

**ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT
MINUTES OF THE 133RD MEETING OF ACRE AT NOBEL HOUSE, LONDON,
THURSDAY, 4TH AUGUST 2011**

Present:

Prof Chris Pollock (chairman)
Prof Rosemary Hails
Prof Jim Dunwell
Mr Jim Orson
Prof Keith Lindsey
Prof David Hopkins
Dr Ieuan Joyce
Prof Les Firbank
Dr Mike Bonsall
Prof Kathy Bamford
Prof James Bullock

Assessors:

Mr Chris Chesterton	NE
Dr Jonathan Davey	SASA
Mr Anthony Hicks	WAG
Dr Simon Warne	HSE
Mrs Sarah Hugo	Fera

Defra:

Dr L Ball (secretary)
Dr K Bainbridge
Ms S Brown
Dr S Popple
Mr M Rowe
Mr D Sherlock

Apologies were received from Prof Bale and Prof Peters.

The chairman welcomed Prof David Hopkins who was attending his first full meeting of the committee since his appointment, although he has already served on the Post-market Environmental Monitoring Sub-group. He is Professor of Environmental Biology and Head of the School of Life Sciences at Heriot-Watt University, Edinburgh. He is a specialist in soil biology and biochemistry with major interests in nutrient cycling, soil management in agricultural systems, and the decomposition of residues from plants with genetic modifications.

The chairman also welcomed Mike Rowe as the new head of the Defra GM team. Mike Rowe has previously served as Senior Private Secretary to various ministers and has worked on Common Agricultural Policy reform, public bodies reform and rural development policy.

1. Minutes of the 132nd meeting, 17th March 2011

ACRE/11/M2

The minutes were agreed with one amendment.

2. Matters arising

2.1 Government policy on GMOs

ACRE/11/INF12

The Government's policy on GMOs, confirmed in June, was tabled. Members noted that it continued to emphasise the importance of scientific evidence as a basis for GM policy.

2.2 Votes on food and feed applications

Since the March meeting Member States have voted on two applications for import and use as food and feed: GHB 614 cotton (ref. EFSA/GMO/NL/2008/51) and MON89034 x MON 88017 maize (ref. EFSA/GMO/NL/2007/39). As there was no qualified majority at standing committee or the Council, the Commission has issued decisions based on EFSA's opinions.

2.3 National decision-making proposal

Mike Rowe updated members on the state of play on the Commission's national decision-making proposal that would allow Member States the option to ban cultivation of GM crops for various reasons. No common position was reached at the June Council. The UK has concerns with the proposal on the grounds of questionable legality, incompatibility with the Single Market and the move away from science-based decision making. Amendments voted through by the European Parliament have also caused concern. The Hungarian Presidency was unable to secure a deal so this has passed to the Polish presidency. ACRE shared the UK Government's concerns with the move away from evidence-based policy making and offered its support for the UK's position in ongoing discussions.

3. Matters agreed by circulation

3.1 Food and feed applications – import and processing

Since the March meeting, the committee has issued advice on an application to import A5547-127 soybean (ref. EFSA/GMO/NL/2008/52). ACRE agreed with EFSA's opinion, which was that this GMO does not pose a greater risk to human health or the environment in the context of its proposed uses (which excludes cultivation).

3.2 Applications to cultivate GMOs

ACRE has agreed preliminary advice on 3 applications to cultivate GMOs. These were for MIR604 maize (ref. EFSA/GMO/UK/2010/83) and 2 GM 'starch potatoes': Avebe's AV43-6 –G7 (ref. EFSA/GMO/NL/2009/69) and BASF's AM04-1020 (ref. EFSA/GMO/SE/2010/88). The first two applications were discussed at ACRE's meeting in March; BASF's starch potato was dealt with by correspondence. ACRE did not identify a risk to human health or the environment from the information provided in these applications. However, in each case it requested further information or clarification

4. Update on notifications for authorisation under the GM Food and Feed Regulation (EC) No. 1829/2003 **ACRE/11/P11**

The secretariat informed ACRE that four new applications had been submitted under the GM Food and Feed Regulation since ACRE's meeting in March 2011. All four applications are for import and processing, food and feed use (excluding cultivation). These are GHB614 x LLcotton25 x MON15985 + LLcotton25 x MON15985 cotton (ref. EFSA/GMO/NL/11/94), GHB119 cotton (ref. EFSA/GMO/NL/11/96), T304-40 cotton (EFSA/GMO/NL/11/97) and 5307 maize (ref. EFSA/GMO/DE/11/95).

ACRE was also informed that there have been two new EFSA opinions on applications to import GMOs for food and feed use. These are for 2 GM soybeans: MON87701 and 356043. ACRE will be consulted on these opinions by circulation.

ACRE discussed amending its advice on notifications for import and processing of GM crops that have a limited potential to flower and grow outside of agricultural conditions in the UK. ACRE considered that this advice should address monitoring for spillage in areas of the EU where establishment of feral plants is likely. ACRE noted that such plants would not be expected to persist for more than one year because of the biology of the crop but considered it appropriate to monitor for unexpected effects. Unless such effects were detected, the committee concluded that it was not appropriate to control the feral plants. ACRE agreed to revise the text in its advice to reflect this view. The committee will discuss and agree the text by email correspondence.

Action: ACRE to agree additional text in its advice to address monitoring of feral plants in areas of the EU where spilled seed is likely to establish – by email correspondence.

5. Application under Part B of Directive 2001/18 (EC) to trial a GM wheat that is repellent to aphids –ref. 11/R8/01 **ACRE/11/P12**

The chair acknowledged the following potential conflicts of interest and noted that the associations declared would not exclude these members from discussions. The honorary fellows would not participate in any voting should the Committee be unable to reach consensus.

Les Firbank – former Rothamsted employee
Keith Lindsey – former Rothamsted employee and BBSRC Council member
Jim Dunwell and David Hopkins - both Rothamsted honorary fellows
Chris Pollock - BBSRC Council member

ACRE considered an application from Rothamsted for a 2 year field trial of GM wheat at Rothamsted Research, Harpenden, UK. The trial is to test whether the GM wheat plants under field conditions are better able to resist aphid attack by expression of a natural alarm pheromone. Plant and seed material arising from the trial will not enter the food and feed chain. The modified wheat will emit the (*E*)- β -farnesene pheromone which is naturally emitted as a warning signal by aphids under attack and will attract aphid predators into the area.

Two GM lines are intended for release. Both have been transformed with a (*E*)- β -farnesene synthase (EBFS) gene. The line 2803R6P1 has also been transformed with an EBFS and farnesyl diphosphate synthase (FPPS) gene. The FPPS gene when expressed will increase the substrate pool available for EBF synthase. Both gene sequences are synthetic and optimised for expression in wheat. The EBFS gene has similarity to that found in peppermint and the FPPS gene to a version found in cow. Both genes are under the control of the maize Ubi1 promoter, which is known to give constitutive expression in wheat. ACRE advised that the use of synthetic genes was common and within accepted practice.

Plant cells were transformed using microprojectile bombardment with separate plasmid vectors. The vector used carries the antibiotic resistant marker gene *nptI* for selection in bacteria and the *pat* gene that confers resistance to glufosinate ammonium herbicides. The herbicide tolerance trait was used for the production of the transgenic plants in the laboratory and will not be utilised in the field trials. The applicant has assumed that the entire vector backbone sequence has been inserted into the genome of the transformed plants.

At this meeting, ACRE assessed the application and provided comments on the molecular characterisation of the GM event, the environmental risk assessment (ERA) and the field trial design. The committee also considered the comments received in response to the public consultation. The public consultation closes on 19 August and ACRE will provide advice on any further representations by email correspondence.

Molecular characterisation

ACRE noted that the applicant had not conducted a thorough molecular characterisation; instead the applicant had adopted a precautionary approach in assuming that the entire plasmid had been inserted into the wheat genome. ACRE did not request further data on the molecular characterisation of the GMO but concluded that a more considered assessment of some of the associated risks was required in the environmental risk assessment.

Environmental risk assessment

With regard to the issue of horizontal gene transfer (HGT) from plants to soil microorganisms, ACRE considered whether the applicant had characterised the risk

effectively and considered the worst case scenario in the unlikely event that HGT would occur.

The committee discussed the likelihood that plasmid DNA from the GMO would transfer to *Agrobacterium* in the soil and agreed that the applicant should provide further information that considers the risks to plants if HGT into wild type *Agrobacterium* were to occur.

The committee discussed the use of the *nptI* marker gene and its existing prevalence in the environment. ACRE agreed with the applicant that the *nptI* gene is derived from bacteria, which are widespread in the environment, but considered that the applicants had not presented a full analysis of the risks in the environmental risk assessment and requested further information.

ACRE noted that the PAT enzyme produced by the GM wheat is expressed in species of bacteria found in UK soils. However, the *pat* gene in the GM wheat has been optimised for expression in wheat cells, which compromises its potential for expression in bacterial cells (if HGT of an intact transgene were to occur).

ACRE agreed that the HGT of the *EBF* and *FPPS* genes into soil microorganisms is extremely unlikely. Even if it is assumed that this could occur, soil bacteria would not be capable of producing the EBF pheromone.

In considering the risks posed to human health and the environment by the pheromone produced by the GM wheat plants, ACRE advised that the applicant should be requested to provide further information on the levels of the (*E*)- β -farnesene pheromone naturally emitted from plants and further information on the levels of (*E*)- β -farnesene produced in the semiochemical trials. This would provide context for the environmental risk assessment.

ACRE discussed the risk of the EBF pheromone to non target organisms. The committee agreed that the changes in behaviour that the EBF pheromone will instigate are highly specific to aphids and their natural predators and that the risk of EBF eliciting a change in non target organisms is negligible. ACRE discussed the wider occurrence of EBF in plants generally and agreed that the pheromone is not toxic but acts as a repellent to aphids.

Field trial design/ risk management

ACRE discussed the potential for birds to disperse seed outside of the trial area, potentially over long distances. ACRE requested further information on the measures the applicant proposes to put in place to keep large birds off the site.

ACRE discussed the proposed measures for volunteer management and recommended that shallow light tillage would be preferable with regard to volunteer management compared to leaving stubble. The Committee recommended that volunteer management measures should be initiated in the autumn rather than waiting until the following spring and that any volunteers are destroyed before the emergence of the inflorescence.

The committee discussed the proposed mitigation measures to prevent cross pollination and considered that these are appropriate as wheat is largely self pollinating and very short separation distances are typically used in commercial wheat seed production. ACRE considered that the applicant had not clearly distinguished between the elements of the trial design that are intended to manage the risk of cross-pollination occurring and those that are part of the experimental design. The committee recommended that further information should be provided to clarify this point.

The management of couch was discussed by the committee. ACRE recommends that couch is managed throughout the trial period and for a 12 month period following the trial using application of a glyphosate herbicide prior to flowering.

ACRE discussed the measures proposed to mitigate the unintentional transfer of material from the trial site. The committee recommended that GM plots were harvested first followed by thorough cleaning on site of the combine before the harvest of the non GM plots and again followed by onsite cleaning of the combine. The Committee noted that the unlicensed burning of straw and stubble in the field is illegal and that alternative steps for disposal of waste including material from the non GM plots, should be specified in the application.

Action: *Secretariat to request additional information from applicant.*

6. The environmental risk assessment of GM stacked events – an ecological assessment of the risks posed by plants containing multiple insecticidal traits **ACRE/11/P13**

This item was included as part of a wider discussion on proposed EU guidance on the environmental risk assessment (ERA) of GM plants.

Previously ACRE has provided a clear view on the general approach it recommends when tackling the ERA of stacked events (i.e. that crossing lines to combine traits does not pose a risk *per se*. However, there may be potential cases of pleiotropy that need to be addressed on a case by case basis). ACRE was requested to consider how applicants should undertake an assessment of the potential impact on target and non-target organisms in GM plants in which insecticidal proteins have been stacked. There have been a number of publications discussing whether an assessment is necessary. A paper by Raybould *et al* (2010)¹ proposes a practical solution and ACRE was asked to consider this approach.

ACRE highlighted the fact that there are established approaches for assessing multiple toxins in ecotoxicological assessments. The committee considered that the approach taken should be directed by problem formulation and hypothesis testing (the null hypothesis being that the effects of the individual toxins are independent). It considered that the assessment should be underpinned by a discussion on the mode

¹ ¹ A. Raybould, G. Graser, K. Hill and K. Ward (2010). Ecological risk assessments for transgenic crops with combined insect-resistance traits: the example of Bt11 x MIR604 maize. *Journal of Applied Entomology* **135** (8).

of action of (e.g.) insecticidal proteins. ACRE advised that subsequently a decision-tree approach should be adopted. If an evidence-based analysis (based on the mode of action and exposure to non-target organisms in the field) suggests a divergence from the null hypothesis, experimental data (from the laboratory or field) should be provided. ACRE considered this systematic approach would aid in the identification of important comparators. The committee noted that the consequences of segregation of GM events in seed should also be considered on a case by case basis.

7. The role of refugia: is resistance an environmental (rather than economic) risk? **ACRE/11/P15**

The insect resistance management (IRM) plan submitted in applications for Bt crops has been developed to reduce the likelihood of field resistance evolving in pest insect populations. The plan was devised in 2003 by an EU working group (based on the approach adopted in the USA). In its responses to EFSA consultations on applications to cultivate Bt maize events, ACRE routinely comments on the IRM plan submitted. In the light of the discussion at ACRE March meeting, a member of the committee suggested a more systematic review of the IRM plan taking into account developments over the last 8 years.

At this meeting ACRE discussed whether this would be appropriate. In coming to its conclusions the committee considered (i) whether the evolution of insect resistance poses an environmental (in addition to an economic) risk and (ii) whether it would be more appropriate for other bodies to act on this initiative e.g. the applicants or the EFSA GMO Panel - noting that the pests targeted by the Bt crops in the current regulatory pipeline are not a problem in the UK and as such, the traits are not valuable to UK farmers.

ACRE highlighted the need to take measures to prevent or to slow down the erosion of biological control measures such as the adoption of Bt crops. However, it did not identify environmental risks consequent with the loss of this trait. ACRE considered that the evolution of IRM plans to account for new evidence (including that resulting from experience) and new GMOs (such as those in which insecticidal proteins have been stacked) should be considered jointly by applicants, scientific advisory bodies and regulators. It noted the advances in IRM strategies in the USA and advised that these should be taken into account when discussing IRM in the EU.

8. Update on the use of a classical biological control agent in the control of Japanese knotweed

In 2010 Defra ministers agreed the release of a non-native insect (a psyllid, *Aphalara itadori*) to control Japanese knotweed. The advice provided by ACRE was important in reaching this decision and in attaching conditions for the release of this biocontrol agent. A licence was issued for phase 1 releases in March 2010. ACRE was provided with an update of the project.

A condition of the licence is the implementation of a post-release monitoring plan designed to address areas of uncertainty in the science. The purpose of this plan is to establish: (i) whether there are any unanticipated impacts on non-target flora or fauna, (ii) the overwintering habitat of the psyllid, and (iii) the psyllid's efficacy in controlling the knotweed.

Early trials suffered from low survival rates, but subsequent phase I releases have shown that the psyllid has a specific preference for Japanese knotweed. There is currently no evidence of any adverse impacts on invertebrates in the receiving environment. There is little information on the psyllid's overwintering habitat, but winter survival was witnessed at one site. Phase II releases, which are subject to less intensive monitoring, were approved in March 2011 and are proceeding at eight sites across England and Wales.

Fera anticipates further applications for classical biological control agents and will refer cases to ACRE for advice as appropriate

9. Items for information

9.1 Feral genetically modified herbicide tolerant oilseed rape from seed import spills: are concerns scientifically justified? ACRE/11/INF10

Members noted this paper.

9.2 Update from sub-group on post-market environmental monitoring ACRE/11/INF11

The sub-group had met five times including its meeting on 4th August and had been working on advice on implementing post-market monitoring in the UK. It expected to submit its draft final report to the October ACRE meeting.

9.3 Proposed dates for ACRE meetings in 2012 ACRE/11/INF13

Members agreed to confirm availability for the proposed 2012 dates by 12th August.

10. Any other business

None

11. Date and time of the next meeting

The main meeting scheduled for 8th September will not be held although a post-market environmental monitoring sub-group meeting may still be required on that day. The next main meeting will be held on Thursday 13th October at 10.30am in Nobel House.

**ACRE Secretariat
August 2011.**