Advisory Committee on Releases to the Environment

Annual Report
Number 19: 2012

May 2013

Published on behalf of the Advisory Committee on Releases to the Environment by the Department for Environment, Food and Rural Affairs
17 Smith Square
London SW1P 3JR
Telephone 08459 33 55 77
Website: www.defra.gov.uk/acre

Information about this publication is available from:

ACRE Secretariat
Area 3B, Nobel House
17 Smith Square
London SW1P 3JR
Telephone 020 7238 2051
acre.secretariat@defra.gsi.gov.uk

CONTENTS

FOREWORD

By the Chairman, Professor Chris Pollock

This report covers ACRE's activities in 2012. Once again, 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 also published advice on applications to release a GM vaccine (PROSTVAC-V and F vaccines using modified vaccinia and fowlpox viruses) in a trial for treatment of prostate cancer. The application covered 10 sites in England and 1 in Wales. This application was revised and 12 more sites in England and a site in Scotland were approved. A Northern Ireland site was also considered but approval was not published until 2013. ACRE published advice on a GM vaccine trial for HIV at 1 site in England. The vaccine is based on the Sendai virus, a member of a family of viruses causing respiratory tract infection in rodents. ACRE advised on an application to market a veterinary medicinal product under Reg (EC) No. 726/2004 and also published advice on MIR162 maize and MON87701 X MON89788 soybean following food & feed applications excluding cultivation. These latter applications were included under ACRE's general advice for GM crops which have a limited potential to grow and flower outside of UK agricultural conditions.

In terms of work carried out under Regulation (EC) No. 1829/2003, ACRE considered seven applications in detail under the food and feed regulations: three applications to cultivate maize and one for soybean together with proposals for import and processing only covering oilseed rape (two applications) and soybean. ACRE also commented on EFSA opinions updating the environmental risk assessment and risk management recommendations for Bt11 and 1507 maize, following development of an EFSA model to characterise hazards posed to non-target lepidoptera by pollen from these events.

As part of a continuing set of discussions on the development of best practice in environmental risk assessments, ACRE responded to an EFSA consultation on its guidance on the environmental risk assessment of GM animals. Additionally the Committee commented on the Commission working group report on new techniques, recommending that a logical, evidence-based framework should be used to determine what falls within or outside the legislation. Following publication of the Commission's report, ACRE finalised the report of the New Techniques Sub-Group and will publish its own advice on the regulatory implications of new and emerging biotechnological approaches.

As part of its on-going work programme considering key elements of the regulatory process, a draft final report of the Post-market Environmental Monitoring Sub-group was presented to the committee in November. ACRE had convened this subgroup to provide scientific advice on PMEM of GM crops. *Inter alia* the subgroup examined whether existing environmental surveillance networks in the UK could be used for general surveillance. Defra commissioned a study to examine further the statistical power of ESNs to detect unanticipated adverse effects correlated with the cultivation of GM crops. In March 2012, the European Commission organised a public hearing on PMEM of GM crops to gather information and the work of the ACRE subgroup was presented at this hearing.

ACRE agreed its work programme for 2012 based around considerations of 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). Leading from the independent review of ACRE in 2010, ACRE agreed to take forward recommendations in the revised Code of Practice for Scientific Advisory Committees, agreed and published a framework setting out the relationship between Defra and ACRE and implemented a formal appraisal system for members.

The committee met on five occasions during the year. In addition urgent and running matters were discussed and agreed by e-mail correspondence. As with all its deliberations, a full account of these meetings can be found on the ACRE web site. ACRE continues to work closely with other relevant advisory committees, particularly

in the area of medicinal products and contained use and we have been particularly grateful to colleagues from these committees for specialist advice on occasions.

During 2012, Jim Dunwell, Andy Peters, Rosie Hails, Kathy Bamford, Ieuan Joyce and Les Firbank were reappointed as ACRE members and Rosemary Collier (University of Warwick), Simon Kerr (NIAB) and Matt Heard (Centre for Ecology and Hydrology) were appointed as new members to replace Jeff Bale, Jim Orson and James Bullock whose terms of office ended. The committee owes a considerable debt of gratitude to retiring members for their contributions.

This is the last occasion when I am responsible for preparing the foreword as my term of office ends in 2013. I wish to take this opportunity to register my thanks to those who have made my tenure so stimulating and enjoyable. Firstly I am very grateful to past and present members of ACRE and to the assessors. They have always responded to our considerable workload with commitment and enthusiasm and have been extremely generous with their time and expertise. They have worked with me to achieve consensus whilst clearly articulating issues of doubt and areas of uncertainty. Officials and ministers should be in no doubt about the quality of the science advice that is delivered as a result of all their efforts. Secondly I would like to thank the secretariat for all their hard work and commitment to the successful operation of ACRE. There have been considerable changes in personnel during my tenure, but invariably the quality of support has remained extremely high and I have valued the knowledge and experience of all of those involved, but particularly of the successive Secretaries to the Committee; Paul Burrows, Steven Hill, Androulla Gilliland and Louise Ball.

Finally I wish to express my gratitude to the Ministers and Officials of the parent Departments (in my case DETR and Defra) and the devolved administrations. Over a period when there have been significant changes within government, the UK has resolutely maintained its commitment to evidence-based decision-making and has demonstrated the value that it places on independent scientific advice. At a time when public attitudes to genetic modification differ so widely when considering medical versus agricultural products, I have really valued this consistency of approach and the direct support for the committee that has resulted. I have enjoyed my tenure enormously and I will miss the opportunity to access the experience and

wisdom of such a range of talents. However, I know that my successor will come to appreciate this just as much as I have.

Chris Pollock

March 2013

CHAPTER 1

Introduction

This is the nineteenth annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2012. 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). We also advise on the release of certain non-GM species used as biocontrols, which are not native to Great Britain. 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 2012 and there was also a significant amount of consultation by e-mail. Through the year we have dealt with many issues summarised below:

We considered and published advice on GM research trials for prostate cancer vaccines using modified vaccinia and fowlpox viruses, and a GM vaccine trial for HIV, with the GMO based on the Sendai virus.

We published advice on MIR162 maize and MON87701 x MON89788 soybean, applications to market as food and feed excluding cultivation.

We considered in detail applications to cultivate two varieties of maize and a soybean, and to import and process two varieties of oilseed rape and a soybean.

We commented on EFSA opinions updating the environmental risk assessment and risk management recommendations for Bt11 and 1507 maize, following development

of an EFSA model to characterise hazards posed to non-target lepidoptera by pollen from these events.

We responded to the EFSA consultation on its guidance on the environmental risk assessment of GM animals

We commented on the Commission working group report on new techniques, recommending a logical evidence-based framework should be used to determine what falls within or outside the legislation.

The draft final report of ACRE's Post-market Environmental Monitoring Sub-group was presented to the committee in November. The sub-group had provided scientific advice on monitoring of GM crops and in particular the subgroup examined whether existing environmental surveillance networks in the UK could be used for general surveillance.

We worked on ACRE's proposals for how the current regulatory framework could be implemented in a more evidence-based and consistent manner. We agreed we should investigate options for better use of definitions and evidence when implementing the current regulatory system and that we should explore the challenges and limitations associated with our work on environmental risk assessment and post-market environmental monitoring.

We took on board recommendations in the revised Code of Practice for Scientific Advisory Committees, published a framework document setting out the relationship between Defra and ACRE and set up a more formal system of appraisal for ACRE members.

1.1 Membership of the committee

ACRE members are selected and appointed in open competition in accordance with guidance from 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 2012 ministers appointed Rosemary Ccollier, Matt Heard and Simon Kerr to the committee. Rosemary Collier is Director of the Warwick Crop Centre at the University of Warwick. 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. Matt 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. Simon Kerr is Head of Regional Trials at the National Institute for Agricultural (NIAB) where he has responsibility for NIAB's field trials across ten regional centres with a range of arable, vegetable and forage crops, with direct experience of supervising GM crop trials.

Three members left during the year – Jim Orson, Jeff Bale and James Bullock – and six were reappointed for a further term - Jim Dunwell, Andy Peters, Rosie Hails, Kathy Bamford, Ieuan Joyce and Les Firbank.

Details of all the members who served on the committee in 2012 are given in Appendix III.

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 and DoE Northern Ireland. We also welcomed representatives from 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 Dr Louise Ball. The secretariat also included Dr Katherine Bainbridge, Dr Martin Cannell, Sarah Brown and David Sherlock. Sarah Brown left the secretariat during the year and Dr Martin Cannell rejoined 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 Framework Agreement

In line with guidance from Treasury and Cabinet Office, the secretariat drew up a draft framework agreement setting out the roles and responsibilities of ACRE, the secretariat and ministers in its sponsoring department Defra. This agreement includes the existing terms of reference and advice on good practice from a variety of sources including the revised Code of Practice for Scientific Advisory Bodies. The Devolved Administrations were consulted for confirmation that their interests were fairly reflected. The agreement was signed and published on ACRE's website in May.

1.3 ACRE sub-groups

As a committee, our terms of reference[1] 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 Post-market Environmental Monitoring Sub-group presented its draft final report, further progress was made on the report of the New Techniques Sub-group and a new sub-group was set up to take forward the various work streams agreed in ACRE's work plan.

[1] See Appendix I for the full terms of reference

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

The sub-group's findings were reported to ACRE in February, following which the group's report was substantially revised with the aim of engaging with a wider audience and also to take account of a supplementary study which Defra commissioned on the sensitivity of existing environmental surveillance monitoring networks to detect unanticipated effects that may occur in the environment in response to the cultivation of genetically modified crops.

The draft final report and the results of the study were reported to ACRE at its November meeting. 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. The reports showed that these networks can be used to detect large effects on relatively abundant species. ACRE members were invited to comment on the reports which are due to be published in 2013.

1.3.2 Public Engagement Sub-group

This group did not meet in 2011 but can be reconvened if required. ACRE will continue to put into practice its recommendations for openness and transparency in the committee's proceedings.

1.3.3 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 its published report was considered at the May meeting. ACRE's sub-group was waiting for the Commission report to be published before the ACRE advice was finalised, to ensure the ACRE advice covered any points from the Commission's report which it needed to address.

ACRE considered the Commission's published report in May, noting that it provides a useful description of the techniques and issues to be considered. The committee expressed concern, however, that the definitions provided in the legislation could be interpreted in different ways. There were differences of opinion amongst members of the Commission's working group as to how these terms should be interpreted. ACRE recommended that a logical, evidence-based framework should be used to determine whether the techniques fall within or outside the legislation. ACRE's comments were taken on board for a subsequent modification of its advice, which is due to be published in 2013.

1.4 Work plan over the next year

In addition to its requirement to advise on applications for the deliberate release and marketing of GMOs and on documents that relate to the environmental risk assessment and risk management (including post-market environmental monitoring) of GMOs, ACRE identifies work streams that underpin this casework. A major focus for the committee in 2012 and 2013 is the based around considerations of 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.

As part of this process, ACRE agreed to hold in March 2013 an evidence-gathering meeting to examine a more effective approach to environmental risk assessment under current GMO legislation. The committee will also ensure that its findings on post-market environmental monitoring and new techniques are published.

A new chair is due to take over in September 2013 and he or she may identify other issues for ACRE to tackle in the future.

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 the 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. No Part C applications were submitted to the committee in 2011.

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 Part B release applications for research and development purposes

In 2012 we advised on three applications for releases under Part B of Directive 2001/18/EC. ACRE recommended that the consents for the trials should be granted with specific conditions attached. The total number of UK applications for releases now stands at 238 since the original Deliberate Release Regulations came into force in February 1993[2].

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

2.1.1 Applications from BN ImmunoTherapeutics, Inc. under Part B of Directive 2001/18/EC to carry out a trial involving a therapeutic vaccine consisting of attenuated GM viruses – ref. 12/R44/01, 12/R44/01/S and 12/R44/01/NI

ACRE considered applications from BN ImmunoTherapeutics, Inc. to release GM vaccines against prostate cancer (PROSTVAC V/F). PROSTVAC V/F is designed to

[2] 214 applications under the 1993 regulations, 24 applications under the 2002 regulations.

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).

ACRE considered applications in 2011 in detail for releases at ten sites in England and one in Wales and advice was published on 5 January 2012. Consents were granted on 8 January for England and 11 January for Wales. In 2012 applications were received for twelve more sites in England, one in Scotland and one in Northern Ireland. ACRE noted that its previous advice on risks to human health and the environment applied in each case. Advice was published on the English and Scottish trials in 2012 but the Northern Ireland application was submitted later, with advice from ACRE due to be published in 2013. A consent for the additional English sites was issued on 10 December and for the Scottish site on 24 December.

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.

2.1.2 Application from the International AIDS Vaccine Initiative under Part B of Directive 2001/18/EC for a trial of a GM therapeutic vaccine against HIV. Ref. 12/R45/01

The International AIDS Vaccine Initiative (IAVI) submitted an application to release a GM Sendai virus [SeV-G (NP)] in a clinical trial. The objective of the trial is to evaluate the safety and immunogenicity of the GMO in healthy adult volunteers following vaccinations with combinations of a SeV-G (NP) and an AD35-GRIN vaccine.

ACRE noted that the application did not contain a risk assessment for the AD35-GRIN vaccine, as this GMO would be biologically contained within the volunteers and as such would be captured by the GMO Contained Use legislation. ACRE confirmed that the wider environment would not be exposed to the AD35-GRIN vaccine because the virus is not capable of replication and would be injected into the muscle of the volunteers.

ACRE noted that the wild type Sendai virus strain was isolated from mice decades ago and that it has been well-studied in the laboratory where extensive propagation had reduced its virulence. The GMO has been modified to express the human HIV-1 *gag* gene. ACRE noted that the gag protein produced by the GM Sendai virus does not form macromolecular structures that would be produced during normal HIV replication. ACRE considered that the GMO was well-characterised and that it could be easily distinguished from wild type Sendai virus. ACRE considered that the GMO was unlikely to recombine with other viruses co-infecting the volunteers. It is a negative sense, single-stranded RNA virus from a family that rarely undergoes genetic recombination.

ACRE discussed the potential for environment exposure, through accidental exposure of personnel administering the vaccine (predominately through aerosols) and respiratory secretions. ACRE considered that the management measures proposed by IAVI would minimise environmental exposure. The committee also noted that the tropism of the virus provided some degree of biological containment, along with the significant attenuation.

ACRE considered the potential for secondary transmission of the GMO to susceptible animals. The Sendai virus is essentially a virus of rodents but there is a possibility that pigs may be susceptible. Humans are not known to harbour the virus. ACRE noted that preclinical studies involving a non-recombinant Sendai virus vaccine did not result in shedding from the human volunteers. Preclinical studies using SeV-G (NP) that involved rodents and non-human primates resulted in transient (up to eight days), low-level shedding. However, the viral titre was not sufficient to cause secondary transmission.

ACRE discussed a hypothetical worst case scenario whereby increased shedding of the GMO occurred e.g. facilitated by the infection of a volunteer with a second virus. ACRE concluded that the monitoring and risk management practices proposed by IAVI were appropriate to deal with unanticipated levels of shedding. It noted that the GMO was a highly attenuated version of the wild type virus.

Whereas ACRE concluded that IAVI had proposed appropriate management measures to minimise potential exposure within the area of administration, including the treatment of waste, it considered that the disinfection of the clinical environment should be carried out with a preparation where the 'in use' dilution is described in terms of parts per million of available chlorine. This should be used at a concentration appropriate to the specific use (e.g. cleaning post procedure or management of spill) in accordance with local NHS trust infection control policy rather than advocating 10% bleach as described in the risk assessment.

ACRE also concluded that the duration and frequency of monitoring of volunteers was sufficient, as subjects would be closely monitored and appropriately assessed and treated should they develop signs or symptoms of infection with the GMO.

ACRE’s advice was published on 5 December and consent was granted on 10 December.

2.2. 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:

2.2.1. Application from Monsanto for authorisation under Regulation (EC) No. 1829/2003 to cultivate MON88017 maize – ref. EFSA-GMO-CZ-2008-54

At its February meeting ACRE considered the EFSA opinion on MON88017 maize, which had been notified for cultivation, import, processing and use as food and feed in the EU. The committee was informed that the EU Commission was not currently bringing forward draft decisions on applications that include cultivation in their scope. However, ACRE was asked to begin formulating its advice on this application.

MON88017 maize contains a modified Cry3Bb1 protein that confers tolerance to certain coleopteran insect pests, including members of the corn rootworm complex. This includes the Western corn rootworm, which is a pest in some parts of the EU. This GMO is also tolerant to glyphosate herbicides (it expresses a modified version of the CP4 EPSPS protein). ACRE was requested to review its comments when this application was submitted in 2008 in the light of the further information provided by the applicant (Monsanto) and in response to EFSA's opinion.

Previously, ACRE considered that Monsanto had not investigated the hazard to non-target chrysomelids (leaf beetles) satisfactorily. EFSA and the competent authority leading on the assessment of this application (Belgium) requested more information from the company on this aspect and on the potential impact on non-target organisms more generally. ACRE noted that EFSA had carried a very detailed consideration in its opinion. ACRE agreed with EFSA's conclusion that 'the risk to valued chrysomelid species is likely to be minimal'.

ACRE also discussed the advice of COGEM, its Dutch counterpart. COGEM had concluded that Monsanto has not demonstrated that the risk to non-target arthropods is negligible and recommended that further studies on susceptible insects are required. ACRE however agreed with EFSA's conclusion that the evidence demonstrates that the Cry3Bb1 protein produced by MON88017 is unlikely to harm populations of non-target arthropods.

With respect to the potential for herbicide regimes used in association with this GMO to have greater indirect effects on biodiversity compared with conventional systems, EFSA has advised that the company recommend stewardship schemes to farmers, the implementation and efficacy of which are tested. EFSA has suggested testing these through questions on herbicide/ crop management practices and weed populations in the farm questionnaire and a strictly limited number of 'more specific and focussed multi-annual scientific studies at sites where baselines have been established'. ACRE agreed with the use of farm questionnaires but was not convinced that further studies would necessarily inform the existing risk assessment. It discussed the use of post-market environmental monitoring to identify locations in the EU where the biodiversity in conventional maize fields may be relatively high. This is because it is feasible, at least in theory, that altered weed management practices in these particular situations could have an ecologically-relevant impact on biodiversity.

EFSA had identified the evolution of pest resistance as an environmental risk. However, this was not discussed in any detail in the opinion and it was not clear what the basis for this view is. ACRE welcomed EFSA's view that insect resistant management practices, including the use of refugia should be continually updated in the light of new evidence and new innovations.

ACRE considered the case specific monitoring of MON88017 maize in the light of the conclusions on the environmental risk assessment. It was then asked to consider the general surveillance plan for MON88017 maize. Monsanto had outlined a multi-tool approach that EFSA and ACRE have agreed with. ACRE discussed the recommendations from EFSA on improving the general surveillance plan. ACRE agreed with some of the points; for example, with respect to the farm questionnaire - the provision of more information on herbicide applications and clarity about what

comparators respondents were using. ACRE considered that in cases where comparisons were made with non-GM maize fields on the same farm at the same time, this may address the need for specific research trials. However, ACRE considered that some of the EFSA's suggestions may not be proportionate or practical. In particular, it was concerned about recommendations to modify existing monitoring networks. ACRE also thought that questions in the farm questionnaire on ease of working the soil, surface ponding and soil pan formation should be included.

2.2.2. Application from Syngenta for authorisation under Regulation (EC) No. 1829/2003 to cultivate GA21 maize – ref. EFSA-GMO-UK-2008-60

At its February meeting ACRE considered the EFSA opinion on GA21 maize, which had also been notified for cultivation, import, processing and use as food and feed in the EU GA21 maize has been genetically modified so that it is tolerant to the herbicide glyphosate. ACRE noted that the applicant, Syngenta, had developed a structured approach to characterising the environmental risk. ACRE also noted that the general surveillance plan provided in this application was more detailed than that for MON88017 maize; in particular, ACRE was positive about the proposed farm questionnaire included in the plan. It considered that the farm questionnaire proposed by Syngenta was better than the questionnaire produced by Monsanto. EFSA's recommendations on the post-market environmental monitoring plan in this application were consistent with those for MON88017 maize.

2.2.3. EFSA Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified 1507 maize for cultivation

ACRE was asked to comment on the EFSA opinion updating the environmental risk assessment for maize 1507. The Committee was asked to consider the robustness and suitability of a model that had been used to estimate the risk of mortality to European non-target Lepidoptera via ingestion of maize 1507 pollen and the efficacy of mitigation measures.

ACRE concluded that the model is sound as is the basic idea of investigating density effects on non-target lepidoptera through modelling. However, the committee considered that the outputs were highly theoretical because of the extreme parameter values used in the model and that these did not provide a sound scientific basis to inform risk management measures.

ACRE considered 1507 maize again in October, together with another insect-resistant maize event, Bt11. A key element in both opinions is a model developed by EFSA to further characterise the hazards posed to non-target Lepidoptera by pollen from these Bt maize events. Following previous discussions of this model, ACRE in October was requested to develop this consideration so that its advice explained how the outputs could be used in making regulatory decisions including imposing conditions of consent.

ACRE reiterated its previous view that the model was helpful in identifying where gaps in data exist and in establishing that there are spatial thresholds of Bt maize cultivation below which, risk to non-target lepidoptera will be minimal. However, it considered that the outputs of the model could be applied inappropriately in a regulatory context and might increase the likelihood that hazard might be interpreted as risk. ACRE emphasised that the models do not provide evidence of harm. With respect to dealing with critical uncertainty associated with characterising the risk to non-target lepidoptera, ACRE considered that case-specific monitoring is likely to be difficult in practice. It considered that management measures described by EFSA, such as the adoption of border rows, could provide alternative options for dealing with uncertainty in situations where Member States have reason to be concerned about the impact on certain non-target lepidopteran species. ACRE recommended that desk studies should be used to determine whether larval stages of non-target Lepidoptera would be exposed to Bt maize pollen in maize fields/ field margins to support the adoption of such measures. The committee noted that EFSA had commissioned a database of non-target arthropod species to support environmental risk assessments (a report describing the database was provided to ACRE for information). ACRE noted that in areas of high pest pressure, where these GMOs are likely to be adopted, it is likely that the most appropriate comparator would be maize sprayed with a foliar insecticide.

2.2.4. Application from Bayer CropScience and Monsanto for authorisation under Regulation (EC) No. 1829/2003 to use Ms8 x Rf3 x GT73 oilseed rape for food and feed, import and processing in the EU – ref. EFSA-GMO-NL-2009-75

In July ACRE considered this application for the import and processing of Ms8 x Rf3 x GT73 oilseed rape. ACRE had previously advised on applications for Ms8 x Rf3 and for GT73 oilseed rape. This application is for a stacked combination, which combines a hybridisation system and tolerance to glufosinate ammonium (Ms8 x Rf3) with tolerance to glyphosate herbicides (GT73).

ACRE was satisfied that on the basis of the information provided at this stage that in the UK, the import and processing of Ms8 x Rf3 x GT73 would not pose a greater risk to the environment or human health than non-GM varieties of oilseed rape. ACRE noted the additional information provided in this application on the location of crushing and processing facilities for oilseed rape in the UK. The committee noted that in the UK processing of imported oilseed rape grain occurs at the port and that therefore viable grain is not transported inland. This further limits the exposure of the environment to Ms8 x Rf3 x GT73 grain.

ACRE concluded that the presence of tolerance to glyphosate and glufosinate ammonium herbicides would confer a fitness advantage only in areas where these herbicides are used. The Committee noted that in the UK, there is no significant use of either herbicide in semi-natural habitats. Glyphosate may, however, be used outside the agricultural environment. ACRE therefore considers it important that clear guidance is provided to operators to ensure that spillage of grain is effectively dealt with if it occurs and to enable effective identification and control of any volunteer plants occurring within the port and processing areas.

2.2.5. Application from Monsanto for authorisation under Regulation (EC) No. 1829/2003 to use MON88302 oilseed rape

for food and feed, import and processing in the EU – ref. EFSA-GMO-BE-2011-101

ACRE considered this application for the import and processing of MON88302 oilseed rape. MON88302 oilseed rape has been modified to produce the CP4 EPSPS protein, conferring tolerance to glyphosate herbicides.

ACRE considered that the genetic characterisation of the MON88302 event was thorough. The committee was also satisfied with the information provided on the phenotypic and agronomic characteristics. ACRE considered that its comments relating to the herbicide tolerance of Ms8 x Rf3 x GT73 oilseed rape applied in this case. Therefore, the committee agreed to draft advice on herbicide tolerant oilseed rape based on this. ACRE would then determine on a case by case basis whether this advice would apply to each new application for import and processing of herbicide tolerant oilseed rape.

2.2.6. Application from Monsanto for authorisation under Regulation (EC) No. 1829/2003 to cultivate MON89034 maize in the EU – ref. EFSA-GMO-BE-2011-90

ACRE considered this application for cultivation of MON89304 maize. MON89304 maize is modified to produce the Cry1A.105 and Cry2Ab2 proteins. This confers resistance to certain *Lepidopteran* pests. ACRE has previously considered the MON89304 event in applications for cultivation of the stacked events MON89034 x MON88017 and MON89304 x NK603. Because of this, the Committee gave particular consideration to the non-target organisms section of the application, which had been the subject of previous discussions.

ACRE noted that the Cry1A.105 and Cry2Ab2 proteins produced in MON89304 maize are specific to *Lepidoptera*. As non--target *Lepidoptera* do not feed on maize, exposure would occur through MON89304 pollen falling onto host plants in the surrounding area. The Committee noted that maximum exposure to pollen would occur within and immediately adjacent to the field and that pollen levels decline

rapidly outside the field area. Therefore, ACRE considered that the risks to non-target organisms from cultivation of MON89304 maize would be negligible.

ACRE considered that the post market environmental monitoring plan proposed by the applicants was appropriate for MON89304 maize, but commented that improvements could be made to the farm questionnaire to maximise its value for detected unanticipated adverse effects.

2.2.7. Application from Monsanto for authorisation under Regulation (EC) No. 1829/2003 to cultivate soybean 40-3-2 – ref. EFSA-GMO-NL-2005-24.

ACRE discussed this application at its October meeting. It considered the relative impact on farmland biodiversity resulting from altered herbicide regimes associated with this GM soybean. ACRE considered that EFSA had provided a very comprehensive and high quality review of this issue and that it had clearly identified the major risk factors to weed communities. ACRE considered that this list provided a good basis for questions in the farm questionnaire to determine whether changes in weed communities had occurred. ACRE considered that uncertainty as to the impacts of herbicide use would be most effectively addressed by post market environmental monitoring using such a farm questionnaire. ACRE did not consider that herbicide management regimes should be specified in more detail, acknowledging that appropriate management regimes, and the baseline comparison, would vary depending on the local environment, on agronomies and over time.

ACRE noted that the herbicide glyphosate has been shown to have impacts on soil microbes and the root nodule forming abilities of legumes. Although this could result in reduced yields in soybean, recent studies suggest this is not the case. ACRE noted that impacts on soil microbes within the field would be affected by the nature of the rotation as well as the innate resilience of the soil microflora. ACRE considered the potential for impacts on legumes in the field margins and concluded that this could be addressed through questions in the farm questionnaire.

ACRE considered the risks to non-target organisms from the cultivation of 40-3-2 soybean. EFSA considered that there were insufficient data on pollinators in the application and recommended that the applicant carry out multi-site studies involving honeybees post authorisation. It did not consider that pre-trial studies were necessary as the CP4 EPSPS protein produced by 40-3-2 soybean is not toxic at biological concentrations and none of the molecular, compositional data or studies with other non-target organisms indicate that there would be an adverse unintended effect on honeybees. As there is no valid risk hypothesis, ACRE did not consider that these additional studies were warranted. However, ACRE noted that weed community shifts caused by altered herbicide use could potentially impact on bees. Therefore, ACRE recommended that general surveillance should be sufficiently sensitive to determine whether significant changes in weed communities had occurred.

2.3 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 noted a report on one such application in 2012. 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 examined a range of different issues including the EFSA guidance on the environmental risk assessment of genetically modified animals and reports from its sub-groups on post-market environmental monitoring and new techniques.

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 225 cases in 2012.

2.3.1. EFSA consultation – guidance on the environmental risk assessment of genetically modified animals

In July ACRE discussed EFSA's draft guidance for public consultation on the environmental risk assessment (ERA) and post market monitoring of GM animals, which had a deadline for comments of 31st August 2012.

ACRE noted that EFSA had adopted the same framework as the guidance on the ERA of GM plants published in 2010. ACRE welcomed the efforts of EFSA to adopt a common approach and to develop a structured methodology (in particular, the use of problem formulation) for the ERA of GM animals. In particular, ACRE found the decision tree, included in the chapter on GM fish provided a useful framework and recommended that this approach should be used consistently throughout the document.

In general, ACRE concluded that the guidance attempted to provide too much detail. ACRE advised that the guidance would be more helpful if it focused on providing a high level framework to enable applicants to identify and define risks on a case by case basis. It considered that in attempting to provide an exhaustive consideration of potential risks, it obscures the essential framework for risk assessment and in attempting to be comprehensive, increased the potential significance of ignoring issues that were not considered in the guidelines.

ACRE recommended that the guidance should be amended to improve consistency between chapters, remove repetition within chapters and to clearly formulate the

scope of each subsection. The committee also noted that EFSA had referred to potential benefits in the guidance. ACRE agreed that the limitations of considering risk in isolation are highlighted when considering some of these GM animals, e.g. GM insects released with the aim of controlling human diseases, such as malaria. In general it noted that there may be more uncertainty associated with the environmental risks posed by GM animals than by GM crop plants. An assessment of the potential benefits may help determine the significance of this uncertainty, ACRE commented that risk /benefit analysis is used in other regulatory assessments e.g. for medicines.

APPENDIX I

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 practise 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 website[1] 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.

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[2] 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 are 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] http://www.defra.gov.uk/acre/meetings/index.htm

[2] http://www.defra.gov.uk/acre/about/interests.htm

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 2012

Chair	**Main Expertise**
Professor Christopher Pollock	Plant breeding, plant physiology, agronomy
Members	
Professor Jeff Bale	Entomology, ecology (until 17/8/12)
Professor Kathy Bamford	Medical microbiology
Dr Mike Bonsall	Entomology, evolutionary ecology, ecology and mathematical biology
Professor James Bullock	Plant population ecology, agricultural ecology and conservation science (until 25/10/12)
Dr Rosemary Collier	Applied entomology, horticultural crops (from 1/9/12)
Professor Jim Dunwell	Plant biotechnology
Professor Les Firbank	Agri-ecosystems
Professor Rosie Hails	Pathogen population ecology, plant ecology, entomology
Dr Matthew Heard	Community ecology, plant population ecology, agricultural ecology, conservation science (from 26/10/12)
Professor David Hopkins	Soil biology and biochemistry
Dr Ieuan Joyce	Farming practice
Simon Kerr	Agronomy (from 1/9/12)
Professor Keith Lindsey	Molecular biology
Mr Jim Orson	Farming practice, agronomy (until 17/8/12)
Professor Andy Peters	Clinical development and regulation of vaccines

Post-market Environmental Monitoring Sub-group

Chair

Professor Rosie Hails

Members

Professor James Bullock

Professor Les Firbank

Professor David Hopkins

Dr Ieuan Joyce

Mr Jim Orson

Professor Chris Pollock

Chris Chesterton, Natural England

Mark Clook, Chemicals Regulation Directorate, Health & Safety Executive

Dr Jonathan Davey, Science & Advice for Scottish Agriculture

Dr Terry Parr, Centre for Ecology & Hydrology

Dr Phil Smith, Environment Agency

Dr Jonathan Storkey, Rothamsted Research

Dr Lawrence Way, Joint Nature Conservation Committee

Secretariat (Defra)

Dr Kath Bainbridge

New Techniques Sub-group

Chair

Professor Jim Dunwell

Members

Professor Chris Pollock

Professor Keith Lindsey

Secretariat (Defra)

Dr Louise Ball

APPENDIX IV

DETAILS OF MEMBERS OF ACRE

Professor Christopher Pollock CBE (Chairman)

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. Appointed as chairman on 1 September 2003. Current term runs from 1 September 2009 to 31 August 2013.

Dr Kathy Bamford

Imperial College

Expertise: Medical Microbiology

Kathy Bamford is a consultant Medical Microbiologist at Imperial College Healthcare NHS Trust (ICHT) and Visiting Professor in the Dept Infectious Diseases and Immunity at Imperial College. She is a member of the Department of Health Gene Therapy Advisory Committee. Her expertise is in the aetiology diagnosis and management of human infection with research interests in the immunopathology 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 2010 to 30 November 2013.

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, a member of the UK Insecticide Resistance Action Group and a member of the Royal Horticultural Society Science Committee. 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 based at the Faculty of Biology at the University of Leeds, where 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 on the Board of the Red Tractor scheme with responsibilities for developing environment standards for UK agricultural produce, and also undertakes consultancy. His research background is in large-scale 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, was a Co-ordinating Lead Author for the International Assessment of Agricultural Knowledge, Science and Technology for Development, 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.

Professor Rosemary Hails MBE

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 9 October 2012 to 8 October 2016.

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. 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 and this term runs until 10 April 2014.

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

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. First appointed to ACRE on 1 September 2003. Current term runs from 1 September 2009 until 31 August 2013.

Professor Andrew Peters

Arpexas Consultancy Ltd.

Expertise: clinical development and regulation of vaccines

Professor Peters runs his own 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 Jeff Bale (retired from ACRE 17 August 2012)

School of Biosciences, University of Birmingham
Expertise: Entomology, plant biology, ecology and statistics

Professor Bale is Professor of Environmental Biology in the School of Biosciences at the University of Birmingham and a Deputy Pro-Vice Chancellor of the University. He has expertise in insect biology, ecology and pest management, including the development of risk assessment protocols for the use of non-native species in biological control. Prof. Bale is a Fellow of the Royal Entomological Society and a Council member of the British Ecological Society. He is a member of the editorial board of the Bulletin of Entomological Research, the Journal of Insect Physiology and Physiological Entomology, and a member of NERC's pool of chairs of grants boards. First appointed to ACRE for 3 years from 18 August 2002.

Professor James Bullock (retired from ACRE 25 October 2012)

Centre for Ecology and Hydrology, Wallingford
Expertise: plant population ecology, agricultural ecology, conservation science

Professor Bullock is a research scientist at the Centre for Ecology and Hydrology, and holds visiting professorships at Liverpool University and Bournemouth University. He carries out research into plant population and community ecology and their applications for species and habitat conservation, risk assessment of genetically modified plants and weeds, control of invasive species and restoration of ecosystems. He is General Secretary of the European Ecological Federation and is lead author for the UK National Ecosystem Assessment. First appointed to ACRE on 26 October 2009.

Mr Jim Orson (retired from ACRE 17 August 2012)

NIAB TAG Group

Expertise: Agronomy, farming practice and plant biology

Mr Orson is a specialist adviser in the NIAB TAG Group. He has experience as a practical agronomist with arable systems and weed control skills and has close links with farmers. He was previously employed by ADAS and has served on the Advisory Committee on Pesticides. He served on the Scientific Steering Committee for the Farm-scale Evaluations. He is Vice-chair of the British Crop Production Council and a board member of the Voluntary Initiative Community Interest Company. First appointed to ACRE on 18 August 2002.

.

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 2012

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, Gillead, Baxter	Support to attend meetings, honoraria	DH	Member of Gene Therapy Advisory Committee Expert Reference Group MRSA Screening	None	
	Pharmacia, Pfizer, Baxter	Advisory boards, expert panel, review	Royal College of Pathologists	Examiner Member of National Quality Assurance Advisory Panels for Microbiology		
	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		

			International Child Care Trust	Charity fundraising committee member		
Dr Michael Bonsall	Oxitec Ltd	BBSRC – Link Grant 2010-13	University of Oxford	Employee	Academy of Medical Sciences	Director of Medical Policy
			St Peter's College, Oxford	Fellow, employee		
			BBSRC, NERC, Royal Society	Funding for research		
			EFSA	Member of the GM insect working group		

Dr Rosemary Collier	Rijk Zwaan	Funding for research	University of Warwick	Employee	Fraser Associates UK Limited	Director; innovation and resilience in the agri-food supply chain.
	DuPont	Funding for research	Harper Adams University College	Visiting Professor	Abacus Organic Associates	Associate
			BBSRC EPSRC Defra AHDB	Funding for research	Warwickshire Rural Hub	Director
	G's	Funding for research	RHS Science Committee	Member (unpaid)		
			Insecticide Resistance Action Group	Member (unpaid)		
Professor Jim Dunwell	None		University of Reading	Employee	None	
			EU	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
	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
			British Ecological Society	Member of the Council, Publications Committee, Policy and Public Committee and Finance Board (unpaid)		
			Oxford University	Senior Research Associate		

			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	Countryside Council for Wales	Member	None	

		business in partnership	Joint Nature Conservation Committee	Member		
			Upland Forum	Member		
			Elan Valley Trust	Trustee		
Simon Kerr			NIAB	Employee		
Professor Keith Lindsey	Creative Gene Technology Ltd.	Scientific Director	Durham University	Employee	Durham University	Employee
			BBSRC, EPSRC	Funding for research		
			BBSRC Council	Paid committee member		
	Sirius Minerals plc	Research funding	Society of Biology	Fellow		
			Society for Experimental Biology	President, Director		
			New Phytologist Trust	Trustee		

Professor Andrew Peters	Arpexas Ltd	Managing director	Global Alliance for Livestock Veterinary Medicines	Consultant	None	
	Aspen BioPharma Inc	Consultant	University of Nottingham	Visiting professor		
	Bayer Animal Health	Consultant	Wildlife Ark Trust	Consultant		
	Avacta Animal Health	Consultant				
	Elanco	Consultant				
	Pfizer	Shares, pension				
	Pinnaderm	Consultant				
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		

Former members:

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 Jeff Bale	Koppert Biobest	Part funding for PhD student	University of Birmingham	Employee	None	
			BBSRC, NERC, Defra	Funding for research		
Prof James Bullock	None		NERC	Employee	None	
			NERC, ESRC, BBSRC, Defra, Natural England, European Commission	Funding for research		
			Bournemouth University, Liverpool University	Visiting professor (no remuneration)		
			British Ecological Society, Dorset Wildlife Trust,	Member		
Jim Orson	Small area of arable/grass land farmed by a tenant	Owner	NIAB TAG Group	Employee	None	
			British Crop Production Council	Vice-chairman		
			International Fertiliser Society	Member		
			Voluntary Initiative Community Interest Company.	Board member		

APPENDIX VI

ACRE advice issued in 2012

Advice on imports and processing of GM crop 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 (October 2011) – added 4 soya bean applications MON 40-3-2, A5547-127, MON87701 and 356043

Advice on a GM wheat research trial (September 2011)

Advice on a plant breeding technique involving oligo-directed mutagensis: RTDS™ (June 2011)

Advice on a GM typhoid vaccine research trial (March 2011)

Advice published on food and feed notifications submitted under Regulation (EC)1829/2003. General advice on notifications for import and processing of GM crops that are unable to grow under UK conditions (March 2011) - text updated

Report published on ACRE information-gathering workshop on GM insects (March 2011)