

Advisory Committee on Releases to the Environment

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FOREWORD

By the Chairman, Professor Chris Pollock

This report covers ACRE's activities in 2010. 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. However, ACRE gave positive assessments on two applications to trial GM potatoes under Part B of Directive 2001/18/EC, from the University of Leeds (evaluating resistance to potato cyst nematodes) and the Sainsbury Laboratory (evaluating resistance to potato late blight). Consent for the Leeds trial was issued on 27th March and the Sainsbury Laboratory trial on 18th May. ACRE also published advice on applications to market three varieties of carnation modified for petal colour and herbicide tolerance

In terms of work carried out under Regulation (EC) No. 1829/2003, ACRE considered nine applications in detail under the food and feed regulations; two applications for the cultivation of herbicide-tolerant and insect-resistant maize and seven applications for import and processing of maize, soybean, rape and cotton. In addition ACRE advised on the environmental risk assessments of an application to market a human medicinal product under regulation (EC) No. 726/2004, and of a veterinary product.

During 2010, ACRE continued the work of the Public Engagement Sub-group and the New Techniques Sub-group. This was established in 2009 to consider plant breeding techniques new to EU regulators and assess whether they are captured by the existing GM legislation. A draft report was discussed in September and this will be published during 2011. The Public Engagement Sub-group was heavily involved in organising an open business meeting of ACRE in June and an open evidence-gathering meeting on GM insects in October. GM insects were chosen as a topic for a single-issue workshop as there are products under development and it is important to consider at an early stage the implications for the regulatory system. The workshop was attended by 25 outside participants, with plenary speakers from Oxitec (a company developing GM insects), the Austrian Federal Environment Agency and

Keele University. ACRE concluded that the current regulatory system offered a sound basis for effective risk assessment but it was important to give careful consideration as to how this should be applied to GM insects. ACRE also considered how the balance between risks and benefits might be incorporated into regulatory practice, an issue drawn into particular focus when considering GM insects developed to combat human diseases such as malaria. The Public Engagement Sub-group has considered feedback from both these events and will be involved in organising future open meetings in line with its previous recommendations. ACRE members were involved in the International Symposium on Plant GMOs held in Buenos Aires in November.

In terms of ACRE's other duties, ACRE provided input to the drafting of Fera's research report on arable weed populations. This study was commissioned in anticipation of EU votes on cultivation of GMHT crops to consider methodologies for weed surveys intended to detect negative effects on biodiversity arising from changes in agricultural practices. ACRE also commented on a research report on adventitious GM presence arising through use of shared farm machinery, transport and storage equipment and considered a report on potato volunteers and the consequences for current EU labelling thresholds for GM. This report was commissioned by Defra to inform co-existence policy for GM and non-GM potatoes. As a result of these considerations, ACRE recommended measures to include in Part B consents to minimise volunteer problems.

ACRE agreed responses to two EFSA consultations on updated guidance for the environmental risk assessment of GM plants and on the potential impacts of GM plants on non-target organisms. ACRE also agreed to provide a paper to UK regulators and ministers concerning potential impacts on biodiversity resulting from altered herbicide regimes used in conjunction with GM HT maize. This paper will explain how its approach has evolved since it advised on the farm-scale evaluations based on considering the biological significance of different weed management schemes.

The committee met on five occasions during the year including the two open meetings. 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. Members of ACRE, including the chairman, participated in a discussion on the regulatory implications of recent advances in synthetic biology.

During 2010, the Government's review of public bodies concluded that ACRE should be retained as it carried out a technical function which should remain independent of Government. Its status as a statutory scientific advisory committee is therefore unchanged.

During 2010 Mike Bonsall was reappointed to the committee. We were given approval to recruit a soil microbial ecologist to replace Penny Hirsch and intend to fill the vacancy in 2011. As chairman, I remain grateful to members and assessors for their commitment, expertise and enthusiasm. As always, we have been ably supported by the secretariat, which has meant that we have fulfilled our role in a timely and effective manner. I look forward to continuing to provide ministers with evidence-based advice in areas of political and scientific significance.

CHAPTER 1

Introduction

This is the seventeenth annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2010. 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 four regular committee meetings during 2010 and a special evidence-gathering workshop on GM insects. There was also a significant amount of consultation by e-mail. Through the year we have dealt with many issues summarised below:

- We published advice on the applications from Florigene Pty Ltd to market three varieties of carnation modified for petal colour and herbicide tolerance,
- We published advice on two potato trial applications, by the University of Leeds (to evaluate resistance to potato cyst nematodes) and the Sainsbury Laboratory (resistance to potato late blight). Consent for the Leeds trial was issued on 27th March and the Sainsbury Laboratory trial on 18th May.
- Recommendations of the Public Engagement Sub-group were followed up, with the June committee meeting open to the public and a special evidence-gathering open meeting on GM insects in October.

- We considered a number of food and feed applications including two maize cultivation applications with stacked events, and applications for import and processing of oilseed rape, soybeans, cotton and maize
- We provided input to the drafting of the Food and Environment Research Agency (Fera) research report on arable weed populations.
- We commented on a research report on adventitious GM presence arising through use of shared farm machinery, transport and storage equipment.
- We commented on the environmental risk assessment of an application to market a human medicinal product under regulation (EC) No. 726/2004, and a veterinary product.
- We considered a report on potato volunteers and the consequences for current EU labelling thresholds for GM, commissioned by Defra to inform co-existence policy for GM and non-GM potatoes, and we recommended measures to include in consents to minimise volunteer problems.
- We worked on a response to two European Food Safety Authority (EFSA) consultations - updated guidance for the environmental risk assessment of GM plants and an opinion on potential impacts of GM plants on non-target organisms
- We considered the potential impacts on biodiversity resulting from altered herbicide regimes used in conjunction with GM HT maize and agreed to provide a paper to explain how our approach had evolved since we advised on the farm-scale evaluations. We invited Syngenta to present its approach in its application to cultivate GA21 maize, to inform the discussion.
- The New Techniques Sub-group continued its investigation of plant breeding techniques new to EU regulators to assess whether they are captured by the existing GM legislation. We discussed its draft report in September.

- The evidence-gathering workshop on GM insects was held on 14th October. GM insects was chosen as a topic for a single-issue workshop as there are products under development and this was an opportunity to consider at an early stage the implications for the regulatory system.

The Government's review of public bodies undertaken during the year concluded that ACRE should be retained on grounds of performing a technical function which should remain independent of Government. ACRE is included in the Public Bodies (Reform) Bill currently going through Parliament, the purpose of which is to ensure that there will be a greater degree of transparency and accountability for all public bodies, and provide ministers with powers to abolish them, merge them or transfer functions. To date ACRE's role and functions remain unchanged and it has retained its status as a statutory scientific advisory committee. The secretariat has provided input as requested into these processes.

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 2010 ministers reappointed Dr Mike Bonsall for a further term, and gave the go-ahead to seek an expert in soil microbial ecology to fill a vacancy on the committee. Details of all the members who served on the committee in 2010 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 Assembly 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 committee welcomed Dr Georgianne Griffiths to the secretariat on a part-time basis and Sarah Brown joined full time. Dr Pierre-Louis Amoussou left during the year. The secretariat also included Dr Katherine Bainbridge and David Sherlock. All staff members making up the secretariat are from the GMO Team in Defra. The committee is grateful to the secretariat for its hard work and support over the period of this report.

1.2 ACRE sub-groups

As a committee, our terms of reference¹ 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. A summary of sub-group activities during the year is detailed below.

1.2.1 The ACRE Public Engagement Sub-group

The ACRE Public Engagement Sub-group was established in February 2008 and its recommendations for 2010 were discussed at the March ACRE meeting. Details of the membership of this sub-group are given in Appendix III and the working group's terms of reference and outputs can be found at <http://www.defra.gov.uk/acre/subgroups/public.htm>. The aim of the sub-group is to develop proposals for a rolling programme of effective public engagement related to ACRE's commitment to openness and transparency. The sub-group has proposed that ACRE should hold each year a normal committee meeting open to the public, except for any confidential issues which would be discussed in a closed meeting afterwards. The sub-group has also proposed that ACRE should hold annual

¹ See Appendix I for the full terms of reference

meetings on a particular topic to gather evidence, with experts giving presentations and opportunities for the public to ask questions. This kind of event would be in addition to normal committee meetings. The third proposal was for participation in wider scientific events. The full committee accepted the sub-group's recommendations for 2010, which involved opening a normal meeting to the public in June and the GM insects evidence-gathering workshop in October.

1.2.2 The New Techniques Sub-group

The New Techniques Sub-group was set up in 2009 following the establishment of an EU Commission working group to identify and consider a list of new techniques that may challenge the definitions of what constitutes a GMO or GM technique in the GM Deliberate Release and Contained Use Directives. The sub-group was asked to consider how new techniques used in biotechnology fit with existing definitions and to consider alternative approaches to regulating novel organisms. The sub-group's work will enable ACRE to provide scientific advice to ministers to underpin discussions at EU-level on definitions in GM legislation about what constitutes a GM process. Details of the membership of this sub-group are given in Appendix III and the working group's terms of reference and outputs can be found at <http://www.defra.gov.uk/acre/subgroups/newtechniques.htm>.

The sub-group's draft report was discussed at the June ACRE meeting, when the committee noted the report's conclusions challenged the concept of a process-based approach to the regulation of GMOs. ACRE also noted that in a number of cases the product of these new techniques would not be distinguishable from non-GM crops and in some cases from naturally occurring variants. ACRE agreed that an appropriate regulatory system should be able as far as possible to deal with future developments in technology and that the techniques under discussion had not been foreseen when definitions in the current GM legislation were drafted. ACRE concluded this was an inherent weakness in a process-based, rather than a product-based system. The sub-group agreed to draft a final version of the report for comment and adoption by the committee.

1.3 Work plan over the next year

In addition to its requirement to advise on applications for the deliberate release of GMOs, ACRE identifies work streams that underpin this casework. These include considerations of future challenges posed by advances in GM technology to environmental risk assessment and environmental risk management and challenges to the current approach to regulating GMOs in the EU. ACRE recognises that its deliberations on current work streams have highlighted challenges for regulators and will focus on the following areas in 2011:

- Its considerations on whether new techniques used in plant breeding give rise to GMOs or not. ACRE's New Techniques Sub-group will report to the committee so that it can advise ministers involved in EU-level discussions;
- Its deliberations on the post-market monitoring of GM crops. ACRE will reconvene its monitoring sub-group in the light of discussions on general surveillance and weed monitoring. Fera will report to ACRE on a project on weed monitoring which will propose options that ACRE will need to consider.
- Updating ACRE's 2004 position on its approach to dealing with the potential for herbicide regimes used in association with GM herbicide tolerant maize to have a greater impact on biodiversity, as compared to regimes used in association with non-GM maize.
- Publishing advice on the development of GM insects and the impact of this on the regulatory system. ACRE will consider writing its own advice on GM insects, linked to the work going on in EFSA on this subject.

ACRE is aware that it needs to keep under review developments in human and veterinary medicine currently taking place under contained use conditions that could progress to the clinic and which could lead to deliberate release applications. Defra has commissioned a desk study to identify advances in the area of GM medicinal products to determine what, if any, challenges new products would pose to environmental risk assessment and to the current regulatory system. This will update a previous report published in 2007. ACRE will review this once complete and has flagged this up as a possible subject for an evidence-gathering workshop.

EU Member States are considering guidance on the environmental risk assessment of GM plants and ACRE will be engaged in providing scientific advice to underpin these discussions.

ACRE will continue to work as openly and transparently as its caseload permits and its Public Engagement Sub-group will continue to recommend initiatives to promote this. ACRE will expect to hold one of its 2011 ordinary committee meetings in public (although any confidential business will be discussed in a closed session) and may arrange another evidence-gathering workshop, subject to availability of Defra funding.

1.4 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) and other committees, for example the Gene Therapy Advisory Committee (GTAC). 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. The so-called 'Part B' applications, which are mainly for research and development trials, are submitted within the UK and consent is given at a national level. The so-called 'Part C' applications (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.

Most of the marketing applications the committee sees are processed through Regulation (EC) No. 1829/2003 on the authorisation of genetically modified food and feed and Regulation (EC) No. 641/2004 on the detailed implementation rules. The scope of these regulations 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 regulations provide 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.

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.

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 also advised during the year 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 2010 we published advice on two applications for Part B releases of GM potatoes. 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 233 since the original Deliberate Release Regulations came into force in February 1993².

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

2.1.1 Application 09/R31/01 from the University of Leeds for consent to release potatoes modified for resistance to potato cyst nematodes

At its January meeting, ACRE discussed this application from the University of Leeds for a trial of GM potatoes to evaluate field resistance to potato cyst nematodes. ACRE noted that the application was for a small scale, experimental trial and

² 215 applications under the 1993 regulations, 18 applications under the 2002 regulations.

assessed the risks with consideration of the risk management measures proposed. The committee considered the molecular characterisation of the GM potato lines, which were generated by transformation with four different constructs. ACRE confirmed it was satisfied with the information provided on the molecular characterisation of the GMOs. ACRE did not consider that the dsRNA or ribosomal inhibitor protein produced by the GM plants would have allergenic or toxic effects on human, animal or environmental health. ACRE referred to its previous advice regarding the safety of the nptII antibiotic resistance marker and agreed that the mechanism of interaction was likely to be specific between the GM potato and the target organism.

ACRE was satisfied that the applicant had provided sufficient information to enable the committee to assess the risks associated with the release. The committee referred to advice provided on a previous release at this site (29th April 2008) and advised that release conditions for the current application should be consistent with these and should ensure that concerns raised by the GM Inspectorate were addressed. In addition the committee advised that it was not necessary for wild relatives to be removed from the field margins, and recommended that monitoring should be carried out until no volunteers are detected over two years rather than the three month period proposed in the application.

ACRE's advice was published on 29th March, taking on board scientific points raised in public representations. The applicant was requested to ensure no potatoes were put into the human food chain or fed to livestock, ensure the release area was left fallow and not ploughed for two years after harvest of the tubers, ensure groundkeepers and volunteers are removed before flowering in the fallow years and ensure a separation distance of 20 metres to non-GM potato plants around the trial site to minimise the possibility of cross-contamination. The consent was issued on 27th March.

2.1.2 Application 10/R29/01 from the Sainsbury Laboratory for consent to release potatoes modified for resistance to potato late blight

At its March meeting, ACRE discussed an application from the Sainsbury Laboratory for a trial of GM potatoes to evaluate field resistance to potato late blight. ACRE noted that the application was for a small scale, experimental trial and assessed the risks with consideration of the risk management measures proposed. ACRE assessed the molecular characterisation of the two GM potato lines, which were generated using two different constructs containing *R* genes from potato wild relatives.

ACRE expressed some reservations about certain aspects of the molecular characterisation and felt that further information should be provided to demonstrate more convincingly that backbone DNA had not been incorporated. Alternatively a risk assessment of the potential consequences if backbone sequence had been transferred should be provided. ACRE also questioned the expression analysis, which did not succeed in detecting expression of the transgenes, and suggested that it would be useful if further information as to why these lines had been chosen for the field trial were provided.

ACRE concluded that the provision of information on copy number or insertion site was not required in this case. It did not consider that expression of the *R* genes would result in a phenotypic change other than resistance to potato late blight. It was also noted that although it was incorrect to state that dispersal by birds would not occur, there was no evidence of this resulting in feral potato populations.

ACRE agreed with the applicant's view that the mechanism of interaction was likely to be specific between the GM potato and the target organism. The committee did not consider that expression of the introduced *R* genes would have allergenic or toxic effects on human, animal or environmental health. ACRE referred to its previous advice regarding the safety of the *nptII* antibiotic resistance marker gene (29th April 2008).

ACRE was satisfied that the applicant had provided sufficient information to enable the committee to assess the risks associated with the release. Members noted the proposal to harvest early should signs of senescence be observed. It was agreed that this was a control measure that might assist in preventing the shedding of true seed and making the subsequent post trial control of volunteers easier. It was agreed that it would be preferable for the site to be left fallow unless it was particularly erosion prone. If this was the case, and it was necessary to sow with grass, mowing would need to be carefully timed to facilitate identification of volunteers.

ACRE considered proposals for disposal. The applicant had proposed that after autoclaving, material should be tested to ensure that it was not able to regenerate before sending for composting. ACRE agreed that autoclaving would be effective at inactivating the GM material and that there was no reason to believe that composting should pose a risk. ACRE recommended that further details should be provided on how the material would be tested for ability to regenerate after autoclaving.

ACRE'S advice was published on 21st May with similar recommendations to those given for the Leeds trial. The consent was issued on 27th May.

2.2 Part C notifications for placing GMOs on the European Community market

ACRE published advice on three carnation applications in 2010. Further details on the notifications are provided below.

2.2.1 Notifications from Florigene Pty Ltd to renew authorisation to market carnation variety FLORIGENE Moonshadow, line 1363A – ref. C/NL/97/13, and for authorisation to market varieties FLORIGENE IFD-25958-3 (ref. C/NL/09/01) and IFD-26407-2 (ref. C/NL/09/02)

ACRE considered in 2009 three notifications from Florigene to import, distribute and retail cut flowers from carnations that have been genetically modified for altered flower colour. These GM carnations have also been modified to be tolerant to sulfonylurea herbicides. This tolerance was used to facilitate the detection of transgenic plants during the development phase. One of the notifications (C/NL/97/13) was to renew an existing consent to market GM carnation Florigene Moonshadow line 1363A. This consent was issued under Directive 90/220/EEC and unlike the notification for renewal, included cultivation in its scope. Two notifications (IFD-25958-3 and IFD-26407-2) were for GM carnations that have not been authorised for placing on the EU market previously.

ACRE's advice on these notifications was published on 29th March 2010. ACRE concluded it did not need to alter its previous advice which was that the import and distribution of these flowers did not pose an increased risk to human health and the environment as compared with non-GM carnation varieties. ACRE had considered the further information provided by the notifier in response to requests from other Member States.

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. Application from Monsanto for authorisation under regulation (EC) No. 1829/2003 to cultivate maize MON 89034 X NK603 – ref. EFSA/GMO/NL/2009/68

ACRE was asked in January to consider the application for cultivation in the EU of maize MON 89034 x NK603 in which GM events conferring herbicide tolerance (NK603) and insect resistance (MON 89034) have been stacked by conventional breeding. ACRE is very familiar with NK603 maize having assessed an application to cultivate this GMO in 2009.

ACRE was content with the molecular characterisation of the GMO provided in the application. The committee considered that sufficient evidence was provided to demonstrate that the two GM events are conserved and independent in this hybrid, and that there was no risk of recombination leading to the formation of novel proteins through the creation of new open reading frames. Therefore, ACRE had no specific concerns about the evidence as presented.

ACRE noted that the survivability had not been tested specifically by the applicant but agreed it was very unlikely to survive outside of cultivated conditions in the UK. ACRE was satisfied that the likelihood for the introduced traits in this stack to confer any competitive advantage or disadvantage of relevance in the agronomic or natural environment is negligible.

ACRE discussed the difference between Cry1A.105 and Cry2Ab2 proteins and other Bt proteins that target Lepidopteran species. ACRE had not considered these particular Cry proteins previously in applications to cultivate GMOs. It concluded that they have the same mode of action but target different receptors in the digestive tracts of the target insects. In considering the applicant's conclusion that these Cry proteins are not toxic to non-target organisms at biologically relevant concentrations, ACRE noted that tests involving the stacked GMO (including non-target *Lepidoptera*) were not provided in the application. It also noted that non-target *Lepidoptera* living in field margins could be exposed to these Cry proteins as data in the application showed that Cry1A.105 and Cry2Ab2 proteins are expressed in pollen.

As these Cry proteins generate pores in the digestive tract of target organisms, ACRE considered it feasible that they could alter the sensitivity of these organisms to other compounds in the digestive tract, in this case, the modified EPSPS protein. The applicant did not submit data to support its argument that a synergistic effect between the Cry and CP4-EPSPS proteins produced by MON89034 x NK603 maize does not occur. ACRE concluded that applicants should consider this possibility and where there is a viable hypothesis to test, carry out experiments.

The statutory nature conservation agencies voiced their concern that Monsanto would not place sufficient emphasis on the adoption of refugia in reducing the likelihood of target *Lepidoptera* developing resistance to these Bt proteins.

ACRE considered that the applicant had not addressed the potential for herbicide regimes used in association with this GM maize to have a greater impact on biodiversity as a consequence of more effective weed control compared with regimes used in association with non-GM maize. ACRE noted that EFSA had carried out an assessment of this type in its opinion on NK603 maize. ACRE concluded that a post-market monitoring system needed to be implemented to manage the risk that herbicide regimes used in association with this GMO could be more harmful to farmland biodiversity than those used in association with non-GM maize.

ACRE examined the farmers' questionnaire included in the application and considered that as a range of weed control strategies could be adopted (with different impacts on wider biodiversity), questions on the dosage and timings of herbicide applications should be included.

2.3.2 Application from Monsanto for authorisation under Regulation (EC) No. 1829/2003 to cultivate maize MON 89034 x MON 88017 - ref. EFSA/GMO/BE/2009/71

ACRE was asked in January to consider an application for cultivation in the EU of maize MON 89034 x MON 88017 in which GM events conferring insect resistance to certain Lepidopteran species (MON 89034) and to certain Coleopteran insect pests belonging to the *Chrysomelidae* family (*Diabrotica* spp.) and herbicide tolerance

(MON 88017) have been stacked by conventional breeding. ACRE assessed the MON 89034 event when considering MON 89034 x NK603 maize and had considered the MON 88017 event in November 2008. ACRE considered the implications of stacking these events.

ACRE was content with the molecular characterisation provided in the application. The committee considered that sufficient evidence was provided to demonstrate that the two genetically modified (GM) events are conserved and independent in this hybrid. ACRE considered that there was no risk of recombination between the two GM events from these GMOs leading to the formation of novel proteins through the creation of new open reading frames. Therefore, ACRE had no specific concerns about the evidence as presented.

ACRE noted that the survivability had not been tested specifically by the applicant but agreed it was very unlikely to survive outside of cultivated conditions in the UK. ACRE was satisfied that the likelihood for the introduced traits in this stack to confer any competitive advantage or disadvantage of relevance in the agronomic or natural environment is negligible.

ACRE discussed the difference between Cry1A.105, Cry2Ab2, and Cry3b1 proteins and other Bt proteins that target Lepidopteran species and Coleopteran species (Chrysomelids). ACRE agreed with the applicant's statement that stacking Cry genes (as in MON 89034 x MON 88017) can reduce the probability of resistance occurring. ACRE noted from data on expression of the transgenes that Cry1A.105, Cry2Ab2, and Cry3b1 proteins are expressed in pollen. Therefore, non-target Lepidoptera and non-target Chrysomelids living in field margins will be exposed to these proteins.

As these Cry proteins generate pores in the digestive tract of target organisms, it is feasible that they could alter the sensitivity to other chemicals in this case, the modified EPSPS protein. ACRE considered this unlikely but would consider it on a case-by-case basis taking a hypothesis-based approach unlike EFSA which adopted an evidenced-based approach on this issue. Therefore, ACRE suggested that for example, the dossier could have included questions to investigate whether or not the presence of a second and third Cry protein induces the formation of more pores in

the larval digestive tract, and whether their combination with the ESPS has any toxic effect.

ACRE considered that the applicant had not addressed the potential for herbicide regimes used in association with this GM maize to have a greater impact on biodiversity as a consequence of more effective weed control compared with regimes used in association with non-GM maize. ACRE noted that EFSA had carried out an assessment of this type in its opinion on NK603 maize.

ACRE concluded that a post-market monitoring system needed to be implemented to manage the risk that herbicide regimes used in association with this GMO could be more harmful to farmland biodiversity than those used in association with non-GM maize.

ACRE examined the farmers' questionnaire included in the application and considered that as a range of weed control strategies could be adopted (with different impacts on wider biodiversity), questions on the dosage and timings of herbicide applications should be included.

2.3.3. Other food and feed applications

ACRE considered a number of other food and feed applications during the year.

In January ACRE finalised its preliminary advice on an application to cultivate H7-1 sugar beet (ref. EFSA/GMO/DE/2008/63). It was also notified of a joint application from Bayer CropScience and Monsanto to import, process (and use as food and feed) a GM oilseed rape Ms8 x Rf3 x GT73 (ref. EFSA/GMO/NL/2009/75) and asked for the environmental risk assessment included with his application once validated.

ACRE was notified in January of an application from Monsanto to import and process MON 87769 soybean, for which it agreed it would provide advice once EFSA had completed its assessment.

In March ACRE was notified of an application to import, process and use as food and feed GM cotton that is tolerant to glufosinate ammonium and glyphosate

herbicides (ref: EFSA/GMO/NL/2010/77). These traits have been combined through crossing GM plants containing the individual events (LLCotton25 and GHB614). As ACRE is familiar with the individual GMOs and because environmental exposure to this GMO will be negligible, it concluded that it did not need to revisit the scientific evidence until after EFSA has issued its scientific opinion on this application.

ACRE was asked to advise on three GM maize applications: MIR604 X GA21 (ref. EFSA/GMO/UK/2007/48); Bt11 X MIR604 (ref. EFSA/GMO/UK/2007/50) and Bt11 X MIR604 X GA21 (ref. EFSA/GMO/UK/2008/56). The committee agreed that these would not cause a risk to human health and the environment and that the generic advice would apply, covering applications to import and process GM crops that have limited potential to grow and flower outside of agricultural conditions in the UK, would apply.

In June ACRE considered an application to import, process and use as food and feed MON87705 soybean (Ref. EFSA/GMO/NL/2010/78). The seeds of this GMO have an altered fatty acid profile and tolerance to glyphosate herbicide. Its altered oil composition had been achieved by RNA interference. ACRE considered the molecular data included in the summary notification. It concluded this to be sufficiently clear and detailed for the committee not to require further information until EFSA publishes its scientific opinion on this application. ACRE noted that there are likely to be a significant number of applications for GMOs with altered fatty acid profiles in the near future.

ACRE was notified in June of an application to import MON877701 x MON89788 soybean (insect resistant and herbicide tolerant) (ref. EFSA/GMO/NL/09/73) and to use it as food and feed, has been validated. Previously ACRE concluded that it did not need to consider the detailed application prior to EFSA's opinion because environmental exposure would be minimal.

ACRE considered three applications in September to import and use as food or feed. These are NK603 x T25 maize (tolerant to glyphosate and glufosinate ammonium herbicides – ref, EFSA/GMO/NL/2010/80), and MIR162 maize (resistant to certain lepidopteran pests and able to utilise mannose – ref. EFSA/GMO/DE/2010/82) maize, and a soybean (MON 87701) that is resistant to certain lepidopteran pests –

ref. EFSA/GMO/BE/2010/79. ACRE had considered information on all these GM events previously and concluded that it did not require further information on these applications until EFSA has published its opinions.

2.4 Other Advisory Duties

ACRE may be called upon to assess the environmental risk assessment aspects of marketing applications for human or veterinary medicinal products containing or consisting of a GMO, submitted to the European Medicines Agency in accordance with Regulation (EC) No. 726/2004. The committee considered two such applications in 2009. 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 (sometimes at short notice) 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 research reports, EFSA's guidance on environmental risk assessment and its opinion of potential impacts of GM plants on non-target organisms.

Members of the secretariat are involved day to day in advising HSE on the environmental risks of GMO contained use notifications and processed 176 cases in 2010.

2.4.1 Defra-funded research project: Monitoring of arable weed populations

The secretariat introduced this scoping study at the 12th January meeting, indicating that the report was currently a working draft and that input from the committee was sought before it was finalised. This desk study had been commissioned in anticipation of EU votes on the cultivation of GMHT crops. The study was intended to establish methodology for a weeds survey, which could be used as an early warning system to detect any negative impacts on farmland biodiversity arising from changes in agricultural practices. ACRE specifically considered the use of this methodology in detecting impacts resulting from specific herbicide management regimes used with GMHT crops.

ACRE considered the study was a valuable step forward in determining the requirements for a weeds survey for use with GMHT crops and that the report suggested that the scale of analysis was at least feasible. The committee welcomed the proposal from the contractors to provide costings for different sampling intensities and felt that this would contribute to establishing how feasible such a study would be. The committee noted that costs rapidly increase if a higher resolution is required and more samples per farm are needed. The point was made that if high resolution was required few organisations could afford to fund this kind of study. Although a survey could be reasonably expected to detect big changes in common weeds, detecting changes in rare weeds would be much more costly.

Members discussed whether the report went far enough towards defining best practice. It was suggested that this aspect could be developed further in the final version and that it might be helpful to provide a guidance document on what should definitely be avoided in designing a weeds survey.

The committee noted the need to better define the aims of the survey. Whilst agreeing that the survey represented a practical solution, members noted that it would be necessary to think carefully about whether it provided the necessary information to address the objective of protecting farmland biodiversity. Members suggested that the study might benefit from further statistical analysis and simulation to resolve the issues with power of analysis. The report should consider further the implications of sampling multiple fields per farm. It should also discuss further the implications of recording presence/absence rather than abundance, and could be extended to look at the implications of scenario based sampling.

ACRE agreed to work with the secretariat to provide specific questions to the contractors to help in finalising the report. ACRE indicated its intention to use the report in writing a best practice paper with suggestions for companies and EFSA.

ACRE agreed with Fera that they should extend the study with more emphasis on detecting GMHT effects, including comparisons between GM and non-GM effects.

2.4.2 Defra-funded research report: Review of the establishment and persistence of potato volunteers and the potential consequences for current EU labelling thresholds for GM

This report by Fera, discussed at the March 18th meeting, had been commissioned by Defra to inform co-existence policy for GM and non-GM potatoes. ACRE was aware that co-existence is not a safety issue as any crop which is approved for EU cultivation will have undergone a rigorous risk assessment to ensure it is safe for release. The committee was reminded that although its remit focuses on safety, it is also asked to provide advice on scientific evidence that contributes to formulating co-existence policy. The results of the report might be useful in informing consent conditions for Part B potato research trials.

The report highlighted that farmers currently undertake measures to prevent the occurrence of potato volunteers in subsequent crops. Data were presented to show that good agronomic practice could reduce volunteers to levels in a subsequent conventional crop, which would not exceed the 0.9% threshold specified for adventitious presence of GM. The committee noted that if disease resistant GM potato were introduced, that farmers might be inclined to include potatoes more frequently in the rotation, which would make the control of volunteers more challenging. It was, however, also noted that this would not pose difficulties for co-existence if the short rotation relied on GM varieties only being used. In summary the committee agreed with the report's findings that if best practice measures were employed to control volunteers, adventitious GM presence in a subsequent conventional crop should not exceed the 0.9% threshold.

ACRE then considered the implications of the report in informing consent conditions for potato Part B research trials. ACRE noted that post-trial management conditions attached to consents had evolved and that longer monitoring and volunteer control and these sites reflected different harvesting and post-trial management practices. Cultivation of sites immediately after completion of trials was considered very important in controlling potato volunteers.

ACRE discussed other measures that could be implemented following research trials to reduce the likelihood of true potato seed and tubers remaining in the soil and ensure volunteers were effectively identified and eliminated if they did occur. ACRE recommended that vegetative tissue should be removed and destroyed as soon as practical in the research trial, preferably before seed set. Harvest should be undertaken wherever possible under good harvest conditions to ensure effective removal of tubers from the soil. Immediately after harvest ACRE recommended that steps were taken to ensure all tubers were removed from the site and that the site should not be ploughed. The site should be left fallow unless there were real issues with soil erosion, in which case an annual cereal might be the most appropriate option for cover. Light tillage should be carried out annually in the spring to stimulate germination. Regular monitoring for volunteers should continue during the growing season for at least two years following completion of the trial and until two consecutive years had been recorded in which no volunteers had been found. It was agreed that volunteers could be removed either by hand-pulling or treatment with an appropriate herbicide.

ACRE agreed that the above recommendations should be incorporated into potato consents or provided as recommendations to the applicants as appropriate.

2.4.3 Defra-funded research report: adventitious GM presence arising through use of shared farming machinery, transport and storage equipment

This project had been commissioned by Defra to inform policy on the co-existence of GM and non-GM crops. ACRE was asked in September to consider the report as part of its remit to provide advice on any scientific issue relating to GM. In this project, the amount of GM carry-over, which could occur if farm machinery were shared with non-GM producers, was determined experimentally. ACRE noted the outcomes of this report and commented that the figures for GM carry-over presented in the report were likely to represent worst case scenarios as a small field size was used in calculations. It was also noted that if best practice recommendations were followed, sharing farm machinery was unlikely to pose a problem for co-existence.

2.4.4. Consultations on the EFSA updated guidance document for the environmental risk assessment of genetically modified plants and the EFSA scientific opinion on the assessment of potential impacts of genetically modified plants on non-target organisms

ACRE considered these two documents at its March meeting and subsequently. The chairman highlighted the importance of the guidance in establishing the scientific standards for the environmental risk assessment of GM plants in the EU. ACRE agreed to submit preliminary comments and a group of members will then develop the full response, to be circulated to the whole committee for comment and adoption.

Members considered that guidance should be clear and as far as possible, inclusive rather than exclusive in establishing evidence requirements. They concluded that case studies would have been useful in this respect. In general, members considered that the text was dense and lacked the clarity that is required from guidance. ACRE noted that it had not agreed with EFSA's existing view on assessing stacked GM events and this was an area in the revised guidance where it would need to challenge the scientific rigour of EFSA's position.

2.4.5 Assessing potential impacts on biodiversity resulting from altered herbicide regimes in conjunction with GM HT maize

ACRE was requested to consider producing a paper that would update ministers and other stakeholders on its approach to dealing with the potential for herbicide regimes used in association with GM herbicide tolerant (HT) maize to have a greater impact on biodiversity as compared to those associated with conventional maize.

ACRE has not published formal advice on this subject since 2004 when it advised on the farm-scale evaluations (FSEs). These trials included a comparative assessment

of the impact on biodiversity associated with herbicide regimes used in association with GM glufosinate ammonium-tolerant maize and non-GMHT maize. Since 2004, ACRE has considered a number of applications to cultivate GMHT maize events but there had been no votes on the authorisation of these applications and ACRE had not been asked for formal advice. The objective of the paper would be to explain how ACRE's approach had evolved since 2004.

ACRE's approach had evolved such that more emphasis had been placed on post-market monitoring (PMM). ACRE explained that it considers that applicants can either provide detailed environmental risk assessments (ERA) based on a defined set of cultivation practices or produce a broader ERA and manage the development of management practice during the period of authorisation by adopting appropriate monitoring. ACRE considered that this latter approach was proportionate because in-field biodiversity in maize crops (both GM and non GM) is very low. In addition, ACRE emphasised that it is not possible to predict absolutely how the management of a crop and its non-GM comparator will change over the period of authorisation. It felt that practices (and consequently their impact) will alter as farmers become more experienced in using this system and with changes in the availability of pesticides.

ACRE discussed the relationship between the ERA and PMM. ACRE emphasised that PMM should be formulated on the basis of the results of the ERA. The poor biodiversity value of maize was considered a significant consideration when assessing the risks posed by the weed management regimes associated with GMHT maize, but the committee felt that this approach might also have value for other GMHT crops. ACRE also considered the relevance of the FSE results in the ERA of different GMHT maize events that are associated with different broad spectrum herbicide regimes. It emphasised that the FSE results (including subsequent analyses that took into account the ban on atrazine) demonstrated that under the specific conditions used, herbicide regimes used in association with glufosinate ammonium-tolerant maize posed no greater risk to biodiversity as compared to those used with non-GM counterparts.

ACRE considered that its paper should discuss the concept of 'mitigation'. It discussed the option for applicants to propose measures that would provide greater confidence (without a detailed analysis of all the possible herbicide regimes that

could be used with the GMHT crop and their relative impact on biodiversity) that the risks posed by herbicide regimes used in association with GMHT maize would be no worse for biodiversity as compared to those associated with non-GM counterparts. ACRE noted that 'out of crop' measures are used increasingly in conventional arable agriculture to deliver ecological benefits without compromising on the management of the crop. ACRE agreed that a small group of members would work on the paper and a revised version would be circulated to the committee for comment and adoption.

To inform its consideration of the issues, ACRE invited representatives of Syngenta to its September meeting to present their application to cultivate GA21 maize, tolerant to the herbicide glyphosate. In its application, Syngenta had described a suite of herbicide regimes that are likely to be used in association with conventional maize and then considered the structural and functional differences in biodiversity that might arise if weed management regimes making use of the glyphosate-tolerance system were adopted. Syngenta presented sections in its farmer questionnaire that were relevant to this discussion and ACRE asked the representatives about the type and level of differences it might be able to identify through the use of such questionnaires.

2.4.6 Evidence-gathering workshop on GM insects

As parts of its public engagement initiative, ACRE agreed to hold an evidence-gathering workshop on GM insects on 14th October. GM insects was chosen as a topic as products are currently under development and it was important for ACRE to be able to consider at an early stage the implications for the regulatory system. Three speakers were invited to give presentations – Dr Luke Alphey from Oxitec Ltd, Dr Michael Eckerstorfer from the Austrian Federal Environment Agency and Prof Paul Eggleston of Keele University.

The presentations focussed on GM insects currently under development, what types of GM insects might result in applications for release under the EU regulatory system within the next ten years, and factors which would need to be considered in assessing the risks posed by a proposed release of such GM insects to the environment. Dr Alphey described the current field trial of a GM mosquito in the Cayman Islands to combat dengue fever, where sterile males had been released to

mate with wild females. An alternative approach was described by Prof Eggleston in his research on another GM mosquito engineered to be resistant to the malaria parasite which could be released to breed with the wild population.

ACRE concluded that research on developing GM insects was centred around achieving two objectives in two situations. The first objective is the self-limiting approach where the aim is to eliminate the target population by releasing sterile GM insects. The second is the self-sustaining approach where the aim is to drive population change, for example driving the persistence of parasite resistance genes, introduced by genetic modification, in wild mosquito populations. These two objectives could both be used either to combat human and animal disease or to control populations of crop pests. ACRE noted that whilst the current regulatory system offered a sound basis for effective risk assessment, it was important to give careful consideration to how this should be applied to GM insects. Issues included giving consideration to how the balance between risks and benefits should be considered, an issue which is drawn into particularly sharp focus when considering GM insects developed to combat human diseases such as malaria. ACRE agreed to take the outputs of the workshop forward by preparing and publishing a document summarising the issues raised for regulation of GM insects.

2.5 Release of non-native organisms

ACRE also considers and advises on the possible impact of releasing certain non-native plants and animals under the Wildlife and Countryside Act 1981 (WCA). The WCA 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 is not obliged to provide advice on these licence applications, but is consulted mainly on non-native biocontrol agents, wherever its expertise is considered to add value to the advice that is routinely sought from the Statutory Conservation Agencies and others.

During the year ACRE was not asked to advise on any new licence applications. Table 2.1 lists all the licences issued in 2010.

In many respects the release of non-native organisms potentially poses more of a threat to the environment than the much higher profile GMOs. There are numerous examples of introducing plants and animals into areas of the world where they are not naturally found, only to have them become serious and invasive pests.

Table 2.1 Licences to release non-native biocontrol agents under the Wildlife and Countryside Act 1981

Licence number	Bio-control agent	Purpose	Applicant
NN-BCA-10-08	<i>Heterorhabditis bacteriophora</i>	Control of pests in soft fruit and nursery stock and amenity turf and pasture	Becker Underwood
NN-BCA-10-09	Supernemos' (<i>Steinernema carpocapsae</i>)	Control of pests on ornamentals, nursery stock, soft fruit, fruit and vegetables	Nemos Horticultural Ltd
NN-BCA-10-10	<i>Heterorhabditis bacteriophora</i>	Control of vine weevil and beetle larvae in soft fruit production and ornamentals	Koppert UK Ltd
NN-BCA-10-11	Supernemos' (<i>Heterorhabditis bacteriophora</i> and <i>Steinernema</i>)	Control of pests on soft fruit and vegetable crops in commercial nurseries and private gardens	Nemos Horticultural Ltd

	<i>carpocapsae)</i>		
NN-BCA-11-01	<i>Amblyseius swirskii</i>	Control of pests in edible and ornamental horticultural crops grown in glasshouses	Biological Crop Protection Ltd
NN-BCA-11-02	<i>Amblyseius swirskii</i>	Control of pests in edible and ornamental horticultural crops grown in glasshouses	Syngenta Bioline

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 <http://ww2.defra.gov.uk/environment/quality/gm/>

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 website¹ in advance of each meeting and invite comments. The minutes of our meetings are also published on the website, and the secretariat aims to do this within a target period of 15 working days after each meeting. Meeting minutes are supported by detailed advice on individual deliberate release applications which are produced once the assessment process has been completed. We advise on other specific issues when required. Our advice to ministers is published on the web or is available on request from the secretariat, and for deliberate release applications it is also placed on the GMO statutory public register. We have begun a new 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 available² and reproduced each year in our annual report (Appendix V). We also have transparent working practices that allow us to deal openly with the infrequent conflicts of interest that arise at ACRE meetings. If a member's interests conflict with an item of ACRE business, for example where release applications are received from institutes or companies with whom a member is involved, the member is required to inform the committee. The committee then decides whether the link requires the member to be absent from discussions. The decision of the committee and its reasons for including or excluding the individual is minuted and published on the web site.

¹ <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, we have placed an ACRE publication scheme on the web at http://www.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 2010

Chair

Professor Christopher Pollock

Main Expertise

Plant breeding, plant physiology, agronomy

Members

Professor Jeff Bale

Entomology, ecology

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

Professor Jim Dunwell

Plant biotechnology

Professor Les Firbank

Agriculture and biodiversity

Professor Rosie Hails

Pathogen population ecology, plant ecology,
entomology

Dr Ieuan Joyce

Farming practice

Professor Keith Lindsey

Molecular biology

Mr Jim Orson

Farming practice, agronomy

Professor Andy Peters

Clinical development and regulation of
vaccines

Public Engagement Sub-group

Chair

Professor Rosie Hails

Members

Professor Chris Pollock

Professor Jim Dunwell

Professor Andy Peters

Secretariat (Defra)

Dr Louise Ball

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. He was acting chief scientific advisor to the First Minister of the Welsh Assembly 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 until 31 August 2013.*

Professor Jeff Bale

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. Current term runs from 18 August 2008 until 17 August 2012.*

Professor 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 for 3 years from 12 March 2009. Current term runs until 11 March 2012.*

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 until 30 November 2013.*

Professor James Bullock

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. Current term runs until 25 October 2012.*

Professor Jim Dunwell

University of Reading

Expertise: Plant biotechnology

Professor of Plant Biotechnology in the School of Biological Sciences 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 for 3 years from 9 October 2006. Current term runs until 8 October 2012.*

Professor Les Firbank

University of Leeds

Expertise: agriculture and biodiversity

Les Firbank is an independent scientist based in the Faculty of Biology, University of Leeds, where he is a Visiting Professor in Sustainable Agriculture. His research focusses on the interactions between agriculture and the environment (in particular biodiversity) using large scale survey, experimentation and modelling. He led the UK

farm-scale evaluations of genetically modified herbicide-tolerant crops, and is now increasingly interested in the delivery of ecosystems services from agriculture, and the extent to which technologies and farming systems can deliver both increasing agricultural production and environmental quality. 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 is 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 until 25 October 2012.*

Professor Rosemary Hails MBE

Centre for Ecology and Hydrology, Wallingford

Expertise: Pathogen population ecology, entomology

Prof Hails is a Biodiversity Section Head at the Centre for Ecology and Hydrology, Wallingford 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 a member of EFSA's Non-target Organism Working Group and the Environmental Risk Assessment Working Group, chair of the Natural Capital Initiative and sits on the Council for the Society of Biology and the British Ecological Society. She was awarded an MBE for services to environmental research in June 2000. *First appointed to ACRE on 9 October 2006. Current term runs until 8 October 2012.*

Dr Ieuan Joyce

Farmer, Ceredigion and Herefordshire

Expertise: Farming practice

Manages in partnership a mixed farm integrating nature conservation and food production objectives. He is a board member of the Countryside Council for Wales and the Joint Nature Conservation Committee and a former lecturer in animal science at the University of Leeds with research interests in mammalian reproductive

genetics. He is also a member of the Upland Forum, advising the Welsh Assembly Government on rural issues. *First appointed to ACRE on 26 October 2009. Current term runs until 25 October 2012.*

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-elect 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 until 31 August 2013.*

Mr Jim Orson

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. *First appointed to ACRE on 18 August 2002. Current term runs until 17 August 2012.*

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 until 8 October 2012.*

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 2010

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		

Professor Kathy Bamford	Pfizer, Pharmacia, Wyeth, Gilead, 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	Diector of Medical Policy
			St Peter's College, Oxford	Fellow, employee		
			BBSRC, NERC, Royal Society	Funding for research		

Prof James Bullock	None		NERC	Employee	None	
			NERC, ESRC, BBSC, Defra, Natural England, Bournemouth University	Funding for research		
			Bournemouth University, Liverpool University	Visiting professor (no remuneration)		
			Oxford University	External examiner		
			British Ecological Society Ecological Society of America, Dorset Wildlife Trust,	Member		
Professor Jim Dunwell	Plastid AS	Consultancy	University of Reading	Employee	None	
			BioHybrids	Funding for research		
			BBSRC	Funding for research		
			Rothamsted Research	Rothamsted Fellow		
			University of Nottingham	Special lecturer		

Professor Les Firbank	None		ESRC	Funding for research	None	
			University of Leeds	Visiting professor		
			Defra	Member, Livestock Link PMC		
				Member, Demonstration Catchments Research Advisory Group		
	Co-ordinating lead author, Enclosed Agricultural Land, UK National Ecosystem Assessment					
	BBSRC, ESRC, NERC	Member, RELU Strategic Advisory Committee				
Professor Rosemary	None		NERC Centre for Ecology and Hydrology	Employee	Natural England	Employee

Hails			British Ecological Society	Member of the Council, Publications Committee, Policy and Public Committee and Finance Board (unpaid)		
			Oxford University	Senior Research Associate		
			European Food Safety Authority	Member of the Environment Working Group, the Environmental Risk Assessment Working Group and the Non-target Organism Working Group (paid committee work)		
			Oxford Brookes University	Visiting Professor		
			NERC, BBSRC, MRC, Defra, EU	Funding for research		

			Society of Biology	Member of Council (unpaid)		
			Natural Capital Initiative (special interest group of the Society of Biology)	Chair (unpaid)		
Dr Ieuan Joyce	Ochr Fawr	Manager of farm business in partnership	Countryside Council for Wales	Member	None	
			Joint Nature Conservation Committee	Member		
			Upland Forum	Member		
Professor Keith Lindsey	Creative Gene Technology Ltd.	Scientific Director	Durham University	Employee	None	
			BBSRC, EPSRC, DTI	Funding for research		
			BBSRC Council	Paid committee member		
			Society of Biology	Fellow		
			Society for Experimental Biology	President-elect		
			American Society of Plant Biologists, International Society for Plant Molecular Biology	Member		

			New Phytologist Trust	Trustee		
Mr Jim Orson	Small area of arable/grass land farmed by a tenant	Owner	NIAB TAG Group	Employee	None	
			European Weed Research Society	Member		
			International Fertiliser Society	Member		
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		
Professor Christopher Pollock			Aberystwyth University	Honorary professor	None	
			BBSRC	Paid member		
			Welsh Assembly Government and National Non-food Crops centre	Paid committee work		
			Aberystwyth University and Welsh Assembly Government	Unpaid committee work		

APPENDIX VI

ACRE advice issued in 2010

May 2010 (*published 21 May 2010*)

Advice on an application for deliberate release of a potato genetically modified for resistance to potato late blight - Sainsbury Laboratory ref. 10/R29/01

March 2010 (*published 29 March 2010*)

Advice on an application for deliberate release of a potato genetically modified for resistance to potato cyst nematodes - University of Leeds ref. 09/R31/01

December 2009 (*published 29 March 2010*)

Advice on a notification for marketing of a carnation genetically modified for petal colour and herbicide tolerance, line IFD-25958-3 – Florigene Ltd ref. C/NL/09/01

December 2009 (*published 29 March 2010*)

Advice on a notification for marketing of a carnation genetically modified for petal colour and herbicide tolerance, line IFD-26407-2 – Florigene Ltd ref. C/NL/09/02

December 2009 (*published 29 March 2010*)

Advice on a notification for marketing of a carnation genetically modified for petal colour and herbicide tolerance, line Florigene Moonshadow – Florigene Ltd ref. C/NL/97/13