

Advisory Committee on Releases to the Environment

Annual Report 2014

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Foreword by the Chair, Professor Rosie Hails

This report covers ACRE's activities in 2014. Through the year ACRE held two full committee meetings which were open to the public as well as seven 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 published eight pieces of written advice. 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 oilseed rape, cotton, 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.

During the year we considered two applications to market cut GM carnation flowers, and published advice in June and November on the marketing of one of these. As the applications did not include food or feed in their scope they have followed the procedures for marketing under 2001/18/EC. We considered the other carnation application in February, when we concluded no new issues had emerged which would affect our previous advice on this variety, issued in 2013.

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.

Advice on research trials

In February 2014 we considered an application from Rothamsted Research for a 4-year research trial of GM camelina modified to produce omega-3 fatty acids in seed oil, to test the agronomic and yield performance of the GMO under field conditions. Omega-3 fatty acids have been shown to be beneficial for human health and contribute to protection against coronary heart diseases. Defra ministers granted consent for the trial in April having noted our advice and included the conditions we recommended in the consent. The trial may, if

successful, lead to more sustainable method of producing omega-3 which will help to protect the aquatic food web.

Advice on non-native species

Although ACRE spends most of its time on GM-related issues it is also asked on occasions to advise on the environmental risks arising from proposed releases of non-native species, usually bio-control agents. In February 2014 we were asked to advise on an application to release two species of non-native predatory mites for the control of thrips, whiteflies and phytophagous mites. These mites were authorised for use in glasshouses and the applicant wished to extend this to plastic polytunnels and open fields. We considered that more information should be included in the risk assessment on the potential environmental impact of releasing large numbers of these mites over the summer months but this could be based on existing information in the literature.

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. The sub-group's final report will be published in 2015.

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 was asked during the year to advise on GM-related consultations and recently published research. We considered and commented on EFSA's consultation on its new draft guidance on the agronomic and phenotypic characterisation of GM plants. The guidance applies to studies that generate plant material for compositional analysis (GM food/ feed safety) and data for environmental risk assessment in applications to import or cultivate GM crops.

The EU's Scientific Committee on Emerging and Newly Identified Health Risks was considering synthetic biology and aimed to produce a working definition of synthetic biology that can frame its future considerations on implications for

risk assessment and future research priorities. In June it consulted on its proposal for a definition of synthetic biology and ACRE provided comments.

ACRE also gave written evidence to the Commons Science and Technology Select Committee, which undertook an inquiry into GM foods and the application of the precautionary principle in Europe, and I was invited to give oral evidence in January 2015.

ACRE also considered in October a research paper on the indirect effects of GMHT crops on monarch butterflies.

Membership

We were pleased to welcome two new members to the committee in October, Ian Crute and Peter Lund. Ian brings many years of experience in plant pathology and genetics and has a particular interest in the sustainability of agricultural systems. Peter Lund's expertise is in molecular biology, genomics, systems biology and synthetic biology. In addition we welcomed back David Hopkins for a further term.

Looking forward to 2015

I am very keen to see ACRE operating in an open and transparent manner so will continue to holding our committee 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.

We are expecting the harm sub-group to complete its work and publish its report in 2015. 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.

The role and function of ACRE was the subject of a triennial review starting in March 2014. The review has examined whether ACRE's functions are still needed and what would be the best form for delivery. The results have now been published and announced to Parliament. The recommendation is that ACRE should retain its current role and status as an advisory NDPB.

We will also consider the recommendations from the Commons Science and Technology Select Committee and any action we need to take, in discussion with the secretariat.

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 (such as SACGM) and undertaking horizon scanning projects that engage key stakeholders from the relevant sectors (food, medicine, industrial biotech, research funders etc.).

Finally, the publication in 2015 of the Juncker review and the new directive following adoption of the GM cultivation proposals mean that there will be major changes in the EU regulatory system in 2015. We will take a keen interest in developments and will provide advice if required.

I am grateful to all members, the 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

April 2015.

Chapter 1

Main activities in 2014

1.1 Introduction

This is the twenty-first annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2014. 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 2014 but there was also a significant amount of consultation by e-mail and via our new Huddle shared workspace, which was set up in June. 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 seven times during 2014. 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 2015.

ACRE considered in February an application for a research trial at Rothamsted of GM camelina modified to produce omega-3 fatty acids in seed

oil, to test the agronomic and yield performance of the GMO under field conditions. Defra ministers granted consent in April for a 4-year trial.

During the year we also considered applications to market cut GM carnation flowers, and published advice in June and November on the marketing of line FLO-40685-2. As the applications do not include food or feed in its scope they have been processed under 2001/18/EC. We also considered another carnation application in February, SHD-27531-4, when we concluded no new issues had emerged which would have an impact on our previous advice issued in 2013.

EFSA opinions on food and feed marketing applications for oilseed rape, cotton, maize and soybeans were considered by the committee and advice was published on eight of them. 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 our advice.

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

EFSA launched a consultation on its new draft guidance on the agronomic and phenotypic characterisation of GM plants, on which ACRE commented.

The EU's Scientific Committee on Emerging and Newly Identified Health Risks was considering synthetic biology and aimed to produce a working definition of synthetic biology that can frame its future considerations on implications for risk assessment and future research priorities. In June it consulted on its proposal for a definition of synthetic biology and ACRE provided comments.

In October ACRE considered a research paper on the indirect effects of GMHT crops on monarch butterflies and commented on its conclusions. .

ACRE also provided advice on an application to release two species of non-native mites to control thrips, whiteflies and phytophagous mites. These were already authorised for glasshouse use but the new application covered plastic polytunnels and open fields.

The Commons Science and Technology Select Committee announced it would undertake an inquiry into GM foods and the application of the precautionary principle in Europe. ACRE was invited to give written evidence

and responded to particular questions. The Chair was invited to give oral evidence in January 2015.

A triennial review of ACRE was announced to Parliament in March. These reviews are a standard requirement for non-departmental public bodies (NDPB) 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 was undertaken by Defra officials and will be published in 2015. It will recommend ACRE is retained in its present format and with its current remit, but ACRE will consider any action needed in response to the report's recommendations.

The secretariat set up a Huddle workspace for the committee which has helped to streamline working methods, allowing members to have speedy access to documents they need to see or comment on.

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.

We welcomed Dr Peter Lund and Professor Ian Crute to the committee in October. Ian Crute was until recently the Chief Scientist of the Agriculture and Horticulture Development Board (AHDB) and is now an independent Non-executive Director of this organisation. His main expertise is in plant pathology and genetics with a particular interest in the sustainability of agricultural systems. Peter Lund is Reader in Molecular Microbiology at the University of Birmingham with expertise on molecular biology, genomics, systems biology and synthetic biology. In addition, Professor David Hopkins was reappointed for a further term.

Biographical details of all the members who served on the committee in 2014 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, which during the year moved from the Food and Environment Research Agency (Fera) to the Animal and Plant Health Agency (APHA).

The secretary to the committee was Louise Ball. The secretariat also included Martin Cannell, Ellen Colebrook 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.

1.4 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.

During the year ACRE set up the Harm sub-group. The sub-group was established to follow 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. Six ACRE members served on this sub-group, chaired by Dr Rosemary Collier, and it met seven times during 2014. Its output will be a report and updated guidance for risk assessors, expected early in 2015.

In October the sub-group reported to the full ACRE committee on the progress made to date. Discussion focussed around a framework that the sub-group

¹ See Appendix I for the full terms of reference

has developed as a possible approach to assessing harm. ACRE agreed that this framework would be useful for putting GMO releases and other agricultural interventions into broader agro-ecological context and as a tool to guide problem formulation in ERA, and suggested that it would be useful to test the framework using a range of case studies. The sub-group agreed to take these comments into account as it continued its programme of work.

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.

Issues around the definition of harm in the context of GM ERA have been raised in evidence presented to the House of Commons Science and Technology Committee inquiry into GM food and the application of the precautionary principle, and ACRE has noted work being carried out by EFSA on harmonisation and translation of protection goals as one approach to resolving questions around harm. The sub-group's findings will inform ACRE and Defra contributions to this area of work as it develops.

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 Triennial review

Following the review of public bodies in 2010, which concluded that ACRE should be retained as an independent arms-length advisory body, there was a commitment to carry out regular triennial reviews of these bodies. The review of ACRE was launched in March 2014 and the intention has been that it will be proportionate to the small scale of ACRE's activities. The review has

examined whether ACRE's functions are still needed and what the best form of delivery for that function is. The review has concluded that ACRE should continue to perform its functions as an NDPB. After publication, ACRE will consider any recommendations and review its functions and working methods if 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. Synthetic biology takes place mainly under controlled and contained conditions in academic and commercial laboratories. Organisms produced using synthetic biology are currently regulated by GMO legislation. However, as this branch of science develops, it may begin to result in organisms with more complex and novel characteristics. Depending on the degree of novelty and the presence or absence of unmodified comparators, these organisms may begin to challenge current approaches to risk assessment. ACRE will assess how it wishes to engage with and monitor new developments.

1.5.6 Commons Science and Technology Select Committee report

ACRE will consider any recommendations for its role and remit from the Commons Science and Technology Select Committee report of its inquiry on GM foods and application of the precautionary principle in Europe "Advanced genetic techniques for crop improvement: regulation, risk and precaution". Any action the committee needs to take will be discussed and followed up with the secretariat.

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.

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 saw two applications follow this route in 2013, which were for cut carnation flowers.

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 under Part B of Directive 2001/18/EC from Rothamsted Research to release *Camelina sativa* genetically modified to accumulate omega-3 long chain polyunsaturated fatty acids in seed oils. Ref. 14/R8/01

In February ACRE considered an application from Rothamsted Research for a research trial of GM camelina, which has been modified to produce omega-3 long chain polyunsaturated fatty acids in its seed oils. The purpose of the trial is to test the agronomic and yield performance of the GM camelina under field conditions. The application is for a four year trial, to be carried out between 2014 and 2017 on a 3 hectare fenced site at Rothamsted. No material from the trial will enter the food or feed chain.

Omega-3 LC-PUFAs have been shown to be beneficial for human health and contribute to protection against coronary heart diseases. The primary dietary sources of these fatty acids are marine fish either wild stocks or farmed fish

(aquaculture). Fish like humans do not produce these oils but rather they accumulate them through the consumption of other marine organisms, e.g. algae, or in the case of farmed fish through fishmeal and fish oil. Around 80 percent of all fish oil is consumed by the aquaculture sector and industry is seeking new Omega-3 LC-PUFAs sources to ensure its production practices remain sustainable and nurture the essential aquatic food web.

The proposed trial involved the release of three GM events, each derived from a different construct. The 3 GM lines have been transformed with four, five or seven genes involved in the biosynthesis of omega-3 LC-PUFAs, these genes are of algal or fungal origin and have been codon-optimised for the Brassicaceae and chemically synthesised. These genes are under the expression of seed-specific promoters. Additionally, each transformation construct also encodes a selectable marker, in two cases DsRed, and in one case nptII. Camelina plants were transformed using Agrobacterium-mediated transformation.

ACRE noted that Rothamsted had not provided data on integration of the vector backbone sequence into the plants genome, or considered the risks associated with this. However, ACRE also noted that the vectors used were derived from pBIN19, which is well-characterised and the sequence of which is readily available. ACRE considered that the integration of vector backbone sequences would not alter the risk assessment, particularly with respect to the likelihood and effects of horizontal gene transfer, beyond those already considered by the applicant.

ACRE noted that the applicant had not provided data on transgene expression in reproductive plants parts, including pollen. ACRE considered that this data would not further inform the risk assessment and that transgene expression in pollen was not considered a risk.

ACRE also considered the risks associated with the use of the nptII antimicrobial resistance marker gene. In line with its previous advice, ACRE noted that the nptII gene occurs naturally in soil bacteria, the likelihood of transfer of a functional gene from plant material to soil bacteria is extremely low, and that acquisition of an intact gene is only one mechanism by which bacteria may develop resistance. ACRE considered that the risks associated with the use of this gene are very low.

ACRE agreed with the applicant that camelina has a low baseline of invasiveness and does not compete well with surrounding vegetation, and that the genetic modification was unlikely to alter this. However, ACRE considered

that the applicant had not given sufficient consideration to the possible presence of wild relatives in the vicinity of the trial and wild relatives that may have the potential to cross-hybridise, such as *Capsella bursa-pastoris* (Shepherd's Purse). Although ACRE recommended that the applicant amend this in the application, it did not consider that cross-pollination of compatible species represented an environmental risk.

The risk of toxic, allergenic or harmful effects to humans or animals of the proposed release were considered. ACRE did not have any concerns and agreed with the applicant that the risks of this are very low.

ACRE considered what measures might be necessary to minimise the dispersal and persistence of the GMO in the environment. ACRE suggested that a separation distance in line with that used for oilseed rape or a pollen barrier as proposed by the applicant would be appropriate. To stimulate any GM seed in the seed bank and minimise persistence, ACRE considered that there is a need for light cultivation of the soil in the spring of the year following harvest (and possibly shortly after harvest). This should be of the whole plot. ACRE also recommended that the numbers of volunteers should be recorded as part of any monitoring requirements, and that subsequent to this data collection all volunteers should be killed before flowering. It was suggested that the plot should be free of volunteers for two years, or monitored for three years, before being used to grow material for the food or feed chain.

ACRE discussed measures for minimising seed dispersal during and after the trial- these were cleaning the combine completely on the plot after harvesting, and ensuring that suitable measures were in place to prevent dispersal by birds. It was noted that seed dispersal by molluscs is one possible route to dispersal and that this had not been considered by the applicant. Although ACRE did not consider this to be a significant route of dispersal, it was recommended that the applicants amend their application to acknowledge this. It was also noted that harvesting slightly early to minimise shedding as suggested by the applicants was probably unnecessary and could compromise the oil content and profile of the seeds, and as such was not recommended.

Ministers issued consent for the trial on 14 April.

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

2.3.1 Application from Suntory Holdings Ltd to import, distribute and retail import, distribute and retail carnation line FLO-40685-2 in the EU – ref. C/NL/13/02

ACRE considered in May an application submitted by Suntory Holdings (Japan) to the Dutch competent authority (CA) under Directive 2001/18/EC. The application was to import, distribute and retail one variety of GM carnation (*Dianthus caryophyllus*) on the EU cut flower market line, genetically modified for petal colour and herbicide tolerance. The application does not include cultivation, or use as food or feed. The carnation had been modified to contain F3'5'H and DFR proteins, which confer the ability to produce a violet pigment and a mutated ALS protein, which confers tolerance to sulfonylurea herbicides.

The Dutch CA concluded that there were no reasons for marketing consent to be withheld. The UK and the other Member states were invited to submit objections and requests for further information. ACRE considered this application by correspondence in May and its advice informed the comments the UK CA submitted. ACRE advised that these carnations would not pose a risk to human health or the environment and confirmed it agreed with the assessment by the Netherlands CA. ACRE's advice informed the comments the UK competent authority submitted to the Commission. The advice was published on the web in June.

In accordance with the authorisation process of Directive 2001/18/EC, some Member States raised issues and requested further information. In October ACRE considered these requests and the associated responses from the applicant and concluded that no new issues had been raised that would impact on previous discussions or advice given. Updated advice was published in October.

2.3.2 Notification submitted under Part C of Directive 2001/18/EC to import, distribute and retail carnation line SHD-27531-4 in the EU – ref. C/NL/13/01

In October 2013, ACRE issued advice on this application to import, distribute and retail a variety of GM carnation in the EU. The application does not include cultivation. SHD-27531-4 is modified to contain F3'5'H and DFR proteins, which confer the ability to produce a violet pigment and a mutated

ALS protein, which confers tolerance to sulfonylurea herbicides. ACRE did not consider that these GMOs posed a greater risk to human health and the environment compared with non-GM varieties and provided advice that was consistent with this view.

However, in accordance with the authorisation process of Directive 2001/18/EC, some Member States raised issues and requested further information. ACRE was asked to consider these requests and the associated responses from the applicant at its meeting in February 2014 and discuss whether there was anything that altered its previous advice. Members referred specifically to the responses provided on molecular characterisation and gene dispersal and also more generally to the rest of the additional information provided. ACRE concluded that no new issues had been raised that would impact on previous discussions or advice given.

2.4. 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:

2.4.1 BPS-CV127-9 soybean ref. EFSA-GMO-NL-2009-64

ACRE considered in January BASF's application to market GM herbicide-tolerant BPS-CV127-9 soybean for food and feed uses, import and processing, once EFSA's opinion was available. This application does not include cultivation within its scope. The soybean contains a single insertion locus of the *csr1-2* gene and expresses a mutant acetohydroxyacid synthase large sub-unit of *Arabidopsis thaliana*, conferring tolerance to imidazolinone herbicides. ACRE was first notified of this application in March 2009 and decided then it would consider this soybean further once the EFSA opinion was published.

ACRE confirmed it agreed with EFSA's view that BPS-CV127-9 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 soybean in its generic advice for GM crops that have a limited potential to grow and flower outside of

agricultural conditions in the UK, and updated advice including this soybean was agreed on 17 February and published.

2.4.2 305423 soybean ref. EFSA-GMO-NL-2007-46

In May ACRE considered EFSA's opinion on an application from Pioneer to market for food and feed, import and processing, a herbicide-resistant soybean 305423 which also has high oleic acid content. This application does not include cultivation within its scope. Soybean 305423 was developed through particle bombardment and contains gm-fad2-1 and gm-hra expression cassettes, conferring a high oleic acid profile and tolerance to acetolactate synthase (ALS)-inhibiting herbicides. It differs from its conventional counterpart in the seed fatty acid profile and for the presence of the gm-hra protein.

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 this soybean in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK, and updated advice including this soybean was agreed on 16 May and published.

2.4.3 NK603 maize ref. EFSA-GMO-NL-2005-22

In June ACRE was asked to consider further an application from Monsanto to market an application for NK603 maize, for food and feed, import and processing, together with a renewal of the existing authorisation for these purposes. Application 2005-22 had originally been submitted with cultivation in its scope and ACRE had produced draft advice on it in 2010.

Maize NK603 has been developed for tolerance to glyphosate (also refer to as GMHT crop) by the introduction, via particle gun acceleration, of a gene coding for 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) from *Agrobacterium* sp. strain CP4 (CP4 EPSPS).

EFSA in its scientific opinion had concluded that that maize NK603 is as safe as conventional maize and that NK603 and derived products are unlikely to have any adverse effect on human and animal health in the context of the intended uses. ACRE concluded there was no evidence that NK603 maize poses a greater risk to the environment compared with non-GM maize.

ACRE agreed it would not issue its earlier advice which covered cultivation but would add NK603 maize to its generic advice for notifications for import

and processing of GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. NK603 was added on 17 June and the updated advice was published.

2.4.4 MON15985 cotton ref. EFSA-GMO-UK-2008-57

In September ACRE received EFSA's opinion and was consulted on an application from Monsanto for MON15985 cotton for food and feed uses, import and processing, submitted together with the renewal of authorisation of existing products produced from this cotton. These applications do not include cultivation within their scope EFSA's opinion was circulated. MON 15985 cotton was developed by biolistic transformation of cotton MON 531 to express Cry2Ab2 and GUS in addition to the Cry1Ac and NPTII proteins. Cry proteins in MON 15985 confer resistance to major lepidopteran cotton pests, whereas the GUS and nptII proteins were used as markers during product development.

ACRE confirmed it agreed with EFSA's view that this cotton is as safe as its conventional counterparts and considered it was appropriate to include this soybean in its generic advice for GM crops that would not grow under UK conditions. Updated advice including this cotton was agreed on 9 September and published.

2.4.5 MON87769 soybean ref. EFSA-GMO-NL-2009-76

In May ACRE received EFSA's opinion and was consulted on MON 87769 soybean for food and feed uses, import and processing, submitted by Monsanto. MON 87769 was developed using *Agrobacterium tumefaciens* transformation and was intended to modify the lipid profile of the extracted oil. Soybean MON 87769 contains a single insert consisting of the Pj.D6D gene encoding the $\Delta 6$ desaturase protein from *Primula juliae* and the Nc.Fad3 gene encoding the $\Delta 15$ desaturase protein from *Neurospora crassa*, both involved in the desaturation of endogenous fatty acids into stearidonic acid. MON 87769 differs from the conventional counterpart in its fatty acid profile and for the presence of the gm-hra protein. EFSA's opinion was circulated to ACRE for advice in May and members agreed this application should be included in the generic advice for crops with a limited potential to grow and flower outside of agricultural conditions in the UK.

ACRE confirmed it agreed with EFSA that this soybean is as safe as its conventional counterparts and considered it was appropriate to include it in its generic advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK. Updated advice including this soybean was agreed on 9 June and published.

2.4.6 GHB614 X LLCotton25 cotton ref. EFSA-GMO-NL-2009-77

ACRE was consulted in May on GHB614 X LLCotton25 cotton, once EFSA's opinion was available. This application was for food and feed uses, import and processing, submitted by Bayer CropScience. The scope did not include cultivation. GHB614 x LLCotton25 cotton was developed for herbicide tolerance and was produced by conventional crossing of inbred lines of cotton GHB614 and cotton LLCotton25, combining tolerances to glyphosate and glufosinate-ammonium herbicides. The newly expressed proteins 2mEPSPS (expressed in cotton GHB614) and phosphinothricin acetyltransferase (PAT) (expressed in cotton LLCotton25) were assessed previously by EFSA.

ACRE confirmed it agreed with EFSA's view that this cotton is as safe as its conventional counterparts and considered it was appropriate to include it in its generic advice for GM crops that would not grow under UK conditions. Updated advice including this cotton was agreed on 2 June and published.

2.4.7 MON88302 oilseed rape ref. EFSA-GMO-BE-2011-101

ACRE was consulted in July on an application for MON88302 oilseed rape, once EFSA's opinion was available. This application was for food and feed uses, import and processing, submitted by Monsanto. The scope did not include cultivation. This oilseed rape was developed by Agrobacterium tumefaciens-mediated transformation to express the CP4 EPSPS protein, which confers tolerance to glyphosate herbicides.

ACRE confirmed it agreed with EFSA's view that this oilseed rape is as safe as its conventional counterparts and considered it was appropriate to include it in its generic advice on applications for herbicide-tolerant oilseed rape for import and processing. Updated advice including MON88302 was agreed on 4 August and published.

2.4.8 MON88913 cotton ref. EFSA-GMO-UK-2007-41

ACRE considered in October EFSA's opinion on an application from Monsanto to market MON88913 cotton, for food and feed uses, import and processing. The scope did not include cultivation. Cotton MON 88913 contains one insert consisting of the CP4 epsps expression cassette, providing herbicide tolerance.

ACRE confirmed it agreed with EFSA's view that this cotton is as safe as its conventional counterparts and considered it was appropriate to include it in its generic advice for GM crops that would not grow under UK conditions. Updated advice including this cotton was agreed on 21 October and published.

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.

3.1 Non-native species

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

ACRE was asked by the Fera in February to advise on an application to release two species of non-native predatory mites *Amblyseius swirskii* and *Amblyseius montdorensis* for the control of thrips, whiteflies and phytophagous mites. These biological control agents are currently authorised for use in glasshouses; this application is to release them into plastic polytunnels and open fields.

ACRE considered there was sufficient data on the over-wintering potential of the mites. It did however consider that more information was required on the potential environmental impact of releasing large numbers of these mites over the summer months. As polytunnels (in addition to having open ends) can be present in high numbers on farms, ACRE considered that environmental exposure to these mites could be significantly higher compared with their release into glasshouses. ACRE considered that this risk assessment could be based on existing information; it was not asking the applicant to carry out further field studies. Fera was asked to discuss this further with certain ACRE members as necessary.

3.2 Consultation on EFSA's draft guidance on the agronomic and phenotypic characterisation of genetically modified plants

EFSA undertook in the autumn of 2014 a consultation on its new draft guidance on the agronomic and phenotypic characterisation of GM plants.

The guidance applies to studies that generate plant material for compositional analysis (GM food/ feed safety) and data for environmental risk assessment in applications to import or cultivate GM crops. For environmental risk assessments, these data are predominantly used to assess whether a GM plant's potential for invasiveness/ persistence has altered compared to its non-GM counterparts. ACRE also considers that these data add to a weight of evidence [along with molecular and compositional data (where appropriate)] that indicates whether the GM event has altered the characteristics of the plant in a way that was unintended and outside of the variation found in plants of the same species.

ACRE welcomed EFSA's initiative in providing greater clarity on information requirements and in particular, why these are important. ACRE referred to EFSA's existing guidance on environmental risk assessment, which sets out how to assess whether a GM plant's potential has altered in terms of invading new habitats and persisting in the agricultural environment. It also considered the requirements for variety testing as there is considerable overlap with the requirements set out in this guidance to support environmental risk assessment. ACRE endorsed the structured, hierarchical approach to evidence-gathering based on problem formulation but was not convinced that some of the data required in the agronomic/ phenotypic guidance was necessary or consistent with this approach. It also considered that certain outcomes described might be questionable in some instances and indicated some sections were unclear. The secretariat agreed to forward ACRE's comments to EFSA.

3.3 . Indirect impacts of GMHT crops on monarch butterflies

ACRE discussed in October a paper by Flockhart et al² on population declines of monarch butterflies. Members agreed that this modelling work adds some

² Tyler Flockhart D.T. et al. Unravelling the annual cycle in a migratory animal: breeding-season habitat loss drives population declines of monarch butterflies. *Journal of Animal Ecology* 2014

weight to the hypothesis that changes in the distribution or abundance of the host plant (milkweed) on which larvae feed are sufficient to account for a purported decline in the population of adult insects. A robust test of the hypothesis will likely require collection of a sufficient volume of data over time to allow reliable quantification of the relationship between successful adult emergence and host plant distribution and/or abundance. Studies reported by Flockhart et al. illustrate that early stages of monarch butterflies are most vulnerable. However, the model presented lumps together all immature (egg, larval and pupal) stages and so it is difficult to predict robust quantitative changes in Monarch butterfly densities if the life-cycle is not appropriately described. Flockhart et al. attribute changes in monarch numbers partly to increases in GMHT crops. However, changes in host plant abundance will also have occurred as a result of broad changes in land-use and crop management practices and the conclusion that increases in GMHT crops are solely responsible for the decline in monarch butterflies cannot be drawn from this study. Additional concerns were expressed over the robustness of the approach used for the long term projections in habitat reduction. The model predicts a decline in milkweed stems across three regions of the US over the next 100 years. Although this decline is estimated to be 14% (770 million milkweed plants) and expected to slow over through this century, there are no levels of uncertainty or sensitivity analyses to support this percentage decline in milkweed abundance.

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

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

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

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

Appendix III

ACRE membership in 2014

Members	Main Expertise
Professor Rosie Hails (chair)	Ecology, entomology
Professor Kathy Bamford	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 (appointed 1 October 2014)	Plant pathology and genetics
Professor Jim Dunwell	Plant biotechnology
Professor Les Firbank	Agri-ecosystems
Dr Matthew Heard	Community ecology, plant population ecology, agricultural ecology, conservation science
Professor David Hopkins	Soil biology and biochemistry
Dr Ieuan Joyce	Farming practice
Simon Kerr	Agronomy
Dr Peter Lund (appointed 1 October 2014)	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 Ieuan Joyce

Dr Matthew Heard

Dr Mike Bonsall

Appendix IV

Biographies of ACRE members

Professor Rosemary Hails MBE (chair from 1 September 2013)

Centre for Ecology and Hydrology, Wallingford

Expertise: Ecology, entomology

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

Dr Kathy Bamford

Imperial College

Expertise: medical microbiology and human infection

Kathy Bamford is a consultant medical microbiologist at Imperial College Healthcare NHS Trust (ICHT) and Visiting Professor in the Dept. of Infectious Diseases and Immunity at Imperial College. Her expertise is in the aetiology diagnosis and management of human infection with research interests in the immunopathology, prevention and management of infection. She is medical microbiology lead in the development of the Centre for Infection Prevention and Management at ICHT, a Fellow and examiner for the Royal College of

Pathologists. First appointed to ACRE on 12 March 2009. Current term runs from 12 March 2012 to 11 March 2015.

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 is on the editorial boards of BMC Ecology, Ecology Letters and Ecological Entomology. First appointed to ACRE on 1 December 2007. Current term runs from 1 December 2013 to 30 November 2016.

Dr Rosemary Collier

University of Warwick

Expertise: applied entomology, horticultural crops

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

Professor Ian Crute CBE

Self-employed consultant

Expertise: plant pathology and genetics

Ian Crute has had a 40 year career in crop research. Until recently 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 has served on several Boards and Committees connected with science and innovation within the UK agri-food sector. Currently, this includes the role of Research Champion for the 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

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. Current term runs from 26 October 2012 to 25 October 2015.

Dr Matthew Heard

NERC Centre for Ecology and Hydrology, Wallingford

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

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

Professor David Hopkins

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

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. Current term runs from 26 October 2012 to 25 October 2015

Simon Kerr

National Institute of Agricultural Botany (NIAB)

Expertise: agronomy

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

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 vaccine research, development regulation and knowledge transfer. He also has considerable experience in reproductive biology with a current research interest in immunocontraceptive vaccines. He also holds a special professorship in animal science at the University of Nottingham. First appointed to ACRE on 9 October 2006. Current term runs from 9 October 2012 until 8 October 2016.

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 2014

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

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

		2014-17	BBSRC, NERC, Royal Society	Funding for research		
			EFSA	Member of working groups on protection goals and endangered species; 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
	Waitrose Agronomy Group	Funding for PhD studentship	Insecticide Resistance Action Group	Member (unpaid)		
	Bayer	Funding for research	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, Defra and HGCA	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	Assured Food Standards Ltd (Red Tractor Scheme) –	Independent Director	University of Leeds	Employee	University of Leeds companies involved in pig nutrition	Employee

	not for profit		Defra	Member, Demonstration Catchments Research Advisory Group		
			WCMC	Contributing researcher, UK National Ecosystem Assessment (Phase 2)		
			EU Framework 7	Funding for research		
Professor Rosemary Hails	None		NERC Centre for Ecology and Hydrology	Employee	Natural England	Employee

			Oxford Brookes University	Visiting Professor		
			Natural Capital Initiative (special interest group of the Society of Biology)	Chair (unpaid)		
			Natural Capital Committee	Member		
			NERC, BBSRC, MRC, Defra, EU	Funding for research		
			Society of Biology	Member of Council (unpaid)		

			British Ecological Society	Vice President and Member of Council (unpaid)		
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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 Enterprises Ltd	Executive Director	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		
			Moredun Research Institute	Board Member		

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

Simon Kerr			NIAB	Employee	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		
			University of Nottingham	Visiting Professor		
	Elanco	Consultant	Wildlife Ark Trust	Consultant		
	Pfizer	Shares, pension				

Appendix VI

ACRE advice issued in 2014

Advice on a notification for the marketing of a GM carnation FLO-40685-2, for the import, distribution and retail of cut carnation flowers. Published 23 June and 5 November 2014

Advice on notifications for import and processing of GM crops that are unable to grow and flower outside of agricultural conditions in the UK, submitted under regulation EC 1829/2003. Generic advice updated to include GHB614 X LLCotton25, MON15985 and MON88913 cotton. Published 12 February and 21 October 2014

Advice on notifications for import and processing of GM herbicide-tolerant oilseed rape, submitted under regulation EC 1829/2003. Generic advice updated to include MON 88302 oilseed rape. Published 25 September 2014

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 BPS-CV127-9 soybean, 305423 soybean, MON87769 soybean and NK603 maize. Published 22 April and 23 June 2014

Advice on an application from Rothamsted Research for a trial of GM *Camelina sativa*. Published 10 April 2014