

# **Advisory Committee on Releases to the Environment**

## **Annual Report Number 14: 2007**

**April 2008**

Published on behalf of the Advisory Committee on Releases to the Environment by  
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# FOREWORD

## By the Chairman, Professor Chris Pollock

This report covers ACRE's activities in 2007. 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 agreed a revised 2001/18 Part B application from BASF, changing the site of a trial of blight-resistant potatoes; a 2001/18 Part C notification to market Florigene Moonqua carnations (modified for herbicide tolerance and violet pigment) and published updated advice on Part C notification for potato modified for starch composition EH92-527-1 following discussion of the EFSA opinion on the use of *nptII* as a selective marker gene.

In terms of work carried out under Regulation (EC) No. 1829/2003, ACRE considered 4 food and feed applications covering GM maize and soybean and commented on the environmental risk assessment prior to EFSA publishing its opinion. ACRE also considered the EFSA opinion on 4 applications covering maize, soybean and cotton and provided comments. ACRE agreed generic advice for 1829/2003 applications where crops do not grow under UK conditions (e.g. rice and cotton) and crops which are cultivated in the UK but do not establish outside agricultural conditions (such as maize). ACRE reviewed advice on MON 863 maize in light of an EFSA statement on *nptII* as a selective marker gene and EFSA's review of a rat feeding study. ACRE also considered annual reports on general surveillance for NK603, MON863 and 1507 maize.

During 2007, ACRE published its report on "Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks" and ACRE members have presented the committee's views on the regulatory environment at a number of national and European meetings. The work programme for 2008 has been agreed and will cover issues of openness and transparency of operation. In terms of ACRE's other duties, the committee considered an application to release mites *Amblyseius ovalis* and *A. montdorensis* to control whitefly and thrips and for a trial to assess the impact of releasing these organisms into open structures such as polytunnels; commented on

various Defra-commissioned research reports and published advice on two: "Agronomic and environmental implications of the establishment of GM herbicide tolerant problem weeds" and "RNA-mediated gene silencing mechanisms and their implications for the risk assessment of GM plants". ACRE also provided advice on a paper considering the effect of toxins in transgenic crop by-products on headwater stream ecosystems, covering the possible hazard to caddisflies from Cry1aB protein in GM maize.

ACRE members participated in a weed monitoring working group, to assist ACRE in making recommendations to Defra about establishing an arable weed monitoring programme.

The committee met on four occasions during the year, including a meeting in Colchester. ACRE has provided government with specific advice related to its remit including the current status of safeguard actions within the EU. As with all its deliberations, a full account can be found on the ACRE web site. ACRE continues to work closely with other relevant advisory committees, and we have been particularly grateful to colleagues from these committees for specialist advice on occasions.

During 2007, Dr Phil Hulme left the committee to take up a position overseas and was replaced by Dr Mike Bonsall. As Chairman, I remain grateful to members and assessors for their commitment, expertise and enthusiasm. As ever, they 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 fourteenth annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2007. 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 of plants and animals, 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 2007. There was also a significant amount of consultation with the committee by e-mail. Through the year we have dealt with many issues including:

- publication of the Wider Issues Sub-group's report "Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks"
- advice on a new research trial application from BASF, changing the site of a trial of GM blight-resistant potatoes
- advice on a variation to a consent issued to Emergent Product Development UK Ltd to release GM *Salmonella enterica* for use in clinical trials
- advice on a notification to market Florigene Moonaqua carnations
- updated advice on a notification to market a potato modified for starch composition (EH92-527-1)

- advice on a number of food and feed applications under Regulation (EC) No. 1829/2003, commented on environmental risk assessments prior to EFSA publishing its opinions, or commented on EFSA opinions when published
- agreed policy of issuing generic advice for 1829/2003 applications where crops do not grow under UK conditions and crops which are cultivated in the UK but do not establish outside agricultural conditions
- advice on an application to release mites *Amblyseius ovalis* and *A. montdorensis* to control whitefly and thrips
- commented on various Defra-commissioned research reports and published advice on two: "Agronomic and environmental implications of the establishment of GM herbicide tolerant problem weeds" and "RNA-mediated gene silencing mechanisms and their implications for the risk assessment of GM plants"
- set up a weed monitoring working group, to assist ACRE in making recommendations to Defra about establishing an arable weed monitoring programme.

Further details on these and other issues are contained in this report.

## **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 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 2007 Ministers decided to appoint Dr Mike Bonsall to the committee, to replace Dr Phil Hulme who stepped down to take up a post in New Zealand. Details of all the members who served on the committee in 2007 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 Executive, the Scottish Agricultural Science Agency, 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 Central Science Laboratory.

Dr Androulla Gilliland was the secretary to the committee and the other members of the secretariat were Dr Louise Ball, Dr Kate Morley (until August), David Sherlock, Paul Holmes and Joe Pereira (until June). The committee welcomed Darryl Carter as Joe Pereira's successor. 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 reference<sup>1</sup> 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 Sub-group on Wider Issues Raised by the Farm-scale Evaluations of GM Herbicide-tolerant Crops**

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<sup>1</sup> See Appendix I for the full terms of reference

The ACRE Sub-group on Wider Issues was established in January 2004. 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:

[www.defra.gov.uk/environment/acre/fsewiderissues/index.htm](http://www.defra.gov.uk/environment/acre/fsewiderissues/index.htm). The aim of the sub-group was to consider the implications of the farm-scale evaluations (FSEs) with respect to deliberate release of GMOs, and to consider their implications for the scientific assessment of the environmental impact of agriculture generally.

The sub-group drafted its report taking into account the evidence presented at the 2004 open meeting, the views of ACRE and the views of stakeholders following circulation of the draft for consultation in 2006. The report, entitled "Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems", was published on 3 May 2007, to serve as a catalyst for debate about the future development and regulation of novel agricultural technologies and practices and their effects on the environment. The report summary is reproduced in Chapter 3.

### **1.2.2 Weed monitoring working group**

The committee identified arable weed monitoring as an area requiring further study and a working group to take this further was convened in February 2007, including some outside experts. This working group was designed to help ACRE in making recommendations to Defra about establishing an arable weed-monitoring programme (or at least a set of experiments that would facilitate this aim). The group reported that monitoring weeds growing in fields was preferable to monitoring seed banks as this would be very labour intensive, and that a structured sampling approach used for monitoring vegetation would enable adverse effects associated with the adoption of a novel crop or a change in agricultural practice to be detected at an early stage.

### **1.2.3 Work plan over the next year**

ACRE reviews its work plan periodically and reconsiders the programme for its active sub-groups for the coming year.

ACRE is aware that there have been an increasing number of enquiries and notifications regarding GM medicines for both human and veterinary use and recognises it will need to focus on the environmental risk assessment of GMOs for

use in human and veterinary medicine. Defra let a research contract on the environmental risks associated with the marketing of GM veterinary and human medicines to inform ACRE's work in these areas, and the final report of this contract will be published in 2008.

ACRE is keen to continue to work as openly and transparently as its caseload permits. It has agreed to hold an open meeting in 2008. The committee will form a sub-group to begin more detailed planning.

ACRE may decide to reconvene an older sub-group in order to revise reports or provide additional guidance documents where appropriate.

## **1.3 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 four main ones are:

- the Scientific Advisory Committee on Genetic Modification (SACGM)
- the Advisory Committee on Novel Foods and Processes (ACNFP)
- the Advisory Committee on Animal Feedingstuffs (ACAF)
- the Advisory Committee on Pesticides (ACP)

The ACRE secretariat maintains strong links with the secretariats of the above committees (especially SACGM 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. Several members of ACRE worked with SACGM members to draft sections for the revision of the GM contained use Compendium of Guidance, published on 1 February 2007, and this guidance was well received.

# 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 now sees are being 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 a marketing application for a medicinal product containing or consisting of a GMO, submitted to the European Medicines Evaluation Agency under Regulation (EC) No. 726/2004.

## **2.1 Part B release applications for research and development purposes**

From January to December 2007 we reviewed and gave advice on two applications for Part B releases of GMOs, of which one was a new release and the other was a variation to a consent previously issued. We recommended that in both cases consent should be granted with specific conditions attached. The total number of UK applications for releases now stands at 227 since the Deliberate Release Regulations came into force in February 1993<sup>2</sup>.

The new application received was for a release of potatoes resistant to potato blight *Phytophthora infestans*, where the applicant had been obliged to find a new site for one of its proposed trials which had already been approved. A variation for consent was given for GM *Salmonella enterica* in relation to clinical trials of vaccine against hepatitis B, where the committee assessed the proposal to change the site where blood samples were being taken.

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

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<sup>2</sup> 215 applications under the 1993 regulations, 12 applications under the 2002 regulations.

### **2.1.1 Application 06/R40/01 from Emergent Product Development UK Ltd (previously Emergent Europe)**

This application was for the release of GM attenuated *Salmonella enterica* (serovar *typhi*) for use as an oral vaccine in a clinical trial in patients suffering from chronic hepatitis B. The GMO is the same strain as that assessed by ACRE in 2003 (ref 02/R37/02) but it involved administering a larger number of doses using higher levels of the GMO so it was processed as a new application.

ACRE was content that consent should be granted for this trial to proceed and issued advice in 2006. Emergent Product Development UK Ltd subsequently requested a variation to their consent to allow blood samples to be taken from previously inoculated patients in a hospital phlebotomy department rather than in the clinical study room. ACRE was content that this did not alter its previous risk assessment and was content for the variation to be issued. Advice was published on 14 May 2007.

### **2.1.2 Application 07/R42/1 from BASF Plant Science GmbH**

ACRE advised in 2006 on an application (06/R42/1) from BASF Plant Science to conduct an experimental field release of potatoes genetically modified for resistance to *Phytophthora infestans* and consent was granted on 1 December 2006.

BASF submitted details of a new site in the East Riding of Yorkshire to replace the site in Derbyshire previously notified, and this proposal was handled as a new application, 07/R42/1. At its February 2007 meeting, ACRE was asked to consider whether it was content with BASF's conclusion that the environmental risk assessment was not changed by the new information provided. ACRE was also asked to consider whether the advice previously issued also applied to the release of GM potatoes at the proposed new release site. The committee agreed that there were no site-specific issues raised in the discussion of the release of the potato lines notified by BASF or in any previous releases of GM potatoes in the UK. The committee reiterated that there are no sexually compatible wild relatives of potatoes in the UK. ACRE therefore concluded from the information provided that there is no evidence or other reason that a release at the newly proposed site would pose a greater risk to human health or the environment than the sites previously notified.

After taking account of the issues raised in public representations, ACRE advised that the release could go ahead under the same conditions as the previously agreed release. Advice was published on 14 May 2007.

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

We published advice on three Part C notifications during the year. Further details on the notifications we considered are provided below.

### **2.2.1 Notification from Florigene Ltd to market carnation variety FLORIGENE Moonaqua™ (line 123-8-12) – ref. C/NL/06/01**

ACRE considered this notification at its May 2007 meeting. Florigene Ltd wished to import, distribute and retail one line of a GM carnation (123-8-12) in the EU cut flower market. The scope of the notification did not include cultivation or use as food or as feed. The Dutch were the lead competent authority for this notification and their assessment report formed the basis of ACRE's considerations.

Carnation line 123-8-12 is modified to contain F3'5'H and *dfi* proteins, which result in the production of a violet pigment in its flowers. The genes for these proteins were cloned from viola and petunia plants respectively. This GMO also contains a mutated *SuRB* (*ALS*) gene, which confers tolerance to sulfonylurea herbicides. The *SuRB* gene was cloned from *Nicotiana tabacum* (cultivated tobacco).

ACRE discussed the molecular characterisation of this GMO in depth and concluded that the notifier had submitted good quality, detailed data. ACRE was content that the results of bioinformatics analyses and database searches demonstrate that this GM carnation is unlikely to have a greater allergenic or toxic potential as compared to its non-GM counterparts.

ACRE considered that the PCR-based detection method provided in the notification is specific to the transformation event.

ACRE agreed with the notifier's conclusion that it is very unlikely that cut carnation flowers will produce vegetative structures (without human assistance), set viable seed or release pollen that will generate hybrids with wild carnations, other *Dianthus* species or other members of the *Carophyllaceae* family. Consequently, ACRE concluded that environmental exposure and therefore, the risk that 123-8-12 carnations pose to the environment, is negligible. However, ACRE recognised that it is possible for individuals to propagate leaf and/or stem cuttings in glasshouses or in gardens. If this were to happen, ACRE considered that the impact on the environment would be minimal because there is no evidence that gene flow from garden-cultivated carnations into related species would occur or that these plants will become invasive or weedy.

ACRE'S advice was published on 13 June 2007 and after considering information provided by Florigene Ltd in response to requests from other Member States, ACRE confirmed it had not altered its previous advice in further advice published on 21 September.

### **2.2.2 Notification from Florigene Ltd to market carnation variety FLORIGENE Moonlite™ (line 123-2-38) - ref. C/NL/04/02**

ACRE originally considered this application in 2005. Florigene Ltd wished to import, distribute and retail a GM carnation (123-2-38) in the EU. The scope of the notification did not include cultivation or use as food or as feed. The Dutch were the lead competent authority for this notification and their assessment report formed the basis of ACRE's considerations. Carnation line 123-2-38 is modified with *hf1* and *dfr* genes, which confer the ability to produce a violet pigment in its flowers, and the *Su RB (ALS)* gene, which confers tolerance to sulfonylurea herbicides.

ACRE's final advice on this notification was published on 13 June 2007. The committee confirmed it had not altered its previous advice in concluding that the import and distribution of cut flowers from 123-2-38 carnations does not pose an increased risk to human health and the environment compared with non-GM carnation varieties. ACRE had considered the further information provided by Florigene in response to requests from other Member States and the EFSA GMO Panel.

### **2.2.3. Notification from BASF Plant Science GmbH to market potato genetically modified for enhanced amylopectin content component of starch – ref C/SE/96/3501**

ACRE considered in 2006 the EFSA GMO Panel opinion on this application from BASF for the cultivation and use of a potato clone EH92-527-1 modified for the production of high amylopectin starch. ACRE advised that cultivation and use of this clone posed no additional risks to human health or the environment compared to the parental potato cultivar. Further ACRE advice was published in June 2007 following the committee's discussion of the use of the *nptII* gene as a selective marker gene.

At its 3 May meeting, ACRE considered in addition to the EFSA opinion a report by the European Medicines Agency (EMA). The Commission had asked the EMA to consider current and future therapeutic use of antibiotics that are substrates for *nptII*. In particular, this request was made with respect to the notification to cultivate GM potato EH92-527-1 which contains an *nptII* gene.

The EMA report (<http://www.ema.europa.eu/pdfs/human/opiniongen/5693707en.pdf>) concludes that 'neomycin, and kanamycin are of importance for veterinary and human use and that their current and potential future use cannot be classified as of no or only minor therapeutic relevance'. EFSA made a statement in the light of the EMA's comments ([http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/statements/npt2.Par.0001.File.dat/gmo\\_statement\\_%20nptII\\_.pdf](http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/statements/npt2.Par.0001.File.dat/gmo_statement_%20nptII_.pdf)).

ACRE discussed the EMA and EFSA documents and considered that no new information had been provided. ACRE was in full agreement with EFSA's conclusion that the therapeutic effect of antibiotics that are substrates for *nptII* will not be compromised by the presence of the *nptII* gene in GM plants. ACRE agrees with EFSA that (a) the likelihood of transfer of a functional gene from plant material to bacteria is extremely low; (b) bacteria with resistance to these antibiotics are widespread in the

environment; and (c) acquisition of an intact gene is only one of the possible mechanisms for bacteria to develop resistance.

In its advice of 28 June, ACRE stated that the EMEA and EFSA documents contained no new information and confirmed its previous advice that cultivation of EH92-527-1 potato posed no additional risks as compared with its non-GM parental cultivar.

#### **2.2.4 Safety of MON 863 maize – ref. C/DE /02/9**

In September 2007, ACRE considered whether the EFSA statement on the use of *nptII* as a selective marker gene, and the results of a rat feeding study using MON 863 maize, would affect its previous advice on this maize variety. MON 863 is an approved GM maize product on the market in the EU, for which consent was issued by Germany in February 2006.

At its May meeting, ACRE considered and agreed with a statement made by EFSA on the use of the *nptII* gene as a selective marker in GM plants<sup>3</sup>. The GM sub-group of the Advisory Committee on Animal Feedstuffs (ACAF) was also consulted on this issue in relation to the safety of MON 863 as it is an approved product for import and use as animal feed and contains the *nptII* gene. The ACAF GM sub-group agreed with EFSA and remained content that its assessment of the safety of MON863 is unchanged. ACRE considered the advice of the ACAF GM sub-group and concluded that its previous assessment of the safety of MON 863 remained unchanged, i.e., that this GM maize does not pose a risk to human health and the environment and that marketing of this product for importation and processing in the UK will be no different from that of other maize imported for processing and animal feed purposes.

A statistical analysis of the results of the 90-day rat feeding study that had formed part of the application dossier for MON863 maize was published in March<sup>4</sup>. Seralini *et al.* concluded that rats fed MON863 maize kernels showed a number of statistically

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<sup>3</sup> ACRE published minutes of the discussion of ARMGs in May 2007, see item 10. <http://www.defra.gov.uk/environment/acre/meetings/07/min070503.htm> .Follow the link in the minutes to the EFSA statement on ARMGs

<sup>4</sup> Seralini, G.E., Cellier, D., de Vendomois, J.,S., 2007. "New analysis of a rat feeding study with genetically modified maize reveals signs of hepatorenal toxicity". Arch. Environ. Contam. Toxicol., 52, 596-602. Available from: <http://springerlink.metapress.com/content/100119/>

significant differences, including some that were indicative of liver and/or kidney toxicity.

The European Commission sought advice from EFSA on this new analysis and EFSA's response was published in June 2007<sup>5</sup>. The EFSA GMO Panel considered the biological significance of all statistically significant differences in the test parameters and has advised that this publication does not raise any new issues that are toxicologically relevant. The GMO Panel has therefore confirmed its previous opinion that "MON863 maize would not have an adverse effect on human or animal health in the context of its proposed use". EFSA has also published a detailed statistical assessment of the data from the rat feeding study, which is available via the Scientific Reports area of the EFSA website:

[http://www.efsa.europa.eu/en/science/scientific\\_reports/statistical\\_analyses\\_MON863.html](http://www.efsa.europa.eu/en/science/scientific_reports/statistical_analyses_MON863.html). As MON863 maize is authorised for animal feed use, the ACAF GM sub-group was consulted and advised that it agrees with the EFSA conclusion that the statistically significant differences seen in body weights at various times during the 90-day study were probably attributable to fluctuations in food intake and not indicative of an adverse response. ACAF agreed with EFSA that the differences seen in the various (bio)chemical parameters and organ weights measured and highlighted in the paper by Séralini *et al.* arose largely by chance and, as it had previously concluded, are without toxicological significance. ACRE took into consideration both the ACAF GM sub-group and EFSA advice and consequently saw no reason to revise its original opinion on the safety of MON 863 when imported, processed or used for animal feed purposes.

## **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:

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<sup>5</sup>EFSA review of rat feeding data available at: <http://www.efsa.europa.eu/en/science/gmo/statements0.html> .

### **2.3.1 Application from Monsanto for authorisation to use NK603 X MON810 maize in the EU including the use for cultivation of varieties – ref. EFSA-GMO-NL-2005-26**

ACRE considered this application in February 2007. Monsanto submitted a notification to cultivate NK603 x MON810 maize, which is produced from a single cross of NK603 and MON810 inbred lines by traditional breeding methods. NK603 maize contains the *cp4 epsps* gene which confers resistance to glyphosate herbicide. MON810 maize contains the *Cry1Ab* gene which confers resistance to lepidopteran insects including the European corn borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.). The hybrid NK603 x MON810 contains both the *cp4 epsps* and *Cry 1Ab* genes and is resistant to lepidopteran insects and tolerant to the herbicide glyphosate.

ACRE was asked to identify any concerns that could be highlighted to the competent authority leading on the evaluation of the environmental risk assessment (ERA) under Directive 2001/18/EC and to EFSA prior to the publication of its opinion. ACRE had already given a positive opinion on an application for import and processing of this maize hybrid under Directive 2001/18/EC. The committee was satisfied from the information provided on the molecular characterisation of this hybrid maize that they were dealing with the same event as before and therefore had no further comments to make on this.

The committee had previously assessed the cultivation of MON810 maize under Directive 90/220/EEC. ACRE noted that this maize now has a history of cultivation in the EU and has been widely studied, particularly with respect to its effect on non-target insects. Published studies and the information provided in the current dossier indicate that the impact of cultivating both MON810 maize and hybrid NK603 x MON 810 maize on non-target organisms will be negligible. The committee was content with the information provided with respect to these effects. The committee was also content that the insect resistance management plan provided was adequate for the proposed release.

ACRE had assessed a previous application from Monsanto which included the cultivation of NK603 maize (application EFSA-GMO-NL-2005/-2) in July 2006. The

committee noted that insufficient information was included by the notifier with respect to impacts of the management techniques to be used on NK603 maize. ACRE considered that Monsanto had provided insufficient information on this aspect of the environmental risk assessment in the current application. Monsanto put forward the argument that this maize is suited to use in reduced till systems which can lead to environmental benefits. However, ACRE considered that evidence has not been provided to support the conclusion that there is a negligible risk posed by the specific management methods associated with the cultivation of NK603 x MON810 maize. Therefore comments made by the committee on the environmental risk assessment for NK603 maize also apply to the current application.

The post-market monitoring plan provided for this application was discussed briefly and the committee believed that it was inadequate in its current form. The committee agreed to wait until a complete application has been received before assessing the post-market monitoring plan in detail.

### **2.3.2. ACRE generic advice on notifications under Regulation (EC) No. 1829/2003**

ACRE agreed that it would continue to assess each 1829/2003 notification on a case-by-case basis but would consider issuing general advice for at least two categories of notifications that include import but not cultivation in their scope. The first would be for GM crops that do not grow under UK conditions e.g. cotton and rice. ACRE would assess these GMOs to determine whether the GM event has increased the potential of the crop to survive in the UK. If this is not the case, then environmental exposure to such GMOs (even if seed is spilled during import and processing) will be negligible. These GMOs will not flower if seed is spilt.

The second category of GMOs that ACRE would consider for general advice includes crops such as maize that do not establish outside of agricultural conditions (but that are cultivated in the UK). These differ from GMOs in the first category in that there is a low potential for GM plants to germinate from seed spilt during transportation and processing. It is unlikely that these plants will flower. ACRE will assess all notifications for GMOs that could be represented by general advice of this type. This will involve

determining whether a GM event alters the ability of the GM crop to survive and persist in the environment (if its seed is spilled during transportation and processing).

ACRE considered that monitoring of seed/ grain spillage that occurs during the importation of GMOs (that do not have approval for cultivation in the EU) may be necessary for risk management purposes. However, if the risk assessment of a GMO does not identify a potential risk associated with seed spillage, then case-specific monitoring is not required.

### **2.3.3. Application from Bayer CropScience for authorisation to market cotton LLCotton25, for food and feed uses, and import and processing – ref. EFSA-GMO-NL-2005-13**

ACRE assessed the EFSA GMO Panel's opinion on Bayer CropScience's notification to import and process GM LLCotton25. The scope of this notification included use as food and feed. Food and feed safety is not within ACRE's remit and as such, the Committee focused on the environmental risk assessment and post-market monitoring plan. ACRE agreed with the GMO Panel's conclusion that it is 'unlikely that LLCotton25 will have any adverse effect on the environment in the context of its proposed uses'. ACRE considered that its view on this notification should be issued within the first category of general advice as described in 2.3.2 above.

### **2.3.4. Application from Pioneer Hi-Bred International and Mycogen Seeds for authorisation to market 59122 maize for import and processing – ref. EFSA-GMO-NL-2005-12**

ACRE received EFSA's opinion on this notification for the placing on the market of insect-resistant GM maize 59122, for food and feed uses, import and processing, and considered the environmental risk assessment and environmental monitoring components of this opinion. EFSA has concluded that it is unlikely that GM maize 59122 will have any adverse effect on the environment in the context of its intended uses. ACRE agreed with this statement and issued advice under the second generic category as described in 2.3.2 above. This advice was published on 4 June 2007.

### **2.3.5. Application from Pioneer Hi-Bred International and Mycogen Seeds for authorisation to market 59122 maize for import and processing – ref. EFSA-GMO-NL-2005-23**

Pioneer Hi-bred submitted a notification to import and cultivate 59122 maize, which contains *Cry 34Ab1*, *Cry35Ab1* and *PAT* genes and is resistant to coleopteran insects and tolerant to the herbicide glufosinate ammonium.

ACRE was asked to identify any concerns that could be highlighted to the competent authority leading on the evaluation of the environmental risk assessment (ERA) under Directive 2001/18/EC and to EFSA prior to the publication of its opinion. EFSA had already given a positive opinion on an application for import and processing of this maize event under the Food and Feed Regulations. ACRE was satisfied with the information provided on the molecular characterisation of this maize.

The committee noted that the target species for the transformation (*Diabrotica* spp.) do not cause economic damage to maize crops in the UK. However the presence of a small population of *Diabrotica virgifera* around Heathrow airport indicates that the insect is probably capable of survival under UK conditions. The committee also noted that the herbicide tolerance trait associated with this maize event may be attractive to UK farmers.

ACRE was asked to consider the environmental risk assessment provided for this application. The committee agreed with the risk assessment provided with respect to gene transfer and persistence and invasiveness of the maize.

The interaction of the target species with 59122 maize was considered by the committee. Pioneer Hi-Bred stated that *Cry34Ab1* protein has a toxic effect on larvae of the target species whereas *Cry35Ab1* protein does not have a toxic effect on the target pest. The mechanism of the synergistic effect was not explained by the notifier and the committee did not accept the argument that it works in the same way as other *Cry* toxins. The committee asked for further information on the mechanism of toxic action of these proteins on the host species and any possible interactions with other *Cry* toxins that are already present in other GM maize varieties. The insect resistance management plan provided had been well researched but was to be applied only to farmers growing over 5 hectares of maize. The committee expressed concern that in

the UK maize is often grown in areas smaller than 5 hectares and this may result in a large quantity of this GM maize being present without non-GM refugia.

ACRE reviewed laboratory studies relating to the impact of this maize event on non-target organisms. The committee was content that the studies provided by the applicant were conducted appropriately but asked the secretariat to provide full details of a study on earthworms. The committee noted that no studies had been conducted on chrysomelid beetles that are likely to be present in crop margins and hedgerows surrounding the crops. The method used by the applicant in the single year field study investigating effects on non-target organisms was not appropriate. ACRE concluded that impacts on non-target organisms associated with the cultivation of this crop had not been adequately assessed and therefore this impact should be assessed through further field investigations either as part of the application or through case specific monitoring.

No information has been included by the notifier with respect to the use and impacts of the management techniques to be used on 59122 maize. ACRE considered that the notifier should provide an environmental risk assessment with respect to the impact of the herbicide glufosinate ammonium.

The post-market monitoring plan provided for this application was discussed briefly and the committee believed that it was inadequate in its current form. The committee agreed to wait until a complete application had been received before assessing the post-market monitoring plan in detail.

### **2.3.6. Application from Pioneer Hi-Bred International Inc. for authorisation to use 59122 x 1507 X NK603 maize in the EU, including the use for cultivation of varieties - ref EFSA-GMO-UK-2006-30**

Pioneer Hi-bred International Inc. submitted an application to import and cultivate 59122 x 1507 x NK603 maize. This maize contains *Cry 34Ab1*, *Cry35Ab1*, *Cry1F*, *epsps* and *pat* genes and is resistant to coleopteran and lepidopteran insect pests and tolerant to glufosinate and glyphosate herbicides.

ACRE was asked to identify any concerns that could be highlighted to the competent authority leading on the evaluation of the environmental risk assessment (ERA) under Directive 2001/18/EC and to EFSA prior to the publication of its opinion.

ACRE was familiar with each of these events having considered applications for GMOs where these events are present singly or in stacked combinations, and noted that the insect-resistant traits associated with this GMO are not relevant to the UK at present (because the pests they are targeted against do not cause economic damage to maize crops here). However, the herbicide tolerance traits associated with this maize event may be attractive to UK farmers.

ACRE was satisfied with the information provided on the molecular characterisation of this maize (which it has assessed previously) and concentrated its efforts on the environmental risk assessment. ACRE agreed with the applicant's assessment of the risks associated with gene transfer, persistence and invasiveness.

In considering the toxicity of this GM maize to target organisms, ACRE reiterated (see discussion of 59122 maize for cultivation at ACRE's meeting in May 2007) its requirement for further information on the synergistic action of the Cry34Ab1 and Cry35Ab1 proteins and the potential for interaction with other Cry toxins. ACRE considered that there was uncertainty about whether the spectrum of activity could be affected.

ACRE considered the potential effects on species that are not intended targets of the GMO. The committee re-visited its discussion on the potential for 59122 maize to adversely affect non-target Coleoptera in field margins. At its May 2007 meeting, ACRE concluded that laboratory studies on non-target coleopteran species were well-designed. However, ACRE considered that chrysomelid beetles should be included as these are likely to be present in crop margins and hedgerows.

ACRE noted that the applicant does not provide evidence to support its conclusion that 'the occurrence of any possible immediate and/or delayed, direct and indirect environmental impacts arising from cultivation, management or harvesting techniques is not expected'. ACRE considered that the applicant should provide an environmental risk assessment with respect to the potential impact of weed management practices involving the use of glufosinate and/or glyphosate herbicides. ACRE considered that the applicant should submit and discuss herbicide regime strategies that would not

adversely affect farmland biodiversity as compared with current strategies used in association with non-GM crops. These discussions should highlight uncertainties that can be tested through post-market monitoring under commercial conditions.

The post-market monitoring plan provided for this application was discussed briefly and ACRE believed that it was inadequate in its current form. ACRE agreed to wait until a complete application has been received before assessing the post-market monitoring plan in detail.

### **2.3.7. Application from Dow Agro Sciences for authorization to use 1507 x 59122 maize in the EU, including the use for cultivation of varieties – ref EFSA-GMO-NL-2005-28**

Dow AgroSciences submitted an application under the EU's Food and Feed Regulation to import and cultivate 1507 x 59122 maize. This maize contains *Cry 34Ab1*, *Cry35Ab1*, *Cry1F* and *pat* genes and is resistant to coleopteran and lepidopteran insect pests and tolerant to glufosinate herbicides.

ACRE was asked to identify any concerns that could be highlighted to the competent authority leading on the evaluation of the environmental risk assessment (ERA) under Directive 2001/18/EC and to EFSA prior to the publication of its opinion.

Whereas the application for 59122 x 1507 x NK603 maize did not address the potential for weed management regimes to adversely affect farmland biodiversity, the application for 1507 X 59122 did. It cited the results of the UK's farm-scale evaluations (FSEs). However, ACRE considered that it should acknowledge and discuss the probability that management practices other than those used in the FSEs will be used (for GM and non-GM maize). These discussions should highlight uncertainties that can be tested through post-market monitoring under commercial conditions.

### **2.3.8 Application from Bayer CropScience to import A2704-12 soybean – ref. EFSA-GMO-NL-2005-18**

ACRE considered EFSA's opinion on an application from Bayer CropScience to import a GM herbicide-tolerant (glufosinate ammonium) soybean into the EU. ACRE examined the molecular characterisation and environmental risk assessment and

monitoring. ACRE noted that extraneous DNA (associated with the vector in which the DNA elements of interest were put together and copied) had been transferred to the GM soybean, including non-functional fragments of the *bla* gene (which confers resistance to the antibiotic ampicillin). Whilst ACRE concluded that this additional DNA did not increase the potential for the GMO to cause harm to the environment, it noted that the inclusion of extraneous DNA in transformation events does not conform to current best practice. ACRE referred to its guidance on best practice in GM crop design. ACRE agreed that its advice on GM crops that would have minimal environmental exposure, applied in this case. There is strong evidence that feral soybean will not persist in the UK if live seed is spilled during import.

### **2.3.9 Application from Syngenta for authorisation to import and process GA21 maize - EFSA-GMO-UK-2005-19**

EFSA issued its opinion on an application from Syngenta to import a glyphosate-tolerant maize into the EU. EFSA has concluded that it is 'unlikely that GA21 maize will have any adverse effect on human health or on the environment in the context of its intended uses'. ACRE supported the content and quality of EFSA's assessment of the environmental risks posed by this GMO and agreed with EFSA's overall conclusion. ACRE considered that its advice on 'applications to import and process GM crops that have limited potential to grow and flower outside of agricultural conditions in the UK' applied to this application..

## **2.4 Other Advisory Duties**

ACRE may be called upon to assess the environmental risk assessment aspects of marketing applications for medicinal products containing or consisting of a GMO, submitted to the European Medicines Evaluation Agency in accordance with Regulation (EC) No. 726/2004. The committee considered one such application in 2007. 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 gave advice during the year on various issues including gene repair technology, a research paper on the effect of transgene crop by-products on headwater stream ecosystems, a paper on farmland biodiversity and the footprint of agriculture and several Defra-commissioned research reports. ACRE's advice on two of the Defra-commissioned reports is reproduced at Chapter 4 and 5.

Full details of the issues the committee considered can be found on the ACRE website as published advice or in the minutes of ACRE meetings.

ACRE maintains close relations with the Scientific Advisory Committee on Genetically Modified Organisms (SACGM) and its secretariat is in regular contact with HSE on contained use issues. In 2006 two joint groups of ACRE and SACGM members had worked closely together to update the new Compendium of Guidance sections covering the use of GMOs in clinical trials and GM plants and GM micro-organisms associated with plants, and this was published in February 2007.

Members of the secretariat are involved day to day in advising HSE on the environmental risks of GMO contained use notifications and processed 184 cases in 2007.

## **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 wherever its expertise is considered to add value to the advice that is routinely sought from the Statutory Conservation Agencies and others.

At its December meeting the committee advised on the predatory mites *Amblyseius ovalis* and *Amblyseius montdorensis*. One licence was issued in 2007, to Koppert for

the mite *Amblyseius swirskii* (ref NN-BCA/07/01). This was for the control of glasshouse whitefly, tobacco whitefly, western flower thrips and two-spotted spider mite, in edible and ornamental horticultural crops grown in glasshouses.

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.

### **2.5.1 Application from Syngenta Bioline to release predatory mites *Amblyseius ovalis* and *Amblyseius montdorensis***

Defra received applications to release the non-native predatory phytoseiid mites *Amblyseius ovalis* and *Amblyseius montdorensis* for the control of whitefly and thrips in glasshouse and tunnel-grown crops of horticultural vegetables, ornamentals and fruit crops, notably strawberries. Both applications were for large-scale trials to determine the efficacy of the organisms. Due to the similarity of the applications they were considered together. Both organisms are slightly more cold-tolerant than the previously licensed mite *Amblyseius swirskii*, but data were presented for each mite to support claims that *A. ovalis* and *A. montdorensis* would not be capable of surviving winter in the UK climate. Both mites are polyphagous predators with broad reported host ranges, and both are reported to be relatively mobile when in contact with plant material. Both organisms offer potential benefits to extend the temperature range for biocontrol in glasshouses and to reduce pesticide use, in particular *A. montdorensis* provides an option for the biological control of whitefly and thrips in tomato crops, which the previously unlicensed *A. swirskii* does not.

The consultation group which considers these applications raised no objections to licences being granted for trials in glasshouse crops, however concerns were raised over the proposal to release the mites into polytunnels. Advice was sought from ACRE firstly to gain agreement as to whether these organisms were suitable for licensing for trials in glasshouses, and secondly, whether the scope of licences should also extend to tunnel-grown crops.

ACRE considered the data provided indicated that release into glasshouses for trials purposes would not present risks to the environment, but when considering release into polytunnels the committee considered there was insufficient evidence that the scale of the potential risks and consequences of release into a wider receiving environment had been assessed, or were understood. The committee raised questions as to the ability of populations of the organisms to evolve increased cold tolerance, given that five or six generations may establish outdoors, and whether, over time, this could lead to localised populations capable of over-wintering, for example in isolated warm spots or microclimates. Linked with this was a lack of data regarding the potential impact of large locally established populations of *A. ovalis* or *A. montdorensis* on the ecology of local native communities during the periods of short-term establishment, in particular in view of the polyphagous nature of the mites. Assurance as to the purity of organisms released was also considered to be of particular importance for releases into conditions of reduced containment.

The committee concluded that the potential impact of the release of these organisms into open structures such as polytunnels could not be quantified on the basis of the evidence provided and that further data was required to provide assurance that the impact on the local environment of reduced containment releases has been assessed. The committee recognised the potential benefits of the availability of these biocontrol agents and considered it may be possible to obtain this data as part of a small-scale single site trial with a detailed post-release monitoring programme under a licence, and that Defra (CSL) should discuss this option with the applicant.

For further information a guidance document “The Regulation and Control of the Release of Non-Native Animals and Plants into the Wild in Great Britain” (March 1997) is available at: [www.defra.gov.uk/environment/gm/nonnav/index.htm](http://www.defra.gov.uk/environment/gm/nonnav/index.htm)

## **CHAPTER 3**

# **Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems**

Report of the ACRE Sub-Group on Wider  
Issues raised by the Farm-Scale Evaluations  
of Herbicide Tolerant GM Crops  
Revised after public consultation

3 May 2007

## Summary

This report has been drawn up by a sub-group of the Advisory Committee on Releases to the Environment (ACRE) in response to requests by the Secretary of State and the Agriculture and Environment Biotechnology Commission to assess the wider implications of the Farm-Scale Evaluations (FSEs) of genetically modified herbicide tolerant (GMHT) crops. ACRE's remit is currently limited to GMOs and the release of certain non-GM species of plants and animals that are not native to the UK. However, this report is based on the experience gained by ACRE in reviewing the findings of the FSEs, on the deliberations of the ACRE sub-group established to examine the wider implications of this study, and on evidence submitted by a variety of stakeholders to an open meeting held in October 2004.

A draft version of this report was sent to a wide range of stakeholders for consultation on 17<sup>th</sup> March 2006, the consultation period ended 9<sup>th</sup> June 2006. The report has now been revised to take into consideration the evidence submitted in consultation responses. A document published alongside this report<sup>6</sup> details the responses made during the consultation period and the revisions made to the report.

In recent years, it has become apparent that there are inconsistencies in the regulatory assessment of the environmental impact of GM crops in comparison with other agricultural crops and practices. The EU Directive 2001/18, which covers the release of genetically modified organisms, requires an environmental risk assessment of possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GM plant as part of a rigorous approval process. Non-GM crops and other changes to agricultural management do not require similar risk assessments.

Quantitative field studies have shown that the environmental impact of changes in agricultural management can be at least as significant as those associated with GM crops. Examples include the change from spring to winter sowing in arable crops and the shift from hay cutting to silage production. There is, however, currently no equivalent regulatory requirement for assessment of the positive and negative effects of such changes in agricultural practice on the environment prior to their widespread adoption.

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<sup>6</sup> Overview of Responses available at [www.defra.gov.uk/acre/fsewiderissues/](http://www.defra.gov.uk/acre/fsewiderissues/)  
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This inconsistency is further illustrated by GM herbicide tolerant crops that require an extensive environmental risk assessment before approval for cultivation and marketing whilst herbicide tolerant crops produced by non-GM breeding methods can be grown without an equivalent assessment. The FSEs showed that differences in the impact on wild flora and fauna can be greater between different conventional crops (e.g. between maize and oilseed rape) than between a GM herbicide tolerant crop and its non-GM herbicide susceptible counterpart. Directive 2001/18, however, requires that the environmental impact of a GM crop is solely judged in comparison with the impact of its non-GM counterpart.

Directive 2001/18 also makes no provision for assessing both potential environmental risks and benefits. For example, the negative effects on weed and invertebrate populations of the herbicide treatment used in the FSEs with GM herbicide tolerant beet was a key factor in the decision not to permit the cultivation of GMHT beet as managed in the FSEs. As the Directive only considers risks, evidence of any potential environmental benefits (such as reduced herbicide use leading to reductions in direct and indirect CO<sub>2</sub> emissions arising from herbicide manufacture, transport and field operations) were not considered.

By contrast, environmental benefits are now a major focus in the introduction of a number of other novel crops (e.g. energy crops) and agricultural management practices in the UK. There is no regulatory requirement to assess potential environmental costs in a fashion similar to GM crops. Environmental benefits (or side-effects) are also the focus of the most recent round of EU and national agricultural policy reforms, which now focus on the multifunctional nature of agricultural systems, and their capacity to contribute to a wide variety of environmental goods and services in addition to food, fibre, oil and other primary products. Under new policies, and some emerging private markets, farmers will increasingly be paid to produce these environmental goods and services (such as flood protection, carbon sequestration, landscape aesthetics, and biodiversity services), as well as to continue to produce food.

It is possible to conceive of transitions towards environmental sustainability as arising partly from systems of management that minimise the negative side-effects of agriculture (environmental costs) whilst maximising positive side-effects (environmental goods). Thus, understanding and balancing the potential risks and benefits of existing and new agricultural technologies (whether GM or non-GM)

should be part of the UK's current support for the goal of greater environmental sustainability in all its agricultural and land management systems. The wider challenge is to achieve such changes whilst sustaining the economic viability of farming. It is commonly stated that the farming industry only contributes a relatively small amount to GDP, yet this contribution rises substantially if all environmental goods and services are counted alongside primary food production.

To assess and manage more effectively the environmental footprint of agriculture as a whole, ACRE suggests that a broader and more balanced regulatory approach is required. This approach would deal not only with GM crops but also with other novel crops and agricultural practices. It would allow the assessment of both environmental risks and benefits, and the development of rigorous and balanced decisions.

The purpose of this report is to serve as a catalyst for debate about the future development and regulation of novel agricultural technologies and practices, and it is hoped that a number of agencies would find some utility in adopting the approach described. The report is primarily aimed at Ministers, policy makers and regulators in Defra, in the devolved administrations and across the EU.

ACRE concluded that the following principles should be used to guide future assessment of novel agricultural products and practices. An effective approach should:

1. take account of benefits as well as risks,
2. be evidence based,
3. recognise that an opportunity will often be needed to assess the impact of novel crops and practices on a limited scale, before widespread use,
4. be based on comparative assessment with current crops and practices,
5. protect and nurture opportunities for innovation and therefore choice of comparator should take care to avoid the rejection of novel crops and practices while retaining more damaging established crops and practices,
6. be straightforward to apply,
7. be sensitive to the competitiveness of all sectors of UK agriculture.

ACRE proposes a matrix-based approach in the form of a Comparative Sustainability Assessment (CSA) that could be used to encourage a more objective and comprehensive approach towards agricultural and rural policy. The CSA presented in this report has been revised in response to comments made during the consultation.

The revised CSA contains ten criteria for assessing sustainability, benefits and risks. None of these criteria have precedence, and all factors will be assessed and evaluated in order to come to a judgement.

This report contains seven worked examples to illustrate how the CSA might be used in practice. The examples were chosen to cover a broad range and include GM as well as non-GM examples. Although the focus of this report is on novel crops, animals and practices, examples of past introductions are included here to show their impact. The examples are:

- i. Japanese Knotweed as an example of the past introduction of an ornamental plant;
- ii. Winter wheat as an example of the past expansion of a crop/practice;
- iii. Biocontrol of the European corn borer with *Trichogramma* as an example of the past introduction of a new practice (compared with two alternative control methods, insecticides and Bt maize);
- iv. The energy crop Miscanthus as an example of a recently introduced crop;
- v. Bt cotton as an example of a novel insect resistant GM crop;
- vi. A comparison of herbicide tolerant amenity grasses developed through GM or conventional means – an example of a potential future introduction;
- vii. American mink as an example of the past introduction of a non-native mammal.

The worked examples are a synopsis of the evidence that would be considered in a full CSA analysis, and illustrate that there are positive and negative side-effects in each case. These examples show that the introduction of ornamental plants and non-native mammals could have significant negative effects; that changes in agricultural

practice can have major environmental impacts and that breeding methods are less important than the nature of the trait expressed by a novel crop. The worked examples highlight some areas of uncertainty and areas of further research, which would be required for the development and use of the CSA.

When defining the scope of 'novel crop' and 'novel practice', to which a CSA should be applied, regulators will have to take into account not only the change, but also the potential scale of introduction and what it is expected to replace.

The report considered important factors to take into account regarding implementation of the suggested approach but its role was not to provide a detailed guide.

In the short-term ACRE envisages that CSAs and currently available supporting evidence could be used in the development or pre-assessment of government schemes to encourage environmental benefits or the use of novel crops (e.g. mitigation measures used in Environmental Stewardship schemes, incentive schemes for biofuels).

In the long-term ACRE envisages CSAs and the comprehensive evidence supporting them to be used to inform the workings of an advisory committee. CSAs would enable the committee to advise policy makers about the balance between negative and positive impacts of a proposed introduction, allowing policy makers to base their decision on all relevant evidence.

By taking into account the overall benefits associated with a new product or practice in comparison with currently available systems, ACRE's proposals are designed to encourage innovations that can assist government commitments for sustainable agriculture. ACRE does not envisage the CSA to be used at the level of the individual farm, thus ensuring that the direct regulatory burden on farmers is not increased. The Committee recommends that any decisions based on the CSAs should be reversible in the light of any new evidence.

All EU Directives are subject to revision over time and in the long-term ACRE believes that the CSA method could be accommodated within European legislation concerning the release of genetically modified organisms. At present applicants wishing to release GMOs are not required to submit any information on the benefits associated with the use of the GM products. However this information is important in

order to determine whether the overall impact of a GM and its management is worse than that of equivalent products in current use. ACRE stresses that a revision of this nature would not represent a “softening” of the current regulatory regime with respect to GMOs.

ACRE notes that before implementing regulation (either by formal legislation, codes of practice or information campaigns) government departments are required to carry out a regulatory impact assessment<sup>7</sup> (RIA). An RIA is a framework for analysis of the likely impacts of a policy change and the range of options for implementing it. These assessments cover the impact of regulation on social, economic and environmental sustainability. Under the current system environmental considerations are assessed using monetary value based on consumer willingness to pay or willingness to accept compensation for environmental damage. ACRE suggests that the CSA method presented in this report could provide a useful alternative to the approaches currently used in these assessments as a mechanism for achieving environmental policy goals and ensuring more consistent regulation with respect to the environment.

This revised report was approved by ACRE in December 2006.

The full text can be found at

<http://www.defra.gov.uk/environment/acre/fsewiderissues/index.htm>

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<sup>7</sup> [http://www.cabinetoffice.gov.uk/regulation/ria/ria\\_guidance/index.asp](http://www.cabinetoffice.gov.uk/regulation/ria/ria_guidance/index.asp)

# CHAPTER 4

## **Advice on the implications of findings in a Defra-funded desk study: ‘Agronomic and environmental implications of the establishment of GM herbicide tolerant problem weeds’**

### **Background**

This study was commissioned by Defra to examine the agronomic and environmental consequences of gene flow from genetically modified herbicide tolerant (GMHT) crops. This follows the publication of a number of studies showing that gene transfer to wild relatives of certain crop plants is possible. Previous studies have demonstrated that GM herbicide tolerance does not confer a selective advantage to plants growing in semi-natural habitats where the associated herbicide is not used (e.g. Crawley et al., 1993, Crawley et al., 2001). However, in agricultural environments where herbicide use is common, herbicide tolerant weeds may have a selective advantage and crop management practices may need to be changed.

The report’s authors reviewed the information on the frequency of hybridisation between oilseed rape and sexually compatible weed species and concluded that such events are relatively uncommon such that changes in management to control any resulting weeds were unlikely, with the possible exception of *B.rapa* hybrids in certain areas. However, the authors noted that GMHT oilseed rape volunteers could persist in fields at levels that may require alteration of crop rotations and herbicide regimes. In GM sugar beet crops the authors concluded that good crop management

should prevent the formation of HT weed beet but that failure to manage bolters would result in HT weed beet.

The authors also concluded that management changes would not be required in fields that have previously contained sexually compatible crops growing adjacent to GMHT crop fields because any HT volunteers would be present at very low levels in these areas.

The second part of the study investigated the agronomic changes that would be required to manage HT weeds in cropped fields. The authors used life cycle models for each of the crops to investigate the build up of volunteers within different crop rotations and their associated management regimes (including herbicide use and methods of soil tillage). The authors concluded that rotations would need to be altered for some HT weeds to be controlled but that this depended on the type of herbicide tolerance conferred to the weed. Predictions were based on 3 types of herbicide tolerance in oilseed rape (glyphosate, glufosinate ammonium and imidazolinone) and two types of HT tolerance in sugar beet (glyphosate, glufosinate ammonium).

The environmental consequences of controlling HT weeds were also investigated. The authors used a risk assessment tool which calculates site specific values for each herbicide product in terms of eco-ratings and ecotox scores (which combine all the toxicological data on the effects of the rates of products used on plants, invertebrates and vertebrates). In addition, the authors used their own expertise in combination with data from the published literature to assess the impact of the management changes to tillage and timing of cultivations. The authors concluded that changes to herbicide regimes were within the bounds of good agricultural practice in terms of their eco-ratings and ecotox scores. However since control of GMHT volunteers is easier in winter wheat than in spring crops farmers may prefer to grow these in order to avoid the build up of HT weed problems. In some circumstances, this would result in the loss of over wintered stubbles which have been associated with the decline in populations of plants, invertebrates and birds over the past few decades.

The authors recommended that fields where HT crops were cultivated, their surrounding margins and adjacent crops should be monitored for the presence of HT

weeds. In particular the consortium noted that detailed records of crop management after the HT crop should be kept since this may be helpful in explaining any adverse effects on the environment that might subsequently arise.

## **Advice**

This research adds to our understanding of possible long-term adverse environmental effects that could be associated with the post-cultivation management following the release of certain GMHT crops. However this study was a desk exercise and the scenarios examined may not be representative of the field situation. ACRE recommends that monitoring for changes in cropping practices and crop management after certain HT crops are grown would be appropriate to address the issues raised by this research.

This research clearly demonstrates that the agronomic regimes associated with the post-harvest management of different crops and different herbicide tolerance traits have different effects on the environment. ACRE therefore advises that it will continue to deal with applications to cultivate GM crops, including GMHT crops on a case-by-case basis.

## **Comment**

There are currently no applications for the commercial cultivation of herbicide tolerant GMHT oilseed rape or sugar beet crops in the EU but this desk study investigates scenarios that may be of some value if future applications are forthcoming.

The report shows that some of the altered management practices required in subsequent crops and post-harvest, such as minimum tillage rather than ploughing may provide environmental benefits. However the report also highlights that certain practices to enhance the control of HT weeds such as a change from spring sown crops to winter wheat could lead to adverse effects on some farmland habitats. This adverse effect is possible in regions with very light soils because overwintered stubbles are retained in these areas if a spring crop is subsequently sown. As the report's authors recognise, overwintered stubbles are valuable foraging grounds for some farmland bird species. The committee also notes that a change from glyphosate to paraquat in subsequent crops in the rotation could lead to adverse effects on mammals such as hares, particularly if recommended risk mitigation

measures were not adopted, even though the use of both chemicals falls within the definition of “low environmental impact” used by the authors of this report.

ACRE notes that most of the alterations to crop management anticipated by this research are necessary because of the requirement to segregate GM (labelled) produce and non-GM (unlabelled) produce (keeping within the EU GM presence labelling threshold of 0.9%). Some of the changes to management practices suggested in this report would also be appropriate to conventionally produced crops for which there is a need for segregation for specialist markets e.g. oilseed rape producing higher levels of linolenic acid or erucic acid. However, although some changes (such as leaving a long period between sowing conventional oilseed rape and the specialist variety and using minimum tillage rather than ploughing) would be necessary for these crops, other changes (such as changes to the herbicide regime used in other crops and the selection of winter wheat rather than spring sown crops) are specific to HT crops. How widespread the requirement to make these changes would be remains a matter of speculation.

The report highlights that some GMHT crops, such as those conferring tolerance to glufosinate ammonium should not alter the herbicide regimes used in subsequent crop management whereas others (glyphosate or imidazolinone tolerant crops) would require alterations to these practices.

The report provides useful information about the financial implications of agronomic changes that could affect farmers choosing to grow GMHT crops. However, ACRE does not take considerations of this nature into account when evaluating environmental risk assessments of GM crops. The report recommends that monitoring of weeds (to determine whether any are HT) in subsequent crops, in adjacent fields and in crop margins should be conducted and that detailed records of crop management after the HT crop should be kept since this may be helpful in explaining any adverse effects on the environment that might subsequently arise. ACRE agrees that this is a sensible and proportionate approach to the possible risks identified in the report.

# CHAPTER 5

## **Advice on the implications of a Defra-funded desk study: ‘RNA-mediated gene silencing mechanisms and their implications for the risk assessment of GM plants’.**

### **Background**

Within the past decade there has been a significant amount of research directed at understanding the mechanisms by which double-stranded RNA<sup>8</sup> in plants and other organisms (including humans) can alter gene expression. RNA-mediated gene silencing interrupts the transfer of information that is encoded in DNA. It therefore affects gene expression but it also has other functions such as providing a defence mechanism against viral infection.

As double-stranded RNA associated with plant transformation events has the potential to alter the expression of endogenous plant genes (unintentionally as well as by design) and of transgenes, Defra has commissioned a desk study to review the current understanding of RNA-mediated gene silencing mechanisms in plants and the implications that these may have for the risk assessment of GM plants. ACRE

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<sup>8</sup> Like DNA, RNA is a nucleic acid (although it has some chemical differences) but unlike DNA, it can move outside of the nucleus into a cell's cytoplasm. There are many forms of RNA, including messenger RNA, transfer RNA, ribosomal RNA. All of these RNA species are single-stranded and involved in protein synthesis. This report concerns double-stranded RNA that alters gene expression through targeting short stretches of RNA or DNA with which it shares a high degree of sequence homology. The target RNA is either degraded, prevented from being translated into protein (both of which represent post-transcriptional gene silencing) or its transcription from DNA is interfered with (transcriptional gene silencing).

has been asked for advice on any environmental hazards identified in the report and the recommendations it makes for further research.

Professor David Baulcombe's group in the Sainsbury Laboratory, Norwich, was commissioned to carry out the desk study. The report of the study concentrates on GM plants in which genes have been silenced intentionally (in particular those containing inserts that generate double stranded RNA directly as opposed to those modified to contain sense and antisense DNA constructs). Unintentional RNA-mediated silencing also can be triggered in these GMOs as it can in GM plants that have been modified to produce a novel protein. It is noteworthy that silencing can, and has, occurred as a result of non-GM breeding e.g. in mutagenesis breeding where the loss of a termination sequence resulted in RNA-mediated silencing<sup>9</sup>.

Both post-transcriptional gene silencing (PTGS) and transcriptional gene silencing (TGS) are discussed in this report. It also suggests best practice in designing GM plants for gene silencing purposes to avoid instability in transgene expression and to minimise 'off-target effects'.

## **Advice**

ACRE considers the report to be well written and comprehensive and notes the eminence of Professor Baulcombe's group in this area of research. We concur with the report's finding that there are gaps in understanding with respect to RNA-mediated gene silencing in plants, but we consider that these gaps are not significant in the environmental risk assessment of GM plants. Consequently we do not recommend that Defra fund further work in this area (with respect to the environmental risk assessment of GM plants).

In coming to this conclusion, we have considered the environmental hazards associated with RNA-mediated gene silencing in GM crops that have been identified in this report:

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<sup>9</sup> Kusaba M., Miyahara K., Lida S., Fukuoka H., Takano T., Sassa H., Nishimura M. *et al.* (2003). *Low glutelin content1*: a dominant mutation that suppresses the Glutelin multigene family via RNA silencing in rice. *Plant Cell* 15: 1455-1467.

(1) Instability/ unpredictability of a GM trait<sup>10</sup> as a result of silencing such that there is loss/reduction in silencing, variability between genetically identical siblings or variability between generations. As part of ACRE's assessment of GMOs for which consent to market is being sought, we consider information on genotypic<sup>11</sup> and phenotypic<sup>12</sup> stability. For most GM plants, the loss of the GM trait through silencing would have an economic, rather than environmental impact e.g. loss of herbicide tolerance or loss of pest resistance (i.e. they would revert to having the same phenotype as their non-GM counterparts). However, the partial or complete loss of other GM traits could affect the environmental risks posed by the GMO e.g. if it were associated with biological containment. Consequently, the risks depend on the particular GMO in question and as such, we consider that our current case-by-case approach to environmental risk assessment is appropriate. It is also worth noting that phenotypic instability (whatever the cause) would almost certainly be detected during the breeding programme at which point, lines exhibiting this characteristic would be discarded.

(2) Unintentional blocking of the translation of endogenous plant genes. Notifications for the release of GM crops must consider whether these organisms present an increased environmental risk as compared to their non-GM counterparts. As such, we assess information on whether there are differences in a range of characteristics that could conceivably alter the environmental consequences of cultivating the GMO rather than a non-GM alternative e.g. modes and/ or rate of reproduction, dissemination and survivability. We consider this to be the most effective approach in determining whether any consequence of a GM event (including gene silencing) has altered the phenotype of the plant such that it poses an unexpected environmental risk to the environment. Again, we consider that abnormalities in the characteristics of a GM crop line (e.g. as a result of gene silencing) would be detectable during its breeding programme.

(3) Transfer of silencing from GM plants. As PTGS is a highly conserved mechanism in plants and animals, we have considered whether plant-generated short interfering (si)RNAs could trigger silencing in animals that feed on plant

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<sup>10</sup> Including GM traits that are the result of intentional silencing of endogenous plant genes.

<sup>11</sup> The genetic constitution of an organism

<sup>12</sup> The physical characteristics of an organism

material. This is not a hazard to humans as in order for silencing to work, a concentrated extract containing RNA from the GM plant would have to be applied to, and be taken up by, human cells or cell cultures. However, the report suggests that there is potential for siRNAs from GM plants to transfer to nematodes that feed on them, and the nematodes could potentially act as vectors of the siRNAs to other plants.

Recently, Huang *et al.*, (2006)<sup>13</sup> reported that they had modified *Arabidopsis* plants to express siRNAs targeted against a parasitism gene present in root-knot nematodes (RKN). These siRNAs, when transferred from the GM plants to four common species of RKN, resulted in silencing of the parasitism gene and reduced nematode infectivity. This demonstrates that siRNAs can be transferred from plants (GM and non-GM) to nematodes. However, for silencing to occur, the genes encoding these siRNAs must be present in the nematode as well in the plant. Consequently, it is unlikely that silencing will occur other than by design (as in this case). It is also worth noting that the nematodes will not become genetically modified as their genome will not have been altered. Consequently, the effects of the transferred siRNAs will be transient. Bacteria do not employ the same gene silencing mechanism as plants and as such they are highly unlikely to be affected by the transfer of siRNAs from crops.

(4) Viruses acquiring virulence by evolving to evade gene silencing. The possibility was considered of the emergence of novel viruses and/or the build up of a reservoir of virus in a supposedly resistant crop. However, gene silencing is a strategy that plants (both non-GM and GM) employ to resist virus infections and that viruses, in their turn, may evolve to avoid this resistance mechanism. Consequently, we do not consider that the potential for viruses to mutate and overcome silencing acquired through GM is a novel risk to the environment. We also note that if a virus did mutate to overcome gene silencing (that had been introduced by GM), then the GM plant would return to its wild type phenotype i.e. sensitive to infection by that particular virus. This would have economic consequences but the environmental impact would be no greater than those associated with growing its non-GM (virus-sensitive) counterpart.

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<sup>13</sup> Huang G., Allen R., Davis E. L., Baum T. J. and Hussey R. S. (2006). Engineering broad root-knot resistance in transgenic plants by RNAi silencing of a conserved and essential root-knot nematode parasitism gene. *PNAS* **103** (39): 14302 –14306.

(5) Saturation of the silencing machinery in GM plants. As yet, such saturation effects in plants have not been researched in any detail. However, as this report points out, we do know that the silencing mechanism can become saturated by high levels of double-stranded RNAs, causing the silencing to fail. As such, certain GM constructs and events could result in a loss of endogenous silencing in the modified plant. Most of the consequences of these saturation effects would impact on the economic value of the GM crop (rather than on its environmental safety). However, the report suggests that there are associated hazards such as increased mutation rates (due to increased transposon<sup>14</sup> activity) and changes in metabolite composition (as a result of defects in micro (mi)RNA-mediated gene regulation). Analysing compositional data submitted in notifications under GM Food and Feed legislation (i.e. Regulation (EC)1829/2003) is not our responsibility. However, as described above, we do consider information on whether there are phenotypic differences between a GM plant and its non-GM counterpart that would alter its impact on the environment. Almost certainly, GM plant lines with increased mutation rates would be detected during the breeding programme and these would be discarded. A plant line with increased mutation rates would not be economically viable (not least because it would fail Distinctness, Uniformity and Stability tests that are required to market a new crop variety, irrespective of whether it is GM or not). We also note that the report makes suggestions on how saturation might be avoided.

(6) Activation of genes by double-stranded RNA

A recent paper by Li *et al.* (2006)<sup>15</sup> reports that, as well as silencing, double-stranded RNA can directly activate the expression of target genes (at least in human cells). This research is controversial as some argue that it is possible that activation of these genes is an indirect result of silencing of regulatory genes (that would otherwise suppress the expression of the target genes). We will continue to monitor this line of research with interest.

If this phenomenon does occur in plants, irrespective of the underlying mechanism, the implications for environmental risk assessment are the same. As discussed in

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<sup>14</sup> Also referred to as 'jumping genes' as these short sections of DNA can move around the genome. They can disrupt gene expression depending where they insert.

<sup>15</sup> Li L-C., Okino S. T., Zhao H., Pookot D., Place R. f., Urakami S., Enokida H. and Dahiya R. Small dsRNAs induce transcriptional activation in human cells (2006). PNAS. **103** (46): 17337 – 17342.

section (2), we assess information on whether there are differences in a range of characteristics that could conceivably alter the environmental consequences of cultivating the GMO rather than a non-GM alternative e.g. modes and/ or rate of reproduction, dissemination and survivability. We consider this to be the most effective approach in determining whether any consequence of a GM event (including gene up-regulation) has altered the phenotype of the plant such that it poses an unexpected environmental risk to the environment. Again, we consider that abnormalities in the characteristics of a GM crop line (e.g. as a result of gene silencing) would be detectable during its breeding programme.

# 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 Commission and 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 [www.defra.gov.uk/environment/gm/regulation/index.htm](http://www.defra.gov.uk/environment/gm/regulation/index.htm).

# APPENDIX II

## Openness and transparency

We have a continuing commitment to openness and transparency in the working of our committee and its sub-groups. We publish meeting agendas on the website<sup>1</sup> 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 Public Register. We hold open meetings on topics where we need to gather evidence to inform our advice to Ministers. These meetings are publicised on the web and we encourage stakeholders to put forward submissions which are published unless requested otherwise by the authors.

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<sup>2</sup> 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. When a member's interests conflict with an item of ACRE business, for example where release applications are received from institutes or companies with whom members are involved, members are 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.

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 [www.defra.gov.uk/environment/acre/pubs.htm#other](http://www.defra.gov.uk/environment/acre/pubs.htm#other). The

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<sup>1</sup> [www.defra.gov.uk/environment/acre/index.htm](http://www.defra.gov.uk/environment/acre/index.htm)

<sup>2</sup> [www.defra.gov.uk/environment/acre/about/interests.htm](http://www.defra.gov.uk/environment/acre/about/interests.htm)

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

<b>Chair</b>	<b>Main Expertise</b>
Professor Christopher Pollock	Plant breeding, plant physiology, agronomy
<b>Deputy Chair</b>	
Professor Jules Pretty	Sustainable agriculture & rural development
<b>Members</b>	
Professor Mark Bailey	Molecular biology, microbiology
Professor Jeff Bale	Entomology, ecology
Dr Mike Bonsall (from 1.12.07)	Entomology, evolutionary ecology, ecology and mathematical biology
Mr Edward Cross	Farming practice
Professor Jim Dunwell	Plant biotechnology
Professor Rosie Hails	Pathogen population ecology, entomology
Dr Penny Hirsch	Molecular biology, microbiology
Dr Phil Hulme (until 22.2.07)	Biodiversity, conservation
Professor Keith Lindsey	Molecular biology
Mr Jim Orson	Farming practice, agronomy
Professor Andy Peters	Clinical development and regulation of vaccines
Professor Mark Rees	Weed ecology, plant biology
Dr Jonathan Stoye	Virology

### **Sub-group on Wider Issues Raised by the Farm-scale Evaluations of GMHT crops**

<b>Chair</b>
Professor Jules Pretty
<b>Members</b>

Professor Jeff Bale

Professor Philip Dale\*

Dr Philip Hulme (until 22.2.07)

Professor David Macdonald\* (Advisory Committee on Pesticides representative)

Mr Jim Orson

Professor Christopher Pollock

Professor Mark Rees

**Secretariat (Defra)**

Dr Kathryn Morley

\*Not ACRE members

# APPENDIX IV

## PEN PICTURES OF MEMBERS OF ACRE

### **Professor Christopher Pollock CBE (Chairman)**

#### **Expertise: Plant physiology, biochemistry and plant breeding**

Professor Pollock is the Chief Scientific Advisor to the First Minister of the Welsh Assembly Government and was, until his retirement in 2007, Research Director at 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 also chair of the 2008 RAE Sub-panel for Agriculture, Food and Veterinary Science. *Reappointed to ACRE and appointed as chairman for 3 years from 1 September 2003. He has been reappointed as chairman for a further 3-year term with effect from 1 September 2006.*

### **Professor Jules Pretty OBE (Deputy Chairman)**

#### **University of Essex**

#### **Expertise: Sustainable agriculture and rural development**

Professor Pretty is Head of the Department of Biological Sciences at the University of Essex. He is an expert on sustainable agricultural systems and farming practice in both developing and industrialised countries. He is an advisor to various international agricultural programmes for governments and UN agencies and was appointed A D White Professor-at-Large at Cornell University for 2001-2007. He is a Fellow of the Institute of Biology and the Royal Society of Arts. Prof Pretty received an international award from the Indian Ecological Society in 1997 and was runner up for the 2002 European Sicco-Mansholt prize. *Reappointed to ACRE for 3 years from 1 September 2003. He has been reappointed for a further term from 1 September 2006 to 17 June 2009.*

## **Professor Mark Bailey**

**Centre for Ecology and Hydrology, Oxford**

**Expertise: Molecular biology and microbial ecology**

Professor Bailey is Science Director for Biodiversity at the National Environmental Research Council (NERC), Centre for Ecology and Hydrology. He has been an adviser for NERC, Health and Safety Executive and the former Department of the Environment (DoE) as well as working for the Organisation for Economic Co-operation and Development. His research interests include bacterial genetics, microbial ecosystem function and, in particular, the role of the horizontal gene pool in bacterial adaptation and evolution. *Reappointed to ACRE for 3 years from 1 September 2003. He has been reappointed for a further term from 1 September 2006 to 17 June 2009.*

## **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. 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 leader of the Organismal and Environmental Biology Research Group at the University of Birmingham, a Fellow of the Royal Entomological Council, and sat on the British Ecological Society Council. He is a member of the editorial board of the *Bulletin of Entomological Research*, the *Journal of Insect Physiology* and *Physiological Entomology*, and the NERC Peer Review College. *First appointed to ACRE for 3 years from 18 August 2002 and reappointed for a further 3 years from 18 August 2005.*

**Dr Michael Bonsall**

**Department of Zoology, University of Oxford**

**Expertise: Entomology, evolutionary ecology, ecology and mathematical biology**

Dr Michael Bonsall is a University Lecturer 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 serves on the Council of British Ecological Society and as a member of the NERC Peer Review College. He is on the editorial boards of Ecology Letters, Oikos, Theoretical Ecology and Ecological Entomology. *First appointed to ACRE for 3 years from 1 December 2007.*

**Mr Edward Cross**

**Farmer, Abbey Farm, Norfolk.**

**Expertise: Farming practice, agronomy and sustainable agriculture**

Mr Cross currently jointly manages a substantial farming concern in the east of England. He has a strong commitment to farming and the environment. He is a Director of the Farmer's Link. *Reappointed to ACRE for 3 years from 18 August 2002 and for a further 3 years from 18 August 2005.*

**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.

**Professor Rosemary Hails MBE**

**Centre for Ecology and Hydrology, Oxford**

**Expertise: Pathogen population ecology, entomology**

Prof Hails is a Biodiversity Section Head at the Centre for Ecology and Hydrology, Oxford, a visiting professor at Oxford Brookes University and a fellow of St Annes College, Oxford. 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 was awarded an MBE for services to environmental research in June 2000. *First appointed to ACRE for 3 years from 9 October 2006.*

**Dr Penelope Hirsch**

**Rothamsted Research**

**Expertise: Molecular biology and microbial ecology**

Dr Hirsch is a Principal Research Scientist at Rothamsted Research. She has expertise in molecular biology with particular interest in soil microbial ecology. Dr Hirsch is a member of the Scientific Advisory Committee on Genetic Modification. *Reappointed to ACRE for 3 years from 1 September 2003. She has been reappointed for a further term from 1 September 2006 to 17 June 2009.*

**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 has been an advisor to the European Federation of Biotechnology and to the Advisory Committee on Novel Foods and Processes, and a

member of the Multinational Arabidopsis Steering Committee, and is currently Chair of the UK Society for Experimental Biology Plant Section. He is a Fellow of the Institute of Biology. *First appointed to ACRE for 3 years from 1 September 2003. He has been reappointed for a further 3-year term with effect from 1 September 2006.*

### **Mr Jim Orson**

#### **The Arable Group**

##### **Expertise: Agronomy, farming practice and plant biology**

Mr Orson is Research and Technical Director of the Arable 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 for 3 years from 18 August 2002 and reappointed for a further 3 years from 18 August 2005.*

### **Professor Andrew Peters**

#### **University of Edinburgh**

##### **Expertise: clinical development and regulation of vaccines**

Professor Peters is Director, Translational Research at the Royal (Dick) School of Veterinary Studies, University of Edinburgh. He also runs his own consultancy business Arpexas Ltd. specialising in vaccine development and knowledge transfer. He has considerable experience in reproductive biology and his current research interest is in immunocontraceptive vaccines. He also holds a special professorship in animal science at the University of Nottingham. *First appointed to ACRE for 3 years from 9 October 2006.*

### **Professor Mark Rees**

#### **University of Sheffield**

##### **Expertise: Weed ecology and plant population biology**

Professor Rees is a professor in the Department of Animal and Plant Sciences at the University of Sheffield. His research interests include plant population dynamics and its application to the biological control of weeds, the evolutionary ecology of plant

traits such as seed size and dormancy, the timing of reproduction and the development of theoretical tools for studying structured populations. He is a member of the Non-native Risk Analysis Panel. *Reappointed to ACRE for 3 years from 18 August 2002 and for a further 3 years from 18 August 2005.*

**Dr Jonathan Stoye**

**National Institute for Medical Research**

**Expertise: Virology, molecular biology and microbiology**

Dr Stoye is Head of the Division of Virology at the Medical Research Council's National Institute for Medical Research. He is a virologist with experience in retroviruses. He has considerable practical knowledge of molecular biology and genomics, with experience of formulating recommendations about risk. He has advised a papal working group on xenotransplantation and was a member of the UK Xenotransplantation Interim Regulatory Authority. *First appointed to ACRE for 3 years from 18 August 2002 and reappointed for a further 3 years from 18 August 2005.*

**Dr Phil Hulme (left February 2007)**

**NERC Centre for Ecology and Hydrology, Banchory**

**Expertise: Ecology, biodiversity and conservation**

Dr Hulme was Head of the Ecosystem Dynamics Section at CEH Banchory. He is an ecologist with expertise in biodiversity, conservation and statistics. He has considerable experience in the study of plant-animal interactions and biological invasions.. He left the committee in February 2007 when he took up a post in New Zealand. *First appointed to ACRE for 3 years from 18 August 2002 and reappointed for a further 3 years from 18 August 2005.*

# 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 magistrates bench; and where they might be affected by the work and advice of the body.

## REGISTER OF MEMBERS' INTERESTS - December 2007

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 Mark Bailey	None		NERC <sup>1</sup> Centre for Ecology and Hydrology	Science Director (employee)	None	
			NERC, Defra, EU, BBSRC <sup>2</sup>	Funding for research		
			Universities of Newcastle, Cardiff and Sheffield	Visiting Professor		
Professor Jeff Bale	Syngenta Koppert Biobest	Part funding for PhD student	University of Birmingham	Employee	None	
			BBSRC, NERC, Defra, CSL, Anglian Water	Funding for research		

<sup>1</sup> National Environment Research Council

<sup>2</sup> Biotechnology and Biological Sciences Research Council

Dr Michael Bonsall (from December 2007)	Oxitec	CASE support partner for 2 BBSRC PhD students	University of Oxford	Employee	Royal Society	Head of Science Policy
			St Peter's College, Oxford	Fellow, employee		
			BBSRC, NERC, Royal Society	Funding for research		
			NERC	Peer Review College Member		
			British Ecological Society	Council Member		
Mr Edward Cross	R S Cross & Son	Partner			None	
	Farmers Link	Consultant and Director				
	Abbey Farm Organics	Sole trader				
Professor Jim Dunwell	None		University of Reading	Employee	None	
			BioHybrids	Funding for research		
			BBSRC	Funding for research		

Professor Rosemary Hails	None		NERC Centre for Ecology and Hydrology	Employee	None	
			St Anne's College Oxford	Fellow		
			Oxford University	Senior Research Associate		
			European Food Safety Authority	Ad hoc member of Environment Working Group		
			Oxford Brookes University	Visiting Professor		
			NERC, BBSRC, MRC, Defra, EU	Funding for research		
			Institute of Biology	Chair of the Environment, Agriculture and Sustainability Committee		
Dr Penny Hirsch			BBSRC Rothamsted Research	Employee	None	
			Scientific Advisory Committee on Genetic Modification	Member		
			EU, BBSRC, NERC, Defra	Funding for research		
			Society for General Microbiology	Member		

Dr Phil Hulme (until February 2007)	None		NERC Centre for Ecology and Hydrology, Banchory	Employee	None	
			NERC, Defra, EU, Scottish Executive and Scottish Natural Heritage	Funding for research		
Professor Keith Lindsey	Creative Gene Technology Ltd.	Scientific Director	Durham University	Employee	None	
			BBSRC, EPSRC, DTI	Funding for research		
			Institute of Biology	Fellow		
			Society for Experimental Biology	Director		
			American Society of Plant Biologists, International Society for Plant Molecular Biology	Member		
Mr Jim Orson	Small area of arable/grass land farmed by a tenant	Owner	The Arable Group	Director (employee)	None	
			European Weed Research Society	Member		
			International Fertiliser Society	Member		

Professor Andrew Peters	Arpexas Ltd	Managing director	University of Edinburgh	Employee - Director, Translational Research	None	
			Global Alliance for Livestock Veterinary Medicines	Consultant		
			University of Nottingham	Visiting professor		
			European Squirrel Initiative	Consultant		
Professor Christopher Pollock	Agricultural Industries Confederation	Consultant	Aberystwyth University	Honorary professor	None	
			Welsh Assembly Government	Chief Scientific Advisor to the First Minister		
			RERAD, HEFCE and National Non-food Crops centre	Paid committee work		
			BBC Rural Affairs Committee, Aberystwyth University	Unpaid committee work		
Professor Jules Pretty	None		University of Essex	Employee	None	
			Suffolk – Action with Communities for Rural England (ACRE)	Vice-President		
			Cornell University, Ithaca, USA	A D White Professor-at-Large		
			Institute of Biology	Fellow		
			Royal Society of Arts	Fellow		
			Operation Wallacea Trust	Board member		

			Essex Wildlife Trust	Trustee		
Professor Mark Rees	None		University of Sheffield	Employee	None	
			NERC	Funding for research		
			Royal Society	Funding for research		
			Leverhulme Trust	Funding for research		
			CSIRO Australia	Funding for research		
			Non-native Risk Analysis Panel	Member		
Dr Jonathan Stoye	None		MRC National Institute for Medical Research	Employee	None	
			MRC	Funding for research		
			Society for General Microbiology, HUGO, Mammalian Genome Society	Member		
			University College London	Honorary Professor		

# APPENDIX VI

## ACRE advice issued in 2007

January 2007 (*published 5 February 2007*)

Advice on the implications of a Defra-funded desk study: 'RNA-mediated gene silencing mechanisms and their implications for the risk assessment of GM plants'

September 2006 (*published 8 February 2007*)

Advice on the implications of a Defra-funded desk study: 'Agronomic and environmental implications of the establishment of GM herbicide tolerant problem weeds'

March 2007 (*published 14 May 2007*)

Updated advice on an application to release GM Salmonella typhi for the purpose of a human clinical trial to test the effectiveness of a vaccine against Hepatitis B - ref 06/R40/01

April 2007 (*published 14 May 2007*)

Advice on an application for deliberate release of a GMO for research and development purposes for a five year programme of work to release potato lines genetically modified for resistance to *Phytophthora infestans* - ref 07/R42/01

May 2007 (*published 4 June 2007*)

Advice on notification EFSA/GMO/NL/2005/12 submitted under regulation EC 1829/2003 for import and processing of GM 59122 maize (modified for insect resistance and herbicide tolerance). Pioneer Hi-Bred International Inc. and Mycogen Seeds

August 2006 (*published 13 June 2007*)

Further advice on a notification for marketing of carnation "Florigene Moonlite" ref C/NL/04/02

May 2007 (*published 13 June 2007*)

Advice on a notification for marketing of carnation "Florigene Moonaqua" ref C/NL/06/01

May 2007 (*published 28 June 2007*)

Further advice on a notification for marketing of potato clone EH92-527-1 modified for enhanced content of the amylopectin component of starch - BASF Plant Science. Ref C/SE/96/3501

September 2007 (*published 21 September 2007*)

Further Advice on a notification for marketing of carnation "Florigene Moonaqua" ref C/NL/06/01