Advisory Committee on Releases to the Environment

Annual Report 2015

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Foreword by the Chair, Professor Rosie Hails

This report covers ACRE's activities in 2015. During the year ACRE held two full committee meetings which were open to the public as well as four meetings of the sub-group set up to examine environmental harm. In addition we carried out some of our more routine business by email and seven pieces of written advice were published. Our advice and other details of ACRE and its output can be found on the ACRE pages of the gov.uk website.

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. We considered EFSA opinions on marketing applications for maize and soybeans and published advice on eight of them. These applications were for import only; none of them included cultivation in its scope. In each case ACRE was satisfied that the GMO posed no greater risk than its conventional counterparts.

As in previous years we were also asked to advise on applications to market human and veterinary medicinal products under Regulation (EC) No. 726/2004. We reviewed three applications for the marketing of veterinary medicines and two for human gene therapy products.

Advice on research trials

We advised on an application made to the Northern Ireland competent authority for a trial of a vaccine against typhoid and E coli. Following our advice, Northern Ireland minsters granted consent in April.

Harm Sub-group

In February 2014 we set up a sub-group to follow up ACRE's 2013 programme of work considering how environmental risk assessment of GMOs could be more effectively implemented under current EU legislation. One conclusion of that work was that there is a need for greater clarity around what type and level of environmental impact should be considered to result in environmental harm. We considered that there is a need to further resolve this issue to give clarity to applicants on what impacts to measure and on what scale, and to ensure that the broader agro-ecological context is taken into account when decisions are made about GM crop cultivation and other GMO releases. We have continued working on this during the year and expect to publish our report in 2016.

I have been one of the members of this sub-group and I am very grateful to Rosemary Collier for chairing us so effectively.

Other activities

ACRE also gave written evidence to the Commons Science and Technology Select Committee, which undertook an inquiry into, and I attended to give oral evidence in January 2015.

The House of Lords Science and Technology Select Committee undertook an enquiry in to GM insects in the autumn. ACRE submitted written evidence on the questions relevant to its remit and I attended to give evidence in October.

We have been taking a continuing interest in developments in synthetic biology and have developed a closer working relationship with the Scientific Advisory Committee on Genetic Modification on this issue. Peter Lund is now a member of this committee as well as ACRE so is acting as a link between the two.

Defra's ministers and chief scientific adviser requested a review of the function of all of the department's scientific advisory bodies, to consider how these bodies could be structured and operate to optimise efficiency and best meet Defra's evidence needs. I was very happy to be able to participate in a meeting of advisory body chairs in September which considered how we should approach this review,

Membership

We were pleased to welcome back Rosemary Collier, Simon Kerr and Matt Heard for a further term. Les Firbank, Ieuan Joyce and Kathy Bamford retired from the committee during the year. I am very grateful to them for their commitment and the valuable contributions they have made our work.

Looking forward to 2016

I am very keen to see that ACRE continues to operate in an open and transparent manner so we will continue to hold meetings in public, for people to attend as observers. We have been able to accommodate this without any disruption to the operation of our meetings.

I am happy for us contribute where appropriate to the review of Defra's advisory bodies to ensure we have a positive outcome for ACRE which does not compromise our ability to provide advice.

We are expecting the harm sub-group to complete its work and publish its report in 2016. This will provide guidance on how environmental risk

assessment of GMOs could be based on a more coherent understanding of environmental harm in its broader agro-ecological context.

ACRE will continue to keep up to date with developments in synthetic biology and will wish to have the opportunity to comment where appropriate. 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. We consider that some form of oversight of this area is necessary and that there are a range of options worth exploring to achieve this, including working more closely with other advisory committees. We now have a very useful link with SACGM in Peter Lund, who now sits on our committee and SACGM.

I am grateful to the members, assessors and the secretariat for the expertise and commitment they bring to the committee. They ensure we can continue to provide the high-quality independent scientific advice which ministers expect.

Rosie Hails

February 2016.

Chapter 1

Main activities in 2015

1.1 Introduction

This is the twenty-second annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2015. 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.

1.2 ACRE's achievements

ACRE held two regular committee meetings during 2015 but there was also a significant amount of consultation by e-mail and via our Huddle workspace. As part of our commitment to transparency and openness in the way we conduct our business, all of our main committee meetings are now open to the public to attend as observers, though if necessary we would still cover any commercially confidential or otherwise sensitive issues in a closed session.

Much of our effort has been concentrated in our harm sub-group which was set up in February 2014. It met four times during 2015. The sub-group has followed up ACRE's 2013 work examining the most effective approach to environmental risk assessment of GMOs under the current regulatory framework. It is developing a framework for assessing harm that can be used in the environmental risk assessment of genetically modified organisms. The sub-group's final report will be published in 2016.

ACRE considered in March an application from Prokarium Ltd for a trial in Northern Ireland of an orally-administered vaccine against typhoid and enterotoxigenic E. Coli. ACRE advised that the trial was safe to proceed and Northern Ireland ministers granted consent on 30 April.

The House of Commons Science and Technology Select Committee completed its inquiry on advanced genetic techniques for crop improvement. ACRE provided written evidence in 2014 and the Chair attended to give oral evidence on 7 January 2015. Two recommendations from the inquiry report related specifically to ACRE; these were expanding its remit to cover all novel plant traits and establishing a citizen's council to advise on social and ethical aspects. These recommendations will not be followed up.

The House of Lords Science and Technology Committee also undertook an inquiry during the year, into GM insects. ACRE submitted a response on questions relating to the EU regulatory framework and the Chair attended to give evidence in October.

The triennial review of ACRE announced to Parliament in March 2014 was published a year later. These reviews are a standard requirement for non-departmental public bodies such as ACRE and aim to provide a robust challenge to the continuing need for the body and to check whether its functions and form are appropriate. The review recommended ACRE should be retained in its present format with its current remit.

Defra's ministers and Chief Scientific Advisor have requested a review of the function of all Defra's expert evidence advisory bodies. In September the Chair participated in a meeting of Defra advisory body chairs, in response to this request. The review will look at how we can structure and operate bodies to optimise efficiency and better meet Defra's evidence needs, in an era of declining resources.

EFSA opinions on food and feed marketing applications for cotton, maize and soybeans were considered by the committee and advice was published on four maize and four soybean applications. These were all for uses excluding cultivation. In each case ACRE agreed with EFSA that the GMO posed no greater risk than its conventional counterpart and this was reflected in the published advice.

ACRE also reviewed applications for the marketing of veterinary medicines and human gene therapy products, in accordance with the medicinal products Regulation (EC) No. 726/2004.

ACRE reviewed developments in synthetic biology and agreed some sort of oversight was necessary with regard to products which could cause regulatory challenges. ACRE agreed to work more closely with the Scientific Advisory Committee on Genetic Modification and during the year Peter Lund was appointed as an expert sitting on both committees. ACRE also agreed to contribute to consultation on an EU opinion considering gaps in knowledge for risk assessment, and research recommendations.

In March ACRE examined a research paper on the distribution of maize pollen from sites where maize was being cultivated, and considered what value this had for devising separation distances which would allow the co-existence of GM and non-GM crops.

In September ACRE considered three EFSA consultation documents on environmental risk assessments, and provided comments. ACRE focussed mainly on the document proposing a framework for defining protection goals for biodiversity which can be used in risk assessments.

1.3 Membership of the committee

ACRE members are appointed through open competition and their appointments 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.

No new members were appointed during 2015 but Rosemary Collier, Simon Kerr and Matt Heard were all appointed for a second term. Les Firbank, Ieuan Joyce and Kathy Bamford all stepped down after six years on the committee and a recruitment campaign was set up to find replacements. .

Biographical details of all the members who served on the committee in 2015 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 in the Animal and Plant Health Agency.

The secretary to the committee was Louise Ball. The secretariat also included Martin Cannell, David Sherlock and Ellen Colebrook (who left during the year). 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.

1.4 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 ACRE's Harm Sub-group continued tis work on defining environmental harm, following up ACRE's 2013 programme of work considering how environmental risk assessment (ERA) of GMOs could be more effectively implemented under current EU legislation. One conclusion of that work was that there is a need for greater clarity around what type and level of environmental impact should be considered to result in environmental harm. ACRE identified a need to further resolve this issue to give clarity to applicants on what impacts to measure and on what scale, and to ensure that the broader agro-ecological context is taken into account when decisions are made about GM crop cultivation and other GMO releases. In 2015 five ACRE members served on this sub-group, chaired by Dr Rosemary Collier, and it met four times. Its output will be a report and updated guidance for risk assessors, expected early in 2016.

ACRE reviewed progress to date at its March meeting. The sub-group had been focussing on developing a framework for assessing harm. ACRE considered that the approach the sub-group is developing provided a useful way of structuring relevant evidence in order to focus attention on key information needed to assess harm, and suggested other relevant work that

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

might inform the tools being developed. The sub-group's final report is expected to be completed in 2016.

1.5 Work plan over the next year

1.5.1 Assessment of release and marketing applications

ACRE will continue to advise on applications for crop and clinical research trials as required, and will advise on food and feed and other marketing applications.

1.5.2 Harm Sub-group

ACRE's Harm sub-group will complete its work, present its findings to the full committee, publish its report to Defra and update ACRE's guidance for risk assessors. The sub-group aims to develop tools that will be of practical use when considering potential for harm in the GM ERA and decision-making process.

1.5.3 Public engagement

ACRE is committed to transparency and openness in the way it conducts its business and will continue to hold its full committee meetings in public. Members of the public are 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.

1.5.4 Review of DEFRA's advisory bodies

Acting for Defra's ministers and Chief Scientific Advisor, the Defra Science Advisory Council will continue to conduct a review of the structure, function and operation of existing groups, to advise the Chief Scientific Advisor on options for how these groups could be structured and operate to optimise efficiency and better meet Defra's evidence needs. The review also covers the governance and administrative aspects of the committees to ensure consistency in approach and adequate reporting. ACRE and the secretariat will contribute to the review as required.

1.5.5 Synthetic biology

The secretariat 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.

ACRE will assess how it wishes to engage with and monitor new developments and expects to benefit from Peter Lund's appointment to SACGM. This should help to ensure that Defra maintains an appropriate level of awareness of scientific and technical developments in molecular and environmental microbiology and synthetic biology, in particular at the boundary between contained use and deliberate release of GMOs

ACRE aims to contribute to the consultation/peer review process for the most recent draft opinion of the three EU scientific committees on synthetic biology. This opinion aims to identify major gaps in knowledge to be considered for performing a reliable risk assessment and to provide research recommendations resulting from gaps.

1.5.6 GM insects

At the end of 2015 the House of Lords Science and Technology Select Committee conducted an inquiry into the potential of, and regulatory environment for, GM insect technologies. ACRE submitted written evidence and the chair appeared before the Committee to give oral evidence on behalf of ACRE. ACRE will consider the Select Committee's recommendations and where appropriate, will take these into account in its 2016 work plan.

1.6 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), where appropriate facilitating initiatives such as joint responses to EFSA consultation documents. As mentioned above, the appointment of Peter Lund to SACGM will strengthen links with that committee on synthetic biology.

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

2.1 Regulatory framework

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 has in recent years seen various applications for cut carnation flowers follow this route.

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. We advised on one human gene therapy and two veterinary products in 2014. 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.

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

2.2.1. Application for Part B consent from Prokarium Ltd to release live attenuated genetically modified Salmonella enteri (serovar typhi) for use in Phase I clinical trials in Northern Ireland ref 15/R47/01/NI

In March ACRE was asked to consider an application from Prokarium Ltd made to the Northern Ireland competent authority to conduct a clinical trial in a Belfast. The product to be used a preparation containing genetically modified Salmonella typhi for use as an orally administered vaccine against Typhoid fever and enterotoxigenic E.coli (ETEC). ACRE had previously reviewed the risk assessments for clinical trials that involved the parental strain (ZH9) and were familiar with this organism. However, it was made clear that their deliberations should be focussed on assessing the risk to human health and the environment posed by the new GMO, rather than comparing the risk to that of the parent. The parental GMO (ZH9) had been attenuated by deletions to two genes resulting in a non-infectious version of Salmonella typhi that was unable to colonise the human host.

The new application concerned a further modification to the genetically modified parent, namely the introduction of a plasmid (pTYPHETEC) encoding proteins intended to raise an immune response against ETEC. Since this is a gastrointestinal bacterium, it is expected to be shed in the faeces of patients and the applicant had provided details of the length of time this shedding persists, based on the ZH9 attenuated precursor strain. The applicant acknowledged that such GMMs entering the sewage system have the potential to come into contact with other environmental niches and had undertaken a number of studies to investigate their likely environmental fate in untreated sewage, river water, seawater and soil.

ACRE was asked to consider the risk assessment in three parts: molecular characterisation, potential hazards and routes of exposure, and risk management measures. Members were satisfied that the mechanism underlying the attenuating deletions in the aroC and ssaV genes were established and well understood, and that the risk of reversion to wild type was negligible (noting also that Salmonella typhi exhibits very low levels of competence for DNA uptake). ACRE noted the absence of antibiotic markers and mobilisation factors on the pTYPHETEC plasmid and that whilst the arrangement of colonisation factors present on the plasmid would not be present in natural populations of ETEC, this would not raise a concern.

Members were satisfied that the applicant had thoroughly characterised the relevant hazards and potential routes of exposure and provided sufficient data to support these. The studies investigating environmental fate and persistence in test media representing niches other than the established sewage system were noted as useful.

Studies on shedding with the parental organism had demonstrated a maximum persistence of 17 days and it was noted that there was no plausible mechanism by which presence of the pTYPHETEC plasmid would alter that statistic.

A potential route of environmental exposure was noted to be at the point of administration. The applicant was considered to have treated this issue thoroughly as well as having outlined ‘clinical waste’ as the appropriate route for waste disposal and strict exclusion criteria to protect vulnerable groups. ACRE noted that there were no specific plans to investigate shedding profiles as part of this trial and advised that producing this information alongside efficacy data might be desirable, especially if the product was to go further along the regulatory pathway towards full commercialisation. In conclusion, ACRE were content that the hazards associated with this trial had been fully

characterised and that appropriate risk management measures were in place to ensure that there would be negligible risk to human health and the environment.

Advice on this trial was published on 13 May and the consent was issued on 30 April.

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 5307 maize ref. EFSA-GMO-DE-2011-95

ACRE considered in May Syngenta's application to market GM insect-resistant 5307 maize for food and feed uses, import and processing, once EFSA's opinion was available. This application does not include cultivation within its scope. This maize has been modified to express two proteins: eCry3.1Ab and PMI. The eCry3.1Ab gene has been synthesised based on cry1Ab and mcry3A genes. The eCry3.1Ab protein confers resistance to certain coleopteran pests including the Western corn rootworm and related Diabrotica species. The pmi gene derived from E.coli encodes phosphomannose isomerise, which is used a selectable marker by allowing transformed maize cells to utilise mannose as a sole carbon source.

This application was reported to the committee in August 2011. ACRE did not request any further information at the time and was content to wait until the EFSA opinion was available before considering this application further. ACRE confirmed it agreed with EFSA's view that 5307 maize is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include this maize in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. This advice was updated on 18 May to include this soybean and published.

2.3.2 MON87708 x MON89788 soybean ref. EFSA-GMO-NL-2012-108

ACRE considered in July Monsanto's application to market GM herbicide-tolerant MON87708 X MON89788 soybeans for food and feed uses, import and processing, once EFSA's opinion was available. This application does

not include cultivation within its scope. This soybean has been developed through traditional breeding of two parental lines: MON 87708 and MON 89788. MON 87708 contains a gene that expresses DMO, an enzyme which confers tolerance to the herbicide dicamba. MON9788 contains a gene that expresses CP4 EPSPS protein, which confers tolerance to glyphosate herbicides. ACRE was notified of this application in July 2012 and agreed to consider it once EFSA's opinion was published. MON87708 was submitted previously as a single event and MON89788 has been submitted in two stacked combinations.

This application was reported to the committee in July 2012 when it agreed to consider it further once EFSA's opinion was available. ACRE confirmed it agreed with EFSA's view that this soybean is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include MON87708 X MON89788 soybeans in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. This advice was updated on 9 July to include this soybean and published.

2.3.3 MON87427 maize ref. EFSA-GMO-BE-2012-110

ACRE considered in July Monsanto's application to market GM herbicide-tolerant MON87427 maize, for food and feed uses, import and processing, once EFSA's opinion was available. This application does not include cultivation within its scope. This maize was developed to express CP4 EPSPS protein, in all tissues except for the male reproductive tissues, conferring tissue-selective tolerance to glyphosate. This tissue-selective tolerance is designed to provide farmers with a novel weed control system and to facilitate the production of viable hybrid maize seed. The CP4 EPSPS protein is expressed in female and vegetative tissue but not in pollen microspores or in tapetum cells.

ACRE was notified of this application in October 2012 and was provided with a summary at that time. ACRE agreed it did not need to consider the application further until EFSA's opinion was published. ACRE confirmed it agreed with EFSA's view that this maize is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include MON87427 maize in its generic advice for GM crops that have a limited potential to grow and flower

outside of agricultural conditions in the UK. This advice was updated on 9 July to include this maize and published.

2.3.4 NK603 X T25 maize ref. EFSA-GMO-NL-2010-80

ACRE considered in August Monsanto's application to market GM herbicide-tolerant NK603 X T25 maize, for food and feed uses, import and processing, once EFSA's opinion was available. This application does not include cultivation within its scope. This two-event stack maize was produced by conventional crossing to produce maize tolerant to glyphosate (NK603) and glufosinate (T25) herbicides. NK603 expresses CP4 EPSPS protein and T25 expresses PAT.

ACRE was notified of this application in September 2010 when it agreed it did not need to consider the application further until EFSA's opinion was published. ACRE confirmed it agreed with EFSA's view that this maize is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include NK603 x T25 maize in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. This advice was updated on 11 August to include this maize and published.

2.3.5 FG72 soybean ref. EFSA-GMO-BE-2011-98

ACRE considered in August Bayer's application to market GM herbicide-tolerant FG72 soybeans for food and feed uses, import and processing, once EFSA's opinion was available. This application does not include cultivation within its scope. FG72 soybean has been modified to express two proteins: 2MEPSPS and HPPD W336. Two genes, hppdPfW336 and 2mepsps, have been introduced using direct gene transfer. The 2mepsps gene encodes the 2MEPSPS protein and confers tolerance glyphosate herbicides. The hppdPfW336 gene encodes the HPPD W336 protein and confers tolerance to IFT (isoxaflutole) herbicide. FG72 soybean provides growers with new options for weed control using IFT herbicide in combination with a glyphosate herbicide.

ACRE was notified of this application in December 2011 when it was informed this is the first time that a GM soybean containing event FG72 has been notified under the GM Food and Feed Regulation. As such, ACRE was provided with a summary of the application. ACRE advised that, given the

extremely limited potential for environmental exposure of this GMO in the UK, it would consider the application after EFSA had published its opinion.

ACRE confirmed it agreed with EFSA's view that this soybean is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include FG72 soybeans in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. This advice was updated on 11 August to include this soybean and published.

2.3.6 MON87705 X MON89788 soybean ref. EFSA-GMO-NL-2011-100

ACRE considered in August Monsanto's application to market MON87705 X MON89788 soybeans, developed for herbicide-tolerance and increased oleic acid content, once EFSA's opinion was available. This application is for food and feed uses, import and processing and does not include cultivation within its scope.

The soybean was produced by conventional crossing to confer tolerance to glyphosate-based herbicides and to have an altered fatty acid profile. The soybean single events MON 87705 and MON89788 both express CP4 EPSPS for glyphosate tolerance. MON87705 has also been developed for seed-specific suppression of the FAD2 and FATB genes and the fatty acid composition of the soybean oil is subsequently reduced.

ACRE was notified of this application in December 2011 when it agreed it did not need to consider the application further until EFSA's opinion was published. ACRE confirmed it agreed with EFSA's view that this maize is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include MON87705 X MON89788 soybeans in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. This advice was updated on 11 August to include this maize and published.

2.3.7 MON87769 X MON89788 soybean ref. EFSA-GMO-NL-2010-85

ACRE considered in August Monsanto's application to market MON87769 X MON89788 soybeans, developed for herbicide-tolerance and stearidonic acid content, once EFSA's opinion was available. This application is for food and

feed uses, import and processing and does not include cultivation within its scope.

The two-event stack soybean MON 87769 × MON 89788 was produced by conventional crossing of the soybean lines MON 87769 and MON 89788, combining the production of stearidonic acid and the tolerance to glyphosate-based herbicides. MON 87769 expresses Δ15 and Δ6 desaturase proteins and MON 89788 expresses the CP4 EPSPS protein. These were both assessed previously by EFSA and no concerns were identified for human and animal health or environmental safety. EFSA has concluded that MON 87769 × MON 89788 is unlikely to have adverse effects on the environment in the context of this application.

ACRE was notified of this application in February 2011 when it agreed it did not need to consider it further until EFSA's opinion was published. ACRE confirmed it agreed with EFSA's view that this soybean is as safe as its conventional counterparts with respect to potential effects on human and animal health and the environment in the context of its intended uses.

ACRE considered it was appropriate to include MON87769 X MON89788 soybean in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. This advice was updated on 16 November to include this soybean and published.

2.3.8 Bt11 x MIR162 X MIR604 x GA21 maize ref. EFSA-GMO-DE-2009-66

In December ACRE considered an application from Syngenta to market Bt11 x MIR162 X MIR604 x GA21 maize for food and feed uses, import and processing. This application does not include cultivation within its scope.

This four-event stack maize was produced by conventional crossing to combine four single maize events. Bt11 produces a modified Cry1Ab protein that confers resistance to certain lepidopteran pests and a PAT protein that confers tolerance to herbicides containing glufosinate ammonium. MIR162 produces a modified Vip3Aa1 protein that confers resistance to certain lepidopteran pests and PMI (phosphomannose isomerise). This was used as a selectable marker in product development. The MIR604 event also produces PMI. The Cry3A protein produced in MIR604 plants confers resistance to western corn rootworm and related species of Diabrotica. GA21 produces a modified EPSPS protein that confers tolerance to herbicides containing glyphosate.

ACRE was notified of this application in April 2009 when it concluded that its strategy for dealing with applications to import and process GM maize was appropriate for this application. EFSA in its opinion concluded that the four-event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope.

ACRE considered it was appropriate to include Bt11 x MIR162 X MIR604 x GA21 maize in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. The advice was updated to include this maize and published on 21December.

Chapter 3

Other Advisory Duties

ACRE may be called upon to advise on any scientific issue relating to GMOs, such as guidance issued by EFSA and research papers. In addition ACRE may be asked in certain cases to advise on releases to the environment in Great Britain of non-native organisms, although there were no such cases in 2015. .

3.1 Maize pollen deposition in relation to distance from the nearest pollen source under common cultivation - results of 10 years of monitoring (2001 to 2010)

ACRE considered in March a paper analysing maize pollen deposition data from 216 sites in Germany, Switzerland and Belgium over a 10 year period, during pollen release. The authors used a power function model to describe the relationship between pollen deposition and distance from the nearest pollen source. The authors argue this more accurately describes the relationship at longer distances compared with the exponential model adopted by EFSA in its opinions on Bt maize events.

ACRE considered that the study was well conducted but that the authors had exaggerated the significance of their analyses. The research demonstrates that most pollen is deposited close to its source but dispersal occurs over longer distances (pollen was collected up to 4.45 km in this study). Long distance deposition is known to be highly heterogenous and this is evident from this study. Consequently, irrespective of the model used there will be considerable uncertainty about the exposure of non-target Lepidoptera to Bt pollen. The authors have discussed two models but have not provided the raw data for others to fit alternative models.

In terms of applying these results to the risk assessment /risk management of Bt crops, this uncertainty about exposure to Bt pollen over longer distances overlays the uncertainty about whether these crops actually pose a hazard to non-target Lepidoptera. Current Bt maize events have been selected, in part, because they express Bt protein at low/ very low levels in pollen and there is a question about whether populations of non-target Lepidoptera species exist with biological and ecological characteristics that make them vulnerable. EFSA had adopted a worst case approach in assessing the risk and in suggesting options for risk management. ACRE was interested to follow EFSA's considerations on how this research impacts on its previous opinion.

The Welsh Government asked ACRE to consider the implication of the research for the co-existence of conventional and GM crops. ACRE noted that this research measures pollen deposition and not cross-pollination between

plants. The authors acknowledge this and the fact that there is a significant amount of research on gene flow, which has been funded because EU member states are required to develop coexistence measures. These include large EU-funded projects such as SIGMEA and CO-EXTRA. On the back of this research the European Coexistence Bureau published a set of guidelines for the coexistence of maize production. In the UK, important data was gained from gene flow studies using the Farm scale Evaluation sites. Cross-pollination data from 55 GM maize sites over 3 years were collected. Whilst pollen movement is a factor in cross-pollination there are other elements that affect cross-pollination frequency. Given this and the size of the evidence base on gene flow that already exists, this research has limited direct value for devising separation distances that would allow the coexistence of GM and non-GM crops.

3.2 EFSA consultations on environmental risk assessment

ACRE considered in September three documents issued by EFSA for consultation, following which comments were submitted to EFSA. These were

Guidance to define protection goals for environmental risk assessment in relation to biodiversity and ecosystem services

Coverage of endangered species in environmental risk assessments at EFSA

Scientific Opinion on the temporal and spatial ecological recovery of non-target organisms for environmental risk assessments.

ACRE concentrated on the first document as it proposes a framework for defining specific protection goals for biodiversity that can be used in ERAs. This aligns with ACRE's conclusions in its 2013 publications on the EU regulatory system that there needs to be more coherence in establishing what constitutes a risk of environmental harm before risk assessments are carried out. EFSA's objective in carrying out this project was to harmonise specific protection goals (as far as possible) across its panels. ACRE welcomed this initiative but was not clear what practical steps will follow.

ACRE also welcomed the use of an ecosystem services approach to rationalise high level protection goals into specific protection goals and the flexibility that EFSA acknowledges will be necessary to facilitate case by case assessments of plausible risk hypotheses. However, ACRE considered that it would be helpful if the framework enabled inconsistencies to become

apparent e.g. the different status of infield weeds depending on whether the herbicide is used with a GM or non GM crop.

EFSA highlighted two key challenges in implementing its proposed framework. The most significant was in quantifying harm. ACRE agreed that the evidence is often not available to calculate thresholds for regulatory decisions and its harm subgroup had found it helpful to use existing approaches related to defining species conservation status to structure semi-quantitative methods. It also considered it important that if thresholds are proposed, these should be discussed openly and be subject to change as scientific understanding improves. ACRE discussed the thresholds proposed/ agreed for honey bee colonies, Lepidoptera mortality and nitrate levels in drinking water as examples.

EFSA also identified the challenge in relating biodiversity to ecosystems services. ACRE considered that the guidance would benefit from distinguishing between the three ways that biodiversity can be considered i.e. from the point of view of (1) taxonomic diversity per se; (2) diversity of function; and (3) impact on iconic species. ACRE noted that the second is more difficult to assess.

The two accompanying EFSA documents dealt with issues associated with defining specific protection goals i.e. taking recovery (of non-target organisms) and endangered species into account in ERAs. Both are detailed academic documents. ACRE members were invited to send specific comments to the secretariat but the main focus for discussion at the meeting was EFSA's guidance on deriving specific protection goals.

3.3 House of Commons Science and Technology Committee inquiry into advanced genetic techniques for crop improvement: regulation, risk and precaution

The Select Committee published the report of its inquiry " Advanced genetic techniques for crop improvement: regulation, risk and precaution" in February[2]. The ACRE Chair and Defra minister Lord de Mauley gave oral evidence to the Select Committee in January. The report contains two

[2] http://www.publications.parliament.uk/pa/cm201415/cmselect/cmsctech/328/328.pdf

recommendations for ACRE. These are that ACRE's remit should be expanded to cover all novel plant traits, not just GMOs, and that ACRE should establish a citizens council to advise on social and ethical aspects. The report also calls for a major reform of the EU regulatory regime and a commitment to move to a trait-based novel plant regulatory system. ACRE's written evidence to the inquiry, submitted in 2014, was attached to the published report.[3]

3.4 House of Lords Science and Technology Committee inquiry on GM insects

The House of Lords Science and Technology Committee announced during the year that it would hold an inquiry into the possible uses of GM insect technologies. Three of the Committee's questions were focussed on whether the current EU and UK GM regulatory frameworks work for GM Insects. ACRE agreed that these questions should be central to its response.

ACRE noted that it had already given a great deal of consideration as to whether the GMO regulatory framework is fit for purpose and the conclusions it reached are relevant to this inquiry. The main points are that:

- Ideally, regulatory systems should capture products based on the novelty of their traits rather than on how they are developed.

- Regulatory decisions should be informed by benefits as well as risks.

- Recasting the regulatory framework in the current political climate would be difficult and the outcome unclear. Taking this into consideration, ACRE noted that the nature of the regulatory trigger for capturing products becomes less significant if the assessment process is efficient. ACRE highlighted some of the problems with the interpretation and operation of the environmental risk assessment process in one of its 2013 reports. This report was based on ACRE's experiences with GM crop applications; but ACRE would expect the same sort of problems to arise with GM insects.

ACRE highlighted that it had no practical experience of assessing applications to release GM insects. It noted that Spain is the only Member State in the EU

[3] http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/gm-foods-and-application-of-the-precautionary-principle-in-europe/written/8632.pdf

that has; it is currently considering an application for the release of a GM olive fly in a research trial. However, ACRE has maintained an interest in this area having held an evidence-gathering workshop on GM insects in Oct 2010 and followed/ commented on guidance developed for the environmental risk assessment of GM insects since then.

The inquiry asked specifically about EFSA's guidance on the ERA of GM insects. After reviewing its comments on a draft version of this guidance, ACRE considered that these still apply to the final version. ACRE also noted that EFSA's guidance was helpful in highlighting the fact that the EU Directive dealing with the 'Deliberate Release of GMOs' was drafted with GM plants in mind (including sections dealing with non-plant GMOs). This means that some of the questions will have to be interpreted for GM insects. Another important message to be taken from the guidance was the need for careful consideration to be given to the selection of comparators in environmental risk assessments.

The inquiry also referred to the WHO document on testing GM mosquitoes and asks whether it provides the basis for an effective regulatory framework. This document compiles information on a range of issues that researchers should consider when developing GM mosquitoes. Whilst it did not propose a regulatory framework it was a clear, practical document that discusses elements that could be part of a regulatory framework i.e. case by case, increasing environmental exposure in incremental steps, risk/ benefit, efficacy and stakeholder engagement. An important conclusion is that developers should contact regulators as early as possible to establish what information is required/ what questions need to be answered.

The inquiry referred specifically to issues associated with the evolution of resistance. ACRE noted that it is inevitable that there will be an evolutionary response to an altered characteristic in a population. It also highlighted the importance of using an integrative approach where the intention is biological control. ACRE observed that when the evolution of resistance can be linked to environmental harm, this will have to be addressed in environmental risk assessments.

The inquiry also asks specifically about the use of gene drives in GM insects developed for population replacement. ACRE also discussed the potential use of gene drives in population suppression. ACRE noted that the application of the CRISP/ Cas9 system for targeting the modification of genomes has fuelled a great deal of optimism in a number of areas, including as a basis for gene drives in GM insects.

ACRE's response was submitted to the Committee and has been published.[4] as well as the report.[5] The Chair attended to give evidence in October.

3.5. Synthetic Biology

In September ACRE reviewed key developments on synthetic biology since its last meeting in March. This included a recent agreement from the Secretary and Chair of the Science Advisory Council on Genetic Modification (SACGM), that ACRE's Dr Pete Lund should be appointed as a cross-committee expert sitting on both committees. The purpose is to ensure that Defra maintains an appropriate level of awareness of scientific and technical developments in molecular and environmental microbiology and synthetic biology, in particular at the boundary between contained use and deliberate release of GMOs.

Committee members were also informed that the online forum on synthetic biology, which was co-ordinated by the Convention on Biological Diversity (CBD), had been completed and that as a result, Mike Paton of the HSE had been invited to participate in the CBD's Ad Hoc Expert Group (AHTEG) on synthetic biology.

ACRE considered the most recent draft opinion of the three EU scientific committees on synthetic biology. It aims to identify major gaps in knowledge to be considered for 'performing a reliable risk assessment' and to provide research recommendations resulting from gaps. A number of areas have been identified where the narrative requires adjustment for scientific accuracy, robustness and clarity. ACRE intends to submit specific comments as part of the consultation / peer review process for this opinion document.

Due to the level of technical complexity inherent to this and previous discussions on synthetic biology, the Chair and other members requested that a primer document be prepared explaining exactly what synthetic biology is and its implications for Defra business.

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[4] http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-lords-committee/genetically-modified-insects/written/21662.html

[5] http://www.publications.parliament.uk/pa/ld201516/ldselect/ldsctech/68/68.pdf

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 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 Gov.UK 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. From 2014 all the standard committee meetings have been 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 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] 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, the ACRE publication scheme is set out at section D of the ACRE framework document, published on the Gov.UK website[6].

The scheme sets out the classes of information that ACRE publishes and the manner in which the information is published. All ACRE publications are free to download.

[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239094/acre-framework-agreement.pdf

Appendix III

ACRE membership in 2015

Members	Main Expertise
Professor Rosie Hails (chair)	Ecology, entomology
Professor Kathy Bamford (retired 11 December 2015)	Medical microbiology and human infection
Dr Mike Bonsall	Entomology, evolutionary ecology, ecology and mathematical biology
Dr Rosemary Collier	Applied entomology, horticultural crops
Professor Ian Crute	Plant pathology and genetics
Professor Jim Dunwell	Plant biotechnology
Professor Les Firbank (retired 25 October 2015)	Agri-ecosystems
Dr Matthew Heard	Community ecology, plant population ecology, agricultural ecology, conservation science
Professor David Hopkins	Soil biology and biochemistry
Dr Ieuan Joyce (retired 25 October 2015)	Farming practice
Simon Kerr	Agronomy
Dr Peter Lund	Molecular biology, genomics, systems

	biology, synthetic biology
Professor Andy Peters	Clinical development and regulation of vaccines

Sub-group on Harm

Dr Rosemary Collier (chair)

Professor Rosie Hails

Professor Les Firbank

Dr Matthew Heard

Dr Mike Bonsall

Appendix IV

Biographies of ACRE members

Professor Rosemary Hails MBE (chair)

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 and. a member of the Natural Capital Committee, which reports to the Economic Affairs Committee, 2012 – 2015. 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 was chair of the Natural Capital Initiative (2009-2015) and sat on the Council for the Society of Biology (2012 – 2014). She and is currently a Vice President of 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. Appointed as chair from 1 September 2013 and the current term runs until 31 August 2016.

Dr Kathy Bamford (retired from ACRE)

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. Retired from ACRE on 11 December 2015.

Professor Michael Bonsall

Department of Zoology, University of Oxford

Expertise: entomology, evolutionary ecology, ecology and mathematical biology

Michael Bonsall is Professor of 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 has been a member of EFSA working groups on GM insects (2010-2012), environmental risk assessment of endangered species (2013-2015) and risk profile of insects as food and feed (2014-2015). Recently he acted as science advisor to the House of Lords Science & Technology committee's enquiry on GM insects. 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. 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. Current term runs from 1 September 2015 to 31 August 2018.

Professor Ian Crute CBE

Self-employed consultant

Expertise: plant pathology and genetics

Ian Crute has had a 40 year career in crop research. Until 2014 he was the Chief Scientist of the Agriculture and Horticulture Development Board (AHDB) and is now an independent Non-executive Director of this organisation. Ian's professional expertise is in plant pathology and genetics with a particular interest in the sustainability of agricultural systems. Prior to joining AHDB in 2009, Ian held the post of Institute Director at Rothamsted Research for 10 years. This followed 25 years in Horticulture Research International as a Research Leader in plant pathology, Head of Department and Director at the organisation's Wellesbourne Laboratory. Professor Crute's scientific contributions are recorded in over 170 publications and his work has been recognised by several awards including a CBE for services to plant science. Ian was a member of the Lead Expert Group for the 'Global Future of Food and Farming' Foresight project and continues to serve on several Boards and Committees connected with science and innovation within the UK agri-food sector. These include: East Malling Trust, John Innes Foundation, Fera Science Advisory Group and Leadership Council of the 'UK Strategy for Agricultural Technologies'. First appointed to ACRE on 1 October 2014 and this term runs until 30 September 2017.

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 (retired from ACRE)

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, with a particular focus on the 'sustainable intensification' of agriculture, through both improved metrics and through changes to how agricultural soils are managed. 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. Retired from ACRE on 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. Current term runs from 26 October 2015 to 25 October 2018.

Professor David Hopkins

The Royal Agricultural University

Expertise: soil biology and biochemistry

David Hopkins is Professor of Soil Science and Dean of Agriculture, Food & Environment at the Royal Agricultural University, Cirencester. 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, a 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 and Stirling, and Heriot-Watt University and the University of 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 (retired from ACRE)

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 Chair 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. Retired form ACRE on 25 October 2015

Simon Kerr

National Institute of Agricultural Botany (NIAB) - consultant

Expertise: agronomy

Simon Kerr was until September 2015 Head of Regional Trials at NIAB, where he had responsibility for NIAB's field trials across 10 regional centres with a range of arable, vegetable and forage crops. He is now working for NIAB and others in a consultancy capacity. 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. Current term runs from 1 September 2015 to 31 August 2018.

Dr Peter Lund

University of Birmingham

Expertise: molecular biology, genomics, systems biology, synthetic biology

Peter Lund is Reader in Molecular Microbiology in the School of Biosciences and Institute of Microbiology and Infection at the University of Birmingham. His research is in the area of bacterial stress responses, using methods from biophysics to large scale post-genomic data analysis to understand the ways in which organisms perceive and respond to stress. Particular areas of interest are bacterial responses to low pH, responses of pathogens to stresses in the human gut, the mechanisms and roles of molecular chaperones, and the evolution and engineering of stress resistance. Before his appointment at Birmingham he did research in agricultural biotechnology in the USA, working on introducing traits such as fungal resistance and frost protection into plants. He has a long standing interest in the application of molecular biology methods in agriculture and food. He was a member of the Food Ethics Council from 1999 to 2008* and of the Advisory Committee on Novel Foods and Processes from 2001 to 2007*. He is an editor of FEMS Microbiology Letters, programme leader for the university's MSc in Molecular Biotechnology, and co-author of a textbook on gene cloning. First appointed to ACRE on 1 October 2014 and this term runs until 30 September 2017.

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 veterinary vaccine research, development, regulation and knowledge transfer. He also holds visiting professorial chairs at the Universities of Edinburgh and Nottingham. First appointed to ACRE on 9 October 2006. Current term runs from 9 October 2012 until 8 October 2016.

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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 2015

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 (retired 11.12.15)	Pfizer, Pharmacia, Wyeth, Gillead, 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		
Professor Michael Bonsall	Oxitec Ltd	BBSRC – iCASE studentship BBSRC - LINK Grant	University of Oxford	Employee	Academy of Medical Sciences	Director of Medical Policy
			St Peter's College, Oxford	Fellow, employee		

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

Dr Rosemary Collier	Rijk Zwaan	Funding for research	University of Warwick	Employee	Agri-food Group, Institute of Food Science and Technology	Chairman
	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)	Fraser Associates UK	Sole trader: innovation and resilience in the agri-food supply chain

			IOBC-WPRS Council	Member (unpaid)		
Professor Ian Crute			John Innes Foundation	Trustee Director	None	
			East Malling Trust	Trustee Director		
			East Malling Research	Trustee Director and Chair of the Science and Industry Advisory Committee		
			Agriculture and Horticulture Development Board	Independent Non-executive Director		

			UK Strategy for Agricultural Technologies	Member of the Leadership Council and Research Champion		
			Innovate UK Sustainable Agri-food Innovation Platform	Member of the Steering Group		
			Agriculture Advanced Training Partnership	Member of the Executive Committee		
Professor Jim Dunwell	Syngenta	Pension	University of Reading	Employee	None	
			EU, Cocoa Research UK, and MARS	Funding for research		

			Rothamsted Research	Rothamsted Fellow		
			University of Nottingham	Honorary lecturer		
			PubGM	Member (unpaid)		
			GM Manual Advisory Panel for the British Crop Protection Council	Member (unpaid)		

Professor Les Firbank (retired 25.10.15)	Assured Food Standards Ltd (Red Tractor Scheme) – not for profit	Independent Director	University of Leeds	Employee	University of Leeds companies involved in pig nutrition	Employee
			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		
			NERC, BBSRC, MRC, Defra, EU	Funding for research		

			British Ecological Society	Vice President and 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			Royal Agricultural 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 (retired 25.10.15)	Ochr Fawr	Manager of farm business in partnership	Upland Forum	Member	None	
			Elan Valley Trust	Trustee		

Simon Kerr	NIAB	Consultant			None	
Dr Peter Lund			University of Birmingham	Employee	None	
			Darwin Trust	Funding for research		
			National University of Ireland	External examiner		

Professor Andrew Peters	Arpexas Ltd	Director	Scotland's Rural College	Employee	None	
			Global Alliance for Livestock Veterinary Medicines	Board Trustee		
	Pfizer	Shares, pension	University of Nottingham	Visiting Professor		
			University of Edinburgh	Visiting Professor		

Appendix VI

ACRE advice issued in 2015

ACRE advice: application for a trial of a GM vaccine against typhoid and E.coli 15/R47/01/NI. Published 13 May 2015.

Advice on notifications for import and processing of GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK, submitted under regulation EC 1829/2003. Generic advice updated to include 5307 maize, MON87708 X MON89788 soybeans, MON87427 maize, NK603 X T25 maize, FG72 soybeans, MON87705 X MON89788 soybeans, MON87769 X MON89788 soybeans and Bt11 x MIR162 X MIR604 x GA21 maize. Published 28 May, 9 July, 12 August, 20 November and 21 December 2015.

ACRE's response to the House of Lords Science and Technology Committee Inquiry on GM insects. Published 18 September 2015 http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-lords-committee/genetically-modified-insects/written/21662.html

Triennial review

Advisory Committee on Releases to the Environment triennial review 2014. Published 26 March 2015