hydrology	Employee	Natural England	Employee
			Oxford Brookes University	Visiting Professor		
			Natural Capital Initiative (special interest group of the Society of Biology)	Chair (unpaid)		
			Natural Capital Committee	Member		

			NERC, BBSRC, MRC, Defra, EU	Funding for research		
			Society of Biology	Member of Council (unpaid)		

Dr Matthew Heard	None		NERC Centre for Ecology and Hydrology	Employee	Amgen Ltd	Programme Manager
			Natural England, Defra, NERC, BBSRC, Wellcome Trust, Scottish Government	Funding for research		
			NERC	Member of Peer Review College		

			Knepp Rewilding Project	Advisor (unpaid)		
Professor David Hopkins	None		Heriot-Watt University	Employee	None	
			NERC	Funding for research		
			NERC	Peer-review college member		
			University of Newcastle	Visiting Professor		
			University of Glasgow	Visiting Senior Research Fellow		
			Rothamsted Research	Rothamsted Fellow		

Dr Ieuan Joyce	Ochr Fawr	Manager of farm business in partnership	Upland Forum	Member	None	
			Elan Valley Trust	Trustee		

Simon Kerr			NIAB	Employee		
Professor Andrew Peters	Arpexas Ltd	Director	Scotland's Rural College	Employee	None	
			Global Alliance for Livestock Veterinary Medicines	Board trustee		
			University of Nottingham	Visiting professor		
	Bayer Animal Health	Consultant	Wildlife Ark Trust	Consultant		

	Avacta Animal Health	Consultant				
	Elanco	Consultant				
	Pfizer	Shares, pension				

Former members, both retired 31 August 2013:

ACRE MEMBER	COMMERCIAL INTERESTS		NON-COMMERCIAL INTERESTS		PARTNER'S INTERESTS	
	Name of Organisation	Nature of Interest	Name of Organisation	Nature of Interest	Name of Organisation	Nature of Interest
Professor Keith Lindsey	Creative Gene Technology Ltd.	Scientific Director	Durham University	Employee	Durham University	Employee
	Sirius Minerals plc	Research funding	BBSRC, EPSRC	Funding for research		

			BBSRC Council	Paid committee member		
			Society of Biology	Fellow		
			Society for Experimental Biology	President, Director		
			New Phytologist Trust	Trustee		
Professor Christopher Pollock			Aberystwyth University	Honorary professor	None	
			BBSRC	Paid member		
			National Non-food Crops Centre	No-executive Director		
			Aberystwyth University and Welsh Government	Unpaid committee work		

Appendix VI

ACRE advice issued in 2013

Advice on an application to market 1507 maize - ref. C/ES/01/01. Published 3 December 2013

Advice on an application to market SHD-27531-4 carnation flowers – Suntory Holdings Ltd ref. C/NL/13/01. Published 3 December 2013.

Towards a more effective approach to environmental risk assessment of GM crops under current EU legislation. Published 27 August 2013

Towards an evidence-based regulatory system for GMO. Published 27 August 2013

Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs. Published 27 August 2013

Report on new techniques in plant breeding. Published 18 July 2013

Advice on a GM wheat trial (Rothamsted Research application 11/R8/01- updated for additional trial). Published 5 June 2013

Advice on gene therapy trials to improve calcium ion transport in heart failure patients (Celladon Corporation applications 13/R46/01 and 13/R46/01/S). Published 25 March 2013

Report on the post-market environmental monitoring of genetically modified crops. Published 12 March 2013

Advice on imports and processing of GM crops submitted under regulation EC 1829/2003: genetically modified crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. Generic advice updated to include MON 87705 soybean and MON 87460 maize. Published 18 February 2013

Advice on a GM prostate cancer vaccine research trial in Northern Ireland. (Bavarian Nordic application 12/R44/01/NI). Published 15 January 2013