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the Environment**

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Nobel House
17 Smith Square
London SW1P 3JR
Telephone 020 7238 6000
Website: www.defra.gov.uk

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Information about this publication and further copies are available from:

ACRE Secretariat
4D Nobel House
17 Smith Square
London SW1P 3JR
Telephone 020 7238 2052
acre.secretariat@defra.gsi.gov.uk

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FOREWORD

By the Chairman, Professor Chris Pollock

This report covers ACRE's activities in 2006. The regulatory changes associated with the European Food Safety Authority assuming a lead role under regulation 1829/2003 are now in place and the majority of our work on applications for commercial release or import of GM crops has been carried out under these regulations. ACRE did, however issue advice on two extant part C applications on the basis of information provided to EFSA. Two research (Part B) applications were considered, one for a vaccine and one for a crop plant. We also advised on a GM medicine application under regulation 726/2004, provided generic advice on import and processing of grain derived from GM maize and supported one application to release a non-native biocontrol agent. The full committee met on five occasions, one of which was in Aberystwyth.

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 has continued to progress its own work packages. In particular, the Wider Issues sub-group finalised its report on "Managing the Footprint of Agriculture" following consultation on the draft report. Publication is scheduled for the spring of 2007. Discussions are under way to develop new work packages for 2007.

During 2006, there have been changes to the membership of ACRE. Dr Sue Hartley has stepped down, Professor Jim Dunwell has been appointed in his own right, following a period as an ex officio member, and Dr Rosie Hails and Professor Andy Peters have joined the committee. 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.

As Chairman, I remain grateful to members and assessors for the unstinting gift of their time and expertise. 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 thirteenth annual report of the Advisory Committee on Releases to the Environment (ACRE). The report covers issues that we as a committee have discussed during 2006. 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 and Wales. 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 Scotland and Wales we advise the Scottish Ministers and the Welsh Assembly Ministers, while in Northern Ireland ACRE's advice is received by the Department of the Environment.

ACRE held five regular committee meetings during 2006 and there were three meetings of the sub-group on wider issues raised by the farm-scale evaluations of GM herbicide-tolerant crops. There was also a significant amount of consultation with the committee by e-mail. Through the year we have dealt with many issues including:

- Assessment of GM marketing applications under Directive 2001/18/EC
- Assessment of a GM research application to release *Salmonella enterica* modified for use in hepatitis B vaccine trials and an application to release potatoes modified for blight resistance
- Publication of the guidance on assessing the environmental impact of GM crops on the soil environment
- Consultation on the report "Managing the Footprint of Agriculture" by the sub-group on wider issues raised by the farm-scale evaluations of GM herbicide-tolerant crops

- Advice on food and feed applications under Regulation 1829/2003
- Advice on technologies for biological containment of GM crops and other research reports
- Assessment of safeguard actions under directive 2001/18/EC
- Contribution to clinical and plant sections for revision of the SACGM compendium of guidance
- General advice on notifications for import and marketing of GM maize grain

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 2006 Ministers decided to appoint Professor Andy Peters and Dr Rosemary Hails to the committee. In addition, Professor Jim Dunwell was appointed as an ACRE member in his own right after having previously served as the ex officio representative for ACNFP. Professor Sue Hartley decided to step down at the end of her term due to her other commitments. Details of all the members who served on the committee in 2006 are given in Appendix III.

Representatives from Government departments and agencies also attended ACRE meetings and received the appropriate briefing papers. These include the Food Standards Agency (FSA) and the Health and Safety Executive (HSE). The Devolved Administrations were represented by officials from the Scottish Executive and the National Assembly for Wales. We also welcomed representatives from the GM Inspectorate at the Central Science Laboratory and English Nature, subsequently Natural England (on behalf of the joint nature conservation agencies).

The role of secretary to our committee in 2006 was shared initially between Dr Louise Ball and Dr Androulla Gilliland and subsequently Dr Gilliland took over the role on her own. The other members of the secretariat were Dr Tanja Schuler (until March 2006), Dr Kate Morley, Mr David Sherlock, Mr Paul Holmes and Mr Joe Pereira. All staff making up the secretariat were from the GMO Scientific Assessment and Crop Co-existence Team in Defra. The committee is grateful to the secretariat for its hard work and support over the period of this report.

1.2 ACRE sub-groups

As a committee, our terms of reference¹ are centred on our statutory duty to advise Ministers on the risk to human health and the environment from the release of genetically modified organisms (GMOs). The casework that we have dealt with in the past year is described in Chapter 2. However, our remit extends further than case-by-case advice on applications to release or market GMOs; we also have a key role in advising Ministers on any science-based GM matter. A summary of sub-group activities during the year is detailed below.

1.2.1 The ACRE Sub-group on Soil Ecology

The ACRE Sub-group on Soil Ecology was established in July 2002. 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/soilecology/index.htm. The aim of the sub-group is to consider the potential generic effects that GMOs and the agronomic management practices associated with them have on soil ecology and to identify meaningful indicators of soil health which may be of relevance when making assessments and monitoring releases of GMOs.

The work of this committee resulted in the publication of an ACRE guidance note in 2006 on assessing the environmental impact of GM crops on the soil environment. The aim of the guidance was to provide marketing and release applicants with a framework outlining the general principles to consider in the environmental risk assessment of GM crops in relation to soil ecosystems.

¹ See Appendix I for the full terms of reference

1.2.2 The ACRE Sub-group on Wider Issues Raised by the Farm-scale Evaluations of GM Herbicide-tolerant Crops

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. The aim of the sub-group is 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.

Following an open meeting involving the whole of ACRE and stakeholders in October 2004, the sub-group held two meetings in 2005 and three in 2006. It drafted its report taking into account the evidence presented at the open meeting and the views of ACRE. The draft report, entitled "Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems", was circulated for consultation in 2006 and was subsequently revised to take on board points made by stakeholders. It will be published in 2007. The report will serve as a catalyst for debate about the future development and regulation of novel agricultural technologies and practices and their effects on the environment.

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. The committee has identified arable weed monitoring as an area requiring further study and a working group to take this further will convene in 2007. This working group is 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).

ACRE is aware that there have been an increasing number of enquiries and notifications regarding GM medicines for both human and veterinary use. In recognition of this, last year's work plan included focussing on the environmental risk

assessment of GMOs for use in human and veterinary medicine and a new member with this expertise was appointed in October 2006. This work package remains part of the committee's active work programme, with a plan for Defra to 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.

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. Of particular note this year, several members of ACRE worked with SACGM members to draft sections for the revision of the GM contained use Compendium of Guidance, including a section on the use of GM micro-organisms in clinical settings (see section 2.4 for further details).

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.

Many of the marketing applications the committee now sees are being processed through Regulation 1829/2003 on the authorisation of genetically modified food and feed and Regulation 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. 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/726/2004.

2.1 Part B release applications for research and development purposes

From January to December 2006 we reviewed and gave advice on two applications for Part B releases of GMOs. In both cases we recommended that consent be granted with specific conditions attached. The total number of UK applications for releases now stands at 226 since the Deliberate Release Regulations came into force in February 1993².

One of the applications received was for a release of potatoes resistant to potato blight *Phytophthora infestans*. The other one was for GM *Salmonella enterica* in relation to clinical trials of vaccine against hepatitis B. In assessing the clinical trial application the committee sought the advice of an external expert and was grateful for the advice received.

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

2.1.1 Application 06/R40/01 from Emergent Europe Ltd

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

² 215 applications under the 1993 regulations, 11 applications under the 2002 regulations.

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 the GMO to be used was the same strain as that previously assessed by the committee for the phase 1 trial in 2003. The results of monitoring carried out under the previous release consent revealed that the bacteria had been effectively attenuated, resulting in no systemic infections and that shedding occurred only in the seven days after dosing. The committee noted that monitoring of a release of a related strain resulted in shedding up to 14 days after dosing, but again no systemic infection was indicated.

The committee discussed the implications of the release of a greater number of GMOs into the sewage system and whether the increased dose was likely to have an impact on the duration of shedding. The committee accepted the conclusion of the applicant that the shedding profile was not likely to be dose dependant. ACRE was content that evidence provided regarding the persistence of this GMO in sewage demonstrated that the organism would not persist for long periods and also noted that sewage treatment effectively controls the wild type *Salmonella typhi*.

The committee considered the proposed monitoring of this release and was satisfied that the proposals were proportionate given the negligible risks posed to human health and the environment from this release. The committee was content that the applicant had provided sufficient evidence for their assessment of this application and concluded that the risks posed to human health and the environment by this release were negligible.

ACRE issued its advice in April 2006 in which it asked the applicant to submit a report seven months after the date of administration of the last dose of the GMO in the trial. The report should cover the general health of volunteers during the period of the study and include information on whether the GMO was shed by volunteers in stool samples taken six months after the final dosing.

2.1.2 Application 06/R42/1 from BASF Plant Science GmbH

The committee gave its advice on an application from BASF Plant Science to conduct an experimental field release of potatoes genetically modified for resistance to *Phytophthora infestans*. BASF proposed to release three potato cultivars containing a range of different GM events in order to monitor their resistance to UK pathotypes of *Phytophthora infestans*. The chairman reminded the committee that the controls placed on Part B trials ensured that GM products resulting from the trial did not enter the human and animal food chain. The committee was therefore asked to discuss the application and advise on any conditions that should be imposed on the trial.

Regarding the molecular characterisation of the GMOs to be released in this trial, members were content that any products of the gene conferring resistance to the antibiotic spectinomycin were not present in the GM lines to be released. Members were also content with the risk assessment provided by the applicant with respect to the potential impact of other sequences inserted into the plant. The committee concluded that the molecular characterisation and associated risk assessment provided was adequate with respect to the proposed release.

The conditions proposed by the applicant for the control of GMOs on the release sites were discussed in detail. ACRE concluded that potato tubers are capable of over-wintering at the proposed trial sites. BASF indicated that some of the cultivars to be planted at the trial sites produce berries and therefore it may be possible for volunteer potato plants to emerge from true seed. These are however extremely vulnerable to herbicide application. ACRE concluded that once the GM potatoes had been harvested on each trial site, the ground should be left fallow to encourage the germination of true potato seed. This strategy also enables the identification and early treatment of potato groundkeepers and volunteers by hand-pulling before viable tubers have set or by herbicide treatment with a systemic herbicide. The committee also advised that the land should not be ploughed after the potato trial harvest but that shallow tillage should be used on the release site for the next two years.

The company proposed to chop or heat-treat the potato tubers following harvest and removal to an off-site location and ACRE was content with this proposal. The company also plans to leave parts of the potato plants other than tubers on the soil

surface at each site to decompose. ACRE was content with this proposal if the fallow cropping and herbicide regime proposed by the committee is followed. The applicant proposed to monitor volunteer potatoes at release sites until none had been found for two years. ACRE was content with this and advised that BASF should provide details of groundkeeper and volunteer presence in annually submitted post-release monitoring reports.

The committee was asked to give their advice on whether it would be necessary to fence the trial site to prevent entry of wild animals and concluded that this would not be required.

The committee discussed the potential for entry into the human food chain through cross-pollination of other potato fields growing close to the trial field. ACRE recognised that rare long-distance cross-pollination events are possible, especially where pollen beetles are common in the release area. However cross-pollination frequencies reduce dramatically over distance and pollen competition from within a non-GM crop reduces the likelihood of successful hybridisation further. If GM pollen hybridised successfully and resulted in GM seed, the chances of such seed germinating successfully and surviving until harvest as a tuber in a non-GM potato crop are low because potatoes are usually grown in rotations and the volunteers resulting from true seed are very vulnerable to herbicide applications and to competition from the following crop.

BASF proposed a separation distance of 20 metres and ACRE considered that this is sufficient to ensure that these potatoes will have an extremely low probability of entering the food chain.

ACRE issued its advice in November 2006. It asked BASF in the two years following harvest of the GM tubers to leave the area of release fallow and not plough but use only shallow tillage. Volunteers growing from true seed and groundkeepers in the fallow years should be treated with glyphosate herbicide and potato plants should be hand-pulled prior to flowering. In subsequent years appropriate herbicides should be used to control potato plants growing from true seed and from groundkeepers prior to flowering. Alternatively plants growing from groundkeepers may be hand pulled. BASF was also asked to provide reports one month after the date of termination of each release or by 30 November in the year each trial was terminated, whichever

was the sooner, and annually on the anniversary of the termination of the release or by 30 November. BASF was requested to report and control all groundkeepers and volunteers until a period of two years when none are observed has elapsed.

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

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

2.2.1 Notification for Part C consent from Monsanto to market insect resistant and herbicide tolerant maize NK603 x MON810 ref C/GB/02/M3/3

ACRE was asked in February 2006 to comment on the European Food Safety Authority's scientific opinion on the Part C marketing application for NK603 X MON 810 maize.

This GM maize is a cross between two existing GM maize lines (NK603 and MON810) that already have marketing approval in the EU. NK603 is modified for tolerance to the herbicide glyphosate and MON810 is modified for insect resistance.

The UK is the lead Member State for this notification under Directive 2001/18/EC and it issued a positive assessment in March 2004 (in line with ACRE's advice). This initial assessment included feed use, but as Monsanto submitted another application for NK603 X MON810 maize under Regulation 1829/2003 for food and feed use, the scope under Directive 2001/18/EC has been reduced to import and processing of grain only.

ACRE issued advice in March 2006 noting that EFSA's GMO Panel was in agreement with ACRE's views. ACRE considered that its earlier advice did not need to be revised.

2.2.2. 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 March 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 had previously assessed this application on two occasions but since its last assessment, use of this product in animal feed has been removed from the scope of this application and it would now be addressed under the Food and Feed Regulations.

ACRE was content that the new information concerning the stability of the insert and bioinformatics analysis was consistent with the conclusions of the applicant and did not indicate any risks to human health or the environment. The committee noted that groundkeepers could persist in the soil and that care should be taken to control volunteers between cultivations of GM and conventional potato varieties in order to ensure compliance with the traceability and labelling requirements for GM products. However ACRE considered there was no indication that this persistence would differ from that of other starch potato varieties and that this was an agronomic problem rather than one affecting human health or the environment.

ACRE considered that the monitoring proposed by the notifier should detect any differences in the flowering performance of this clone. The committee anticipated that any deviations from expected performance of the potato clone indicated through post-release monitoring would trigger case-specific monitoring. The committee agreed with the EFSA GMO panel that there was a very low risk of the cultivation and use of this potato clone leading to risks to human health or the environment.

ACRE's advice was issued in April 2006 when the committee confirmed that cultivation and use of this clone posed no additional risks to human health or the environment compared to the parental potato cultivar.

2.3 Applications to market GM food and feed under Regulation (EC)1829/2003

ACRE was kept informed of marketing applications submitted under Regulation (EC) 1829/2003, many of which were within the committee's remit because they were for the import and/or the cultivation of live GMOs. ACRE considered the environmental risks of the following cases in detail:

2.3.1 Application from Monsanto for authorisation to use NK603 maize in the European Union, including the use for cultivation of varieties - ref EFSA-GMO-NL-2005-22

ACRE was asked to consider this 1829/2003 application from Monsanto to cultivate GM glyphosate-tolerant maize. The committee had already evaluated the risk assessment of this GM event for import into the EU (under Directive 2001/18/EC) and issued a favourable opinion. The committee's discussions were therefore limited to the environmental risk assessment of the cultivation of this crop and its comments were forwarded to EFSA for consideration prior to formal advice which would be given once EFSA published its scientific assessment of the full application.

The environmental risk assessment (ERA) provided by the applicant was considered to be adequate in all aspects apart from those addressing the effect of management of the crop on the environment, which was not addressed in sufficient detail in either the ERA or the post-market monitoring plan. ACRE proposed that the company should provide details of how management regimes associated with the cultivation of this crop would affect biodiversity and on how any assumptions made by the applicant regarding this impact would be monitored by the applicant. The committee concurred with the approach taken in EFSA's published guidance on management practices, which considered that monitoring over a range of different management systems would be appropriate.

The UK submitted comments to EFSA to indicate that the effects of crop management (herbicide use) associated with the GM crop should be included in the risk assessment and the post-market monitoring plan.

2.3.2 Application from Pioneer Hi-Bred International Inc and Mycogen Seeds for authorisation to use 1507 x NK603 maize in the European Union, including the use for cultivation of varieties - ref EFSA-GMO-NL-2005-17

The committee was asked to consider this application from Pioneer Hi-bred and Mycogen Seeds, to cultivate the GM hybrid 1507 x NK603 maize. Event 1507 produces glufosinate ammonium tolerant, insect resistant maize (through expression of the *bar* gene and the *Cry 1F* gene) and NK603 produces glyphosate tolerant maize. The resulting hybrid maize therefore has insect resistance and dual herbicide resistance. The committee had already evaluated a risk assessment for each of the GM events in this GM hybrid (under Directive 2001/18/EC). In both cases a favourable opinion was given when the full dossier was considered (NK603 for import and 1507 for cultivation). The committee's discussions were therefore limited to the environmental risk assessment for the cultivation of this crop. The committee was asked to provide comments which could be forwarded to EFSA for consideration at this stage rather than formal advice, which would be given once EFSA published its scientific assessment of the full application.

The committee was content with the insect resistance plan produced by the company. However ACRE noted that farmers growing total areas less than 5 hectares in size would not be required to implement this plan which could mean that contiguous areas without refugia could occur in areas where maize growing was common and farm sizes were small.

The environmental risk assessment provided by the applicant was considered to be adequate in all aspects apart from those addressing the effect of management of the crop on the environment. The notifier had not addressed this part of the risk assessment in sufficient detail in either the ERA or the post-market monitoring plan. ACRE considered that this aspect should be addressed in the same way as recommended for the previous application. ACRE had no issues to raise related to the environmental risk assessment of GM crop cultivation as a result of the stacking of traits in GM hybrids.

2.3.3 Application from Monsanto under Regulation (EC) No. 1829/2003 on genetically modified food and feed for authorisation of 40-3-2 soybean for cultivation in the EU

ACRE considered this notification to cultivate 40-3-2 soybean in the EU. This GMO already had approval for import, processing, food and feed use within the EU and had been modified to contain the *cp4 epsps* gene (isolated from *Agrobacterium sp.*) that confers tolerance to the herbicide glyphosate.

ACRE undertook a preliminary evaluation to identify any concerns that needed to be highlighted to EFSA in the areas of molecular characterisation, environmental risk assessment and post-market monitoring. ACRE identified as a key issue the risk posed to farmland biodiversity as a result of altered herbicide management practice. Monsanto had not considered the environmental consequences of weed control in 40-3-2 soybean fields as compared with that in non-GM soybean fields in the appropriate section of the notification. However, it had elsewhere provided data to indicate that the use of glyphosate in association with the cultivation of 40-3-2 soybean has the potential to adversely affect farmland biodiversity (as compared to its non-GM counterparts) because of its effectiveness as a weedkiller. Consequently, ACRE was of the view that Monsanto should address how this impact could be offset and this should be considered in the environmental risk assessment section of this notification. The post-market monitoring plan should then describe how the effectiveness of these proposed measures will be monitored. ACRE considered that the GMO itself would not pose a greater risk to biodiversity as compared to non-GM soybean varieties.

With respect to the post-market monitoring plan, ACRE considered that monitoring for glyphosate-tolerant weeds should be included, i.e. those resulting from the use of the herbicide. The committee noted that there are no sexually compatible wild/weedy relatives of soybean in the EU to which gene flow could occur. ACRE criticised the example of a farmer's questionnaire that was appended to Monsanto's general surveillance plan and noted that Monsanto would not be able to report on the output of the questionnaire for at least two years after the GMO was first cultivated in the EU because of the nature of some of the questions asked.

ACRE was content with the quality of the molecular characterisation of 40-3-2 soybean and it considered that the data supplied supports Monsanto's description of the event. Overall, ACRE noted that this product has been approved for feed use in the EU and elsewhere and that, despite its extensive uptake, there is no indication that it is unsafe.

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/726/2004. The committee considered one such application in 2006. 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 generic advice in May on the import and marketing of grain derived from GM maize. The scope excluded cultivation and use as food or feed. ACRE had seen several maize import notifications and was satisfied that the risks to human health and the environment arising from marketing such products for importation and processing would be no different from that of conventionally bred maize imported for processing. The advice is reproduced in this report at Chapter 4.

ACRE also advised on a Defra-commissioned research report on technologies for biological containment of GM and non-GM crops. The advice is reproduced at Chapter 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 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. A key objective of the clinical trials guidance is to help potential applicants determine whether their planned clinical trials best fit the contained use or deliberate release regimes. The guidance on GM plants and GM micro-organisms will assist those carrying out work in containment, helping users to understand the regulatory system and apply the appropriate level of containment and management control. It incorporated recommendations ACRE made in its advice on the Defra-commissioned report on technologies for biological containment. The Compendium of Guidance is due to be 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 189 cases in 2006.

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 our expertise is considered to add value to the advice that is routinely sought from the Statutory Conservation Agencies and others. Table 2.1 shows all licences that were issued in 2006. Of these the committee only advised on the entomopathogenic nematode *Steinernema carpocapsae*.

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 E-Nema GmbH to release an entomopathogenic nematode *Steinernema carpocapsae*.

In July 2006 ACRE considered an application to release the nematode *Steinernema carpocapsae* in England for the biological control of leatherjackets in turf, large pine weevils in forests and caterpillars in greenhouses. ACRE noted there were conflicting views as to whether this species was native to England although it had been released previously. It was known to have a broad host range but outside experts had expressed differing views as to its potential to affect populations of non-target organisms in the soil. ACRE considered the application in the light of results of a number of studies and concluded that it is very unlikely that *S. carpocapsae* would have an adverse effect on the environment based on the committee's knowledge of entomopathogenic nematodes and soil systems. However, the committee considered that there was uncertainty and discussed the significance of these gaps in the knowledge base. ACRE considered that the persistence of the nematode in the soil was a pivotal piece of information that was missing in the application. ACRE felt that if the applicant could provide data to show that the decline in *S. carpocapsae* populations applied to golf courses/forest plantations was typical of that of entomopathogenic nematodes in general, it would have sufficient evidence to support the licensing of *S. carpocapsae* for use in the wider environment as well as for glasshouse use in England.

In response, the applicant provided peer-reviewed papers that investigated the decline of *S. carpocapsae* under different environmental conditions. ACRE noted that persistence was affected by a number of parameters including prey availability, type of prey, soil type and humidity. In September 2006, ACRE concluded it was content with the information provided and would support the licensing for use as a biological control agent.

Table 2.1: Licences issued between 1 January and 31 December 2006

Licence	Licence Holder	Organism	Purpose
WCA/06/04	Wildlife Conservation Research Centre – Oxford University	American Mink	Scientific research
NNR/2006/01	Ms Bruemmer	Grey Squirrel	
NNR/2006/02	The Wildlife Conservation Research Unit – Oxford University		
WCA/06/03	East Winch Wildlife Centre (RSPCA)	Muntjac deer	Rehabilitation
WCA/06/02	Wildlives Rescue Rehabilitation Centre		
WCA/06/13	BCP	<i>Amblyseius californicus</i>	Biological control
WCA/06/06	Koppert		
WCA/06/14	Syngenta Bioline		
WCA/06/07	BCP	<i>Amblyseius degenerans</i>	
WCA/06/08	Koppert		

WCA/06/09	Syngenta Bioline		
WCA/06/20	BCP	<i>Amblyseius swirskii</i>	
WCA/06/18	Koppert		
WCA/06/19	Syngenta Bioline		
WCA/06/10	Syngenta Bioline	<i>Delphastus catalinae</i>	
WCA/06/15	BCP	<i>Eretmocerus eremicus</i>	
WCA/06/16	Koppert		
WCA/06/17	Syngenta Bioline		
WCA/06/12	BCP	<i>Macrolophus caliginosus</i>	
WCA/06/11	Koppert		
WCA/06/05	Syngenta Bioline		
BCA/06/01	Becker Underwood	<i>Steinernema carpocapsae</i>	
WCA/05/08	E-Nema		

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

CHAPTER 3

Guidance on assessing the environmental impact of genetically modified organisms on the soil environment

Guidance for applicants seeking permission to release genetically modified crops into the environment (under Directive 2001/18/EC)

Summary

The objective of this guidance is to provide notifiers with a framework outlining the general principles to consider in the environmental risk assessment of genetically modified crops in relation to soil ecosystems under Directive 2001/18/EC and Regulation 1829/2003/EC on genetically modified food and feed.

SECTION 1

Introduction, Scope and Aims of this Guidance

- 1.1 The release of live genetically modified (GM) crops in Europe is controlled by Directive 2001/18/EC on the deliberate release into the environment of GMOs³ and EC Regulation 1829/2003 on genetically modified food and feed. Applicants for consent to release must supply a dossier of prescribed information⁴ about the GM crop and this should include a detailed risk assessment of its possible impact on human health and the environment⁵.

³ The term “genetically modified organism” used in this guidance refers to the definition used in section 106 of the Environmental Protection Act 1990.

⁴ Annex III and IV of Directive 2001/18/EC, referred to in Article 5.5(a) of Regulation 1829/2003/EC.

⁵ Annex II of Directive 2001/18/EC.

Applicants must also include a post-market monitoring plan in the risk assessment⁶.

- 1.2 Annex II of Directive 2001/18/EC sets out the principles for risk assessment associated with this guidance. General guidance supplementing this Annex has been issued by the European Commission⁷. The objective of an environmental risk assessment (ERA) is, on a case-by-case basis, to identify and evaluate potential adverse effects of the GM crop, either direct or indirect, immediate or delayed on human health and the environment which the deliberate release and the placing on the market of GMOs may have. The ERA should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.
- 1.3 Directive 2001/18/EC stipulates that all releases of GM crops should occur in a stepwise fashion, first in contained use and subsequently on larger scales. The conditions of releases always remain open to re-assessment in the light of new information. New information may be gained through post-market monitoring of the released GM crop.
- 1.4 In the UK, the Advisory Committee on Releases to the Environment (ACRE) reviews all applications to release and market live GM crops and advises Ministers⁸ on the potential risks to human health and the environment arising from the releases. In this document the committee aims to highlight the type of information that is required from notifiers in the environmental risk assessment and post-market monitoring of GM crops with respect to soil ecosystems.
- 1.5 The detail of this guidance has primarily been aimed at applicants wishing to release GM crops on a commercial basis under Part C of Directive 2001/18/EC. However, the principles of the risk assessment process for soil systems apply to part B (experimental) releases of GM crops, though the information required

⁶ Annex VII of Directive 2001/18/EC, referred to in Article 5.5(b) of Regulation 1829/2003/EC.

⁷ EC Decision 2002/623/EC is available at; http://66.102.9.104/search?q=cache:xFhBi2vIhCcJ:europa.eu.int/comm/environment/biotechnology/pdf/dec2002_623.pdf+EC+Decision+2002/623/EC&hl=en

⁸ UK Government and Devolved Administrations of Scotland, Wales and Northern Ireland.

for such releases is much less comprehensive⁹. Therefore, some uncertainty about ecological effects could be accepted for a Part B release provided that these effects are adequately monitored and the trial of sufficiently small scale. This guidance avoids being prescriptive because each risk assessment will be case-specific, depending on the characteristics of the GM crop variety itself, its management and use.

SECTION 2

Background information on Soil Systems^{10 11}

- 2.1 Soils provide important ecosystem services in addition to supporting plant growth, including the regulation of water quality and quantity; carbon sequestration; recycling nutrients and other elements; the bioremediation of waste and the production of biomass. In an agricultural context microbiological components of the soil also have an important role in plant disease and suppression of plant pathogens. However, the soil environment is complex and highly heterogeneous with its chemical, physical and biological characteristics varying significantly in space and time. In agricultural soils some of these fluctuations are the result of agronomic practice whilst others are a consequence of broader non-anthropogenic processes such as carbon and nitrogen cycling, erosion and climatic effects.
- 2.2 Soils are generally resilient ecosystems and this is thought to relate to the diversity of organisms within the soil that can perform the same function. Since the loss of a single group of organisms able to perform that function will not result in the loss of the soil function, this is termed functional redundancy. Despite this resilience, conventional agricultural practices have, in some soils,

⁹ Annex III of Directive 2001/18/EC recognises that the level of detail required in response to each of the categories of information specified for inclusion in the notification depends on the nature and scale of the proposed release.

¹⁰ ACRE's subgroup on soil ecology has produced an interim report which gives more detailed information on soil ecology. This can be found at www.defra.gov.uk/environment/acre/soilecology/acre_soilecology_interim.pdf

¹¹ a Defra-commissioned report examining the effects of GM crops on soil ecosystems also provides further background information on soil systems. This is available at: www.defra.gov.uk/environment/gm/research/epg-1-5-214.htm.

been responsible for long-term physical damage including erosion and compaction¹².

- 2.3 Plants are the key driver of soil processes and can modify the physical, chemical and biological characteristics of the soil through the production of primary nutrients (bottom-up regulation). Different crops, including different cultivars, and different management regimes affect the biological and physical properties of soil systems. However, many of these effects are transient and spatially constrained to the rhizosphere of the plants. In addition to bottom-up regulation, the biomass and activity of the microbiota and soil fauna are also affected by top-down regulation (by predators) and abiotic factors (such as climate and season). Within agricultural soils mechanical processes such as ploughing and chemical additions (e.g. pesticides and fertilizers) also affect soil systems. It is therefore important to assess the impact of changes in management practices associated with genetically modified crops when assessing environmental risk.
- 2.4 The soil characteristics seen as “desirable” are highly subjective, depending on use and location. For example, low nutrient and pH soils may support rich, diverse wild plant communities but are suboptimal for agricultural production. Nitrogen-fixing bacteria are suppressed by the application of nitrogen fertilisers and therefore these may be much less important in some agricultural soils than in natural ecosystems.
- 2.5 The measurement of biodiversity within soils is difficult since all currently available techniques have limitations. Changes in microbial biodiversity can be difficult to detect and are not easily interpreted since unlike other environments, the role of biodiversity in contributing to soil functions is not well understood. This complicates the assessment of environmental risk associated with changes in the soil environment and makes the selection of relevant tests difficult. However, there are certain key processes and indicator species known to be of importance in soil function and other soil properties may be assessed

¹² The Millennium Ecosystem Assessment on biological diversity assesses the consequences of ecosystem change including changes in agricultural systems for human well-being. Further information about the work and reports are available at: www.millenniumassessment.org/en/Products.Synthesis.aspx

by using suitable bioindicators, especially plants. Since soils are so spatially heterogeneous and the nature of a soil is dependent on its previous use, it is necessary in all cases to consider the environment into which the release is to be made (and any other environment into which the GM plants might escape). The impact of GM crops should be assessed against this background and against the normal range of values for each component monitored for the parental plants.

- 2.6 It is important that any monitoring after the release of a crop should be practical and economic to apply. Changes in results from routine soil testing and in inputs to soils by farmers may also be indicative of changes to the soil ecosystem. If these changes are not within the normal range, case-specific monitoring would need to be implemented to determine the underlying cause of the change.

SECTION 3

Research results required for Environmental Risk Assessment

- 3.1. If the altered gene products or the management of crops containing the gene has a greater potential to damage soil systems than similar parental species, the impact should be assessed. Annex 1 provides several examples of GM crop traits which should be evaluated with regard to their potential impact on soil systems. However, this list is not exhaustive and soil systems must be considered in the release of all GM crops. The risk assessment should include a full description of the appropriate commercial management regime, including changes in pesticide applications, tillage, rotations and other crop protection measures where these are different from comparative non-GM crops.
- 3.2 For most releases some relevant research will have been undertaken and this should be reviewed as part of the ERA in the notification. Where previous research has not been carried out the notifier must make a case based on the likely impact of the GM crop. Effects that are expected to be beyond the normal range of variability before the introduction of the GM crop require a detailed environmental risk assessment with regard to soil systems. Where no

increased risk to the environment is perceived, supporting evidence must be provided in the notification.

3.3 Where risks have been identified to soil systems, direct and indirect effects on target and non-target organisms within the soil must be assessed or summarised from previous relevant studies. The extent to which non-target organisms are exposed either directly or indirectly must be identified. The information given in the application must also be indicative of the likelihood and consequences of horizontal gene transfer to soil organisms. In the case of target organisms within soil systems this may include the possibility of development of resistance to the modified trait.

3.4 Given the problems identified in determining relevant measures of soil biodiversity, the assessment should focus on key soil processes and groups of organisms associated with these processes. Many Part B releases are conducted to assess agricultural properties such as yield, quality and disease resistance of GM crop plants; these factors are in themselves useful bioindicators of soil condition and may inform subsequent risk assessments. In general, crop plant yield, colouration and disease are informative bioindicators and should be assessed in GM crops and in soil which has previously contained GM crops. The longevity of any plant response (wild or crop plants) when the GM crop has been removed from the habitat should be determined. If increased disease susceptibility is indicated, further tests should be done to assess impacts on pathogenic and antagonistic bacteria in the rhizosphere. However, certain soil groups and processes have a low level of functional redundancy, and are therefore potential indicators since their loss is likely to have a significant effect on soil ecosystem function¹³. These groups include: earthworms, mycorrhizal fungi, plant growth promoting rhizobacteria, lignin-

¹³ The UK Soil Indicators Consortium, set up in 2003 aims to develop a set of policy relevant and scientifically robust indicators of soil quality. This work is still underway, developments will be updated at; www.defra.gov.uk/environment/land/soil/research/indicators/consortium/

decomposing fungi, nitrogen fixers and nitrifying bacteria. In addition to these specific tests the overall rate of plant matter degradation (for example in litter bags) gives an indication of the speed of decay and can be indicative of effects on a wide range of detritivores. However, it is important that effects on the relevant indicator groups listed above should be assessed when a risk to soil ecosystems has been identified.

- 3.5 The assessment should be proportionate to the intended release, including the temporal and spatial scale of release, the habitat into which the GM plant is released and any habitat which is at risk of colonisation following release. It is not within the scope of this guidance to recommend specific techniques for determining the impact of the use of a GM crop, but a reference list of standard techniques is provided at Annex II. In all cases where additional experimental evidence is required experiments should be designed so that sufficient statistical power is obtained to observe possible negative impacts on soil organisms.
- 3.6 Risks that require management should be defined together with a suitable risk management strategy. An evaluation of the overall risk of the GM crop should be made taking into account the proposed risk management strategies.

SECTION 4

Soils and the Post-Market Monitoring Plan

- 4.1 A post-market monitoring plan must be supplied as part of the conditions of Annex VII of Directive 2001/18/EC. Post-market monitoring regimes should be capable of detecting significant changes in crop performance that might be attributable to changes in soil function. ACRE has produced guidance on post-market monitoring¹⁴ and the general principles of this guidance apply to soil systems.

¹⁴ this guidance document is available at:
www.defra.gov.uk/environment/acre/postmarket/index.htm

Case Specific Monitoring

- 4.2 Where a risk to soil processes or function that could adversely effect crop performance has been identified at any stage of the environmental risk assessment it must be further investigated as part of the post-market monitoring plan through case-specific monitoring.
- 4.3 It is important to recognise that the results of experiments conducted in laboratory/glasshouse tests and microcosms will not always be representative of the situation in the field. It is therefore necessary to implement monitoring to check the conclusions made from the small-scale pre-release experiments as part of the case specific monitoring plan. Cumulative long-term effects of the use of GM crops must also be assessed as part of the ERA¹⁵ and this is not possible in shorter-term experiments.

General Surveillance

- 4.4 Post-release GM crops should be monitored for disease, and disease incidence should also be recorded in crops following on from any GM crop. Unusual levels of disease incidence may be indicative of an effect on the soil organisms that suppress plant disease. Observation and recording of crop yield and colouration should also be done to indicate any effects of plants on soil. Further investigation characterising the biodiversity of the soil might be appropriate if unusual disease incidence, plant growth or colouration are found at this stage.
- 4.5 Farmers often test soil pH and levels of phosphorous, nitrates and potassium and record inputs of fertilizers, lime and other soil amendments. Farmers will also be able to identify changes in the ease of cultivation of the soil in a particular field and could be asked to record changes of this type, which may indicate changes in soil structure. Properly conducted visual assessment of the soil can also give an early indication of changes in its physical and biological properties and can determine effects on non-target species such as

¹⁵ Annex II of Directive 2001/18/EC.

earthworms¹⁶. Records should be made and compared with data from similar conventional crops to determine whether the GM crop or its management are altering existing regimes over time, and the impact of this assessed and if necessary, investigated. If these changes are not within the normal range, case-specific monitoring would need to be implemented to determine the underlying cause of the change. Similarly, records of crop yield, colour and disease may indicate unusual residual impacts of GM crops in the following seasons.

ANNEX 1

List of GM plant traits likely to be of importance to soil systems

a) Traits Associated with Altered Land Management Practices

Traits which might alter land management practices include herbicide tolerance, pest resistance, drought tolerance, salt tolerance and a reduction in the requirement for nitrogen. Modifications which alter the timing of land management may also have different effects on soil systems and agro-ecosystems as a whole.

Although alterations in land management practices can have positive as well as negative effects on soil function and processes the objective of the risk assessment process in soils is to highlight adverse effects on these systems.

Agronomic practice has previously had adverse effects on soil functions through compaction and erosion which have affected water ecosystems through run-off from farm land. Wheel traffic during cultivation is largely responsible for the adverse effects on soil compaction. Reductions in biomass inputs to soil have been responsible for increases in soil bulk density and soil pore water retention. Irrigation of crops can cause soil erosion and increase leaching into water courses.

¹⁶www.smi.org.uk/docs/news/1114438727SMIVSAbrochurefinal.pdf

The timing of cultivation can affect the scale of impacts on biodiversity as a whole and soils which do not contain crops are more prone to leaching which in turn affects water quality.

In some cases modifications such as drought or salt tolerance might allow previously unmanaged land to be cultivated land and the impacts of this would need to be carefully assessed.

b) Trait Specific Genetic Modifications

- i) Crops with modifications that affect the expression and release of organic acids or opines into soil systems.

- ii) Modifications that change the lignin content of plants or other compounds that affect the degradation of organic matter in the soil

- iii) Modifications that alter the resistance or tolerance of plants to invertebrate pests or pathogens (e.g. Bt toxin, T4 lysozyme, lytic peptides, lectins).

ANNEX 2

Sources of Information on Methods to Assess Soil Biodiversity

1. A general assessment of soil health using applied methods in the field from the Soil Management Initiative (SMI):

www.smi.org.uk/docs/news/1114438727SMIVSAbrochurefinal.pdf

2. A full discussion of the importance of soil biodiversity from the FAO can be accessed through the FAO Soil Biodiversity Portal:

www.fao.org/AG/AGL/aqll/soilbiod/default.stm

3. An up-to-date laboratory manual with molecular methods for a wide variety of applications including soil biodiversity:

Kowalchuk, G.A., de Bruijn, F.J., Head, I.M., Akkermans, A.D. and van Elsas, J.D. (eds.) (2004). *Molecular Microbial Ecology Manual* 2nd edition, Pub Kluwer Academic Publishers. pp1780, ISBN: 1-4020-2176-3.

Also available on-line:

<http://reference.kluweronline.com/?xmlid=1402021763>

4. A laboratory manual for more applied methods to assess soil microbial parameters:

Alef, K. and Nannipieri, P. (eds) (1995). *Methods in Applied Soil Microbiology and Biochemistry*. Academic Press, London. pp 576 ISBN: 0-12-513840-7

5. A useful methods text for soils which covers physical, microbial and macrofaunal methods is:

Robertson, G.P. Coleman, D.C., Bledsoe, C.S. and Sollins, P.(eds)(1999). *Standard Soil Methods for Long-Term Ecological Research*. Oxford University Press

6. A general text on soil methods:

Schinner, F., Ohlinger, R., Kandeler, E. and Margesin, R. (eds.)(1996). *Methods in Soil Biology*. Springer-Verlag, Berlin.

7. A comprehensive account across taxa and methods:

Phillipson, J. (1971) *Methods of study in quantitative soil ecology*. IBP. Handbook 18. Blackwell, Oxford.

8. The most up to date general soil ecology text book with a detailed chapter on invertebrates:

Coleman, D.C., Crossley, D. and Hendrix, P. (2004) *Fundamentals of soil ecology*. Academic Press (second edition).

CHAPTER 4

General advice on notifications for import and marketing of GM maize grain

Product: maize grain genetically modified for herbicide tolerance and / or and insect resistance.

Scope: for the import and processing of grain derived from GM maize only. Scope excludes cultivation and use as food or feed.

Advice of the Advisory Committee on Releases to the Environment (ACRE) under S.124 of the Environmental Protection Act 1990 (Part VI) to the Secretary of State for Environment, Food and Rural Affairs, Scottish Ministers, Ministers of the Welsh Assembly Government and the Department of Environment (Northern Ireland).

General advice on import and marketing of GM maize grain:

ACRE is satisfied at this stage on the basis of the evidence previously provided in several herbicide tolerant and / or and insect resistant GM maize import notifications that the risk to human health and the environment arising from marketing such products for importation and processing will be no different from that of conventionally bred maize imported for processing.

The assessment of environmental risks associated with cultivation or use as food or feed of herbicide tolerant and / or and insect resistant GM maize is not addressed in this advice.

Comment

The general advice given here only addresses general environmental safety issues relating to the import and processing of live GMOs (i.e., grain) of maize (*Zea mays* sp.). This advice does not relate to a specific GM maize product; it has been developed from previous advice given by ACRE on a number of maize import notifications made under 2001/18/EC¹⁷. This advice does not relate to cultivation or food and feed safety of GMOs.

Interaction of the Deliberate Release Directive with the GM Food and Feed Regulation

The EU regulations (EC/1829/2003) governing the authorisation of GM food and feed (GMFF) came into force in April 2004¹⁸. The European Food Safety Authority (EFSA) is the lead centralised body with responsibility for assessing GMFF applications made under EC/1829/2003 on behalf of Member States (MS). The lead Competent Authority (CA) in the UK for regulation 1829/2003 is the Food Standards Agency (FSA).

The environmental safety requirements as laid down in Directive 2001/18/EC apply to the evaluation of GMFF notifications to ensure that all appropriate measures are taken to prevent adverse effects on human health and the environment. Under these regulations, EFSA must consult the CA's for Directive 2001/18 regarding the environmental requirements. In the UK it is Defra, advised by ACRE, that is the lead CA for 2001/18/EC.

Due to the experience gathered by the Committee through its consideration of Directive 2001/18 dossiers, ACRE has issued this advice on their general requirements for ensuring environmental safety during the import and transport of GM maize grain for processing. This advice will be applied to specific cases on the understanding that Defra will seek further advice from ACRE if necessary, for example for a GM trait not previously assessed by ACRE. For GMFF applications

¹⁷ Maize import notifications assessed under 2001/18/EC by ACRE are for events Bt11, 1507, NK603, MON810, MON863, and hybrids NK603 X MON810 and MON863 X MON810. Specific advice issued by ACRE on these GMOs can be found at: www.defra.gov.uk/environment/acre/pubs.htm#advice

¹⁸ EC/1829/2003
http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf

involving cultivation, the Committee will continue to make independent and case-by-case evaluations of environmental risk assessments.

Assessment of environmental risks

ACRE has previously assessed the potential risks arising from importation and commercial use of GM maize grain. In arriving at its advice the committee has considered such notifications against the requirements of the legislation as it relates to the UK and in particular:

- Capacity to survive, establish and disseminate
- Potential for gene transfer
- Genetic and phenotypic stability
- Expressed products from the inserted sequences
- Potential adverse effects for humans and animals: toxic and allergenic effects
- Interactions with other organisms
- Potential effects on biogeochemical processes.

In respect of each of these assessment criteria ACRE has developed the following comments over a number of assessments:

- **Capacity to survive, establish and disseminate**

Since maize does not establish properly outside the agricultural environment and is chilling-sensitive, the impact of escape of grain during storage or transport on gene transfer into other maize crops or weeds is considered to be extremely low. Members consider that because of the low germination rate and subsequent low viability of any germinated maize volunteer plants there are no anticipated environmental risk problems. No differences in dissemination capacity or increased potential for gene transfer have been observed in pollen, seed and vegetative material from GM maize compared with non-GM maize.

- **Potential gene dissemination by pollen or seed**

Due to the low germination rate and subsequent low viability of any germinated maize plants there are no anticipated environmental risk problems.

- **Potential for gene transfer**

The potential for transfer of genetic material from GM maize is no different to that for conventional maize varieties. Gene flow will only occur into other cultivated maize plants, and the likelihood of gene transfer is low due to a combination of biological barriers. Additionally, this advice only relates to import and processing of maize grain, where the incidence of fertile male or female flowers will be extremely low.

The committee is of the view that the presence of specific antibiotic resistance marker genes in particular genetic contexts should be considered on a case-by-case basis and has previously advised that antibiotic resistance marker genes should be avoided in the design of future GM crops¹⁹. ACRE recognises that antibiotic resistance marker genes raise concerns because of the impact that they may have on antibiotic resistance in bacterial populations. On the specific issue of the presence of the *npdII* marker gene in MON863 maize (conferring resistance to the antibiotics neomycin and kanamycin) the committee has previously advised that it does not constitute a risk to human health or the environment.

- **Genetic and phenotypic stability**

In general, the environmental risk assessments for imports of GM maize grain have not identified any potential differences between conventionally bred maize and non-transgenic maize varieties for phenotypic characteristics, with the exception of the new characteristics introduced by the genetic modification, such as tolerance to glyphosate (e.g. NK603), tolerance to glufosinate ammonium (e.g. Bt 11; 1507) and insect resistance conferred by a *Cry* toxin gene (e.g. *Cry 1Ab* in MON810 and Bt11; *Cry3Bb1* in MON863; *Cry1F* in 1507).

- **Genetic stability of hybrid GMOs**

In general, ACRE considers that confirmation of the safety profile of the two parent lines is sufficient to support a positive assessment of a GM hybrid that has been produced by conventional breeding. In cases of hybrid GM maize assessed to date ACRE has been satisfied with the evidence presented by notifiers for the genetic stability of the inserts and the negligible likelihood and potential consequences of recombination between the inserted genetic sequences during the production of hybrid GM maize. However, the committee is also of the view that GM hybrids should

¹⁹ www.defra.gov.uk/environment/acre/bestprac/guidance/index.htm

be considered on a case-by-case basis, particularly if one or more of the parental GM lines have not been previously assessed by ACRE.

- **Potential effects on biogeochemical processes**

Potential effects on biogeochemical processes, or impacts resulting from changes in management methods, arising from cultivation of the herbicide tolerant maize do not apply directly to notifications in which the GM maize is not for cultivation. The likelihood of any potential effects being manifest on biogeochemical processes arising from unintentional introduction of the GM maize into the environment is considered to be extremely low.

Post-market monitoring

The aim of the case-specific part of the post-market monitoring plan (PMMP) is to investigate any risks identified in the environmental risk assessment, and to test any assumptions made in the risk assessment. In general, ACRE has agreed that on the basis of previous risk assessments for import of GM maize made under 2001/18/EC, there has been no requirement for case-specific monitoring to date. However, the committee recommends that provision of the detailed arrangements for general surveillance PMMPs should be made a condition of any consent. Details in the PMMP should include: (1) precisely who will be requested to provide information; (2) what type of information will be requested and the frequency of requests and (3) how the company will ensure participation to ensure a robust assessment.

CHAPTER 5

Advice on the implications of findings in a Defra-funded desk study: ‘Technologies for biological containment of GM and non-GM crops’

Background:

The importance of minimising the dispersal of transgenes into the environment (gene flow) was one of the many conclusions reached in the GM Science Review and by the ACRE sub-group on Best Practice in GM Crop Design²⁰. The desk study reviewed and assessed the technologies for biological containment of GM and non-GM crop plants that are aimed at reducing the dispersal of transgenes into the environment and to make recommendations for future research²¹.

The study provides a survey of the European crops with genetic containment issues. It outlines three main GM containment strategies being developed for conventional crop species:

- Physical containment - in greenhouses, growth rooms and bioreactors.
- Biological containment, both natural (using vegetative parts of the plant to produce pharmaceutical products) and plastid transformation (to prevent gene flow via pollen).
- Transgenically controlled genetic containment strategies, such as conditional lethality, inducible promoters, engineered male sterility, seed lethality, apomixis, cleistogamy and others.

²⁰ First Report: www.gmsciencedebate.org.uk/report/pdf/gmsci-report1-pt5.pdf.

Second Report: www.gmsciencedebate.org.uk/report/pdf/gmsci-report2-pt3.pdf, section 4.5.

ACRE sub-group: www.defra.gov.uk/environment/acre/bestprac/index.htm

²¹ The desk study has been published at

www2.defra.gov.uk/research/project_data/More.asp?I=CB02036&M=KWS&V=CB02036&SUBMIT1=Search&SCOPE=0

The study also reviews bio-containment methodologies being developed for plants expressing pharmaceutical products. It highlights that field crops are unlikely to be the vehicle for any future specialised production of plant-made industrial products and pharmaceuticals and that it is more likely that non-food crop systems in contained facilities would be the method of choice in the future. The report identifies some areas where further information would be of value, for example, factors to be considered in environmental risk assessments of lower plants as production platforms for industrial products and pharmaceuticals.

The report concludes that none of the methodologies currently available guarantee transgene containment and that the adoption of any genetic containment strategy will require continuous assessment and monitoring.

ACRE was asked to advise on the findings of this report for future environmental risk assessments - particularly with respect to minimising the dispersal of transgenes - for crops genetically engineered to be biologically contained, including those intended for production of industrial products such as pharmaceuticals.

Advice:

ACRE has considered the report on technologies for biological containment and advises that it serves as a comprehensive and informative review of the current research activity in this sphere.

ACRE accepts that none of the current GM containment technologies, including physical containment, guarantee complete transgene containment and emphasised that whatever method was used, it was clear that strict management of production facilities would be necessary to ensure no significant risks of harm to the environment.

In assessing the potential environmental risks posed by a GMO, the committee always considers whether dispersal of a particular transgene into the environment could have implications for the safety of the GMO. The committee advises that it would continue to deal with applications to cultivate GM crops on a case-by-case basis.

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 the Department of the Environment (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.

APPENDIX II

Openness and Transparency

We have a continuing commitment to openness and transparency in the working of our committee and its sub-groups. We publish meeting agendas on the website¹ in advance of each meeting and invite comments. The minutes of our meetings are also published on the website, and the secretariat aims to do this within a target period of 15 working days after each meeting. Meeting minutes are supported by detailed advice on individual deliberate release applications which are produced once the assessment process has been completed. We advise on other specific issues when required. Our advice to Ministers is published on the web or is available on request from the secretariat, and for deliberate release applications it is also placed on the 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 available² and reproduced each year in our annual report (Appendix V). We also have transparent working practices that allow us to deal openly with the infrequent conflicts of interest that arise at ACRE meetings. 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. The

¹ www.defra.gov.uk/environment/acre/index.htm

² 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

Chair	Main Expertise
Professor Christopher Pollock	Plant breeding, plant physiology, agronomy
Deputy Chair	
Professor Jules Pretty	Sustainable agriculture & rural development
Members	
Professor Mark Bailey	Molecular biology, microbiology
Professor Jeff Bale	Entomology, ecology
Mr Edward Cross	Farming practice
Professor Jim Dunwell	Plant biotechnology
Dr Rosie Hails (from 9.10.06)	Pathogen population ecology, entomology
Professor Sue Hartley (until 31.8.06)	Ecology, entomology
Dr Penny Hirsch	Molecular biology, microbiology
Dr Phil Hulme	Biodiversity, conservation
Professor Keith Lindsey	Molecular biology
Mr Jim Orson	Farming practice, agronomy
Professor Andy Peters (from 9.10.06)	Clinical development and regulation of vaccines
Professor Mark Rees	Weed ecology, plant biology
Dr Jonathan Stoye	Virology

Ex-officio seat until August 2006

Professor Jim Dunwell (ex-officio from the Advisory Committee on Novel Foods and Processes until 31 August 2006. Appointed as an ACRE member in his own right 9 October 2006. The ex-officio arrangement was not renewed).

Sub-group on Soil Ecology

Chair

Dr Penny Hirsch

Members

Professor Mark Bailey

Professor Jeff Bale

Mr Edward Cross

Dr Philip Hulme

Mr Jim Orson

Professor Jules Pretty

Secretariat (Defra)

Dr Kate Morley

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

Professor Jules Pretty

Members

Professor Jeff Bale

Professor Philip Dale*

Dr Philip Hulme

Professor David Macdonald* (Advisory Committee on Pesticides representative)

Mr Jim Orson

Professor Christopher Pollock

Professor Mark Rees

Secretariat (Defra)

Dr Kathryn Morley (from 1 April 2006)

Dr Tanja Schuler (until 31 March 2006)

*Not ACRE members

APPENDIX IV

PEN PICTURES OF MEMBERS OF ACRE

Professor Christopher Pollock CBE (Chairman)

Institute of Grassland and Environmental Research, Aberystwyth

Expertise: Plant physiology, biochemistry and plant breeding

Professor Pollock is Research Director at the Institute of Grassland and Environmental Research (retiring in 2007). His research interests include plant primary metabolism and response to environmental stress. He currently chairs the HEFCE research assessment exercise sub-panel on agriculture, food and veterinary science and sits on the SEERAD Advisory Committee. *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 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.*

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, and a member of their Sustainable Agriculture and Rural Development Working Group. *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.*

Dr Rosemary Hails MBE

Centre for Ecology and Hydrology, Oxford

Expertise: Pathogen population ecology, entomology

Dr Hails is head of Pathogen Population Ecology at the Centre for Ecology and Hydrology, Oxford 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.*

Professor Susan Hartley (until August 2006)

School of Life Sciences, University of Sussex

Expertise: Ecology, entomology and statistics

Professor Hartley is a professor at the School of Life Sciences, University of Sussex. She has expertise in plant ecology specialising in plant-herbivore interactions and has a particular interest in plant defences against herbivory. She is the Vice President of the British Ecological Society and a Fellow of the Royal Entomological Society. *Reappointed to ACRE for 3 years from 1 September 2003. Stepped down from the committee on 31 August 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.*

Dr Phil Hulme

NERC Centre for Ecology and Hydrology, Banchory

Expertise: Ecology, biodiversity and conservation

Dr Hulme is 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 currently leads several international studies assessing the processes and impacts of invasive non-native plants. He is also involved in developing risk assessment tools for invasive species and vulnerable ecosystems. He is the Secretary of the British Ecological Society Invasive Species Specialist Group and an Editor of the Journal of Applied Ecology. *First appointed to ACRE for 3 years from 18 August 2002 and reappointed for a further 3 years from 18 August 2005.*

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. He is currently a member of the Multinational Arabidopsis Steering Committee, Chair of the Society for Experimental Biology Plant Section and 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 immuno-contraceptive 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. Professor Rees was awarded the Founders Prize of the British Ecological Society in 1997.

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 until it was wound up in December 2006. . *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

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 ¹ Centre for Ecology and Hydrology	Science Director (employee)	None	
			NERC, Defra, EU, BBSRC ²	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		
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, EU	Funding for research		

¹ National Environment Research Council

² Biotechnology and Biological Sciences Research Council

Dr Rosemary Hails	None		NERC Centre for Ecology and Hydrology	Employee	None	
			St Anne's College Oxford	Fellow		
			Oxford University	Senior Research Associate		
			Oxford Brookes University	Visiting Research Fellow		
			NERC, BBSRC, MRC, Defra, EU	Funding for research		
			Institute of Biology	Member of the Environment Committee		
Professor Susan Hartley (until August 2006)	None		University of Sussex	Employee	None	
			NERC, EU, British Ecological Society, Royal Society, Rio Tinto	Funding for research		
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	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	
			Genecom Bio	Consultant		
			University of Nottingham	Visiting professor		
			European Squirrel Initiative	Consultant		
Professor Christopher Pollock	None		University of Wales Aberystwyth	Honorary professor	None	
			Institute of Grassland and Environmental research	Employee – Research Director (retiring 2007)		
			University of Nottingham	Visiting professor		
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		
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 2006

December 2005 (*published 11 April 2006*)

Advice on the implications of results in a Defra-funded project: 'non-target effects of transgenic crop plants resistant to virus diseases'

February 2006 (*published February 2006*)

Final guidance on assessing the environmental impact of genetically modified crops on the soil environment

February 2006 (*published 22 June 2006*)

Advice on the implications of findings in a Defra-funded desk study: 'Technologies for biological containment of GM and non-GM crops'

March 2006 (*published 17 March 2006*)

Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems – Draft Sub-group report

March 2006 (*published 27 March 2006*)

Further advice on a notification for marketing of hybrid maize (NK603 X MON810) - Monsanto Europe S.A. - Ref C/GB/02/M3/3

April 2006 (*published 3 May 2006*)

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

May 2006 (*published 24 July 2006*)

General advice on notifications for import and marketing of GM maize grain

November 2006 (*published 1 December 2006*)

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

November 2006 (*published 1 December 2006*)

Advice on an application for a five year programme of work to release potato lines genetically modified for resistance to *Phytophthora infestans* - ref 06/R42/01