

**ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT  
MINUTES OF THE 132<sup>ND</sup> MEETING OF ACRE AT NOBEL HOUSE, LONDON,  
THURSDAY, 17<sup>TH</sup> MARCH 2011**

**Present:**

Prof Rosemary Hails (Chair)  
Prof Jim Dunwell  
Mr Jim Orson  
Prof Keith Lindsey  
Dr Ieuan Joyce  
Prof Les Firbank  
Dr Mike Bonsall  
Prof Kathy Bamford  
Prof Jeff Bale

**Assessors:**

Dr Chris Chesterton           NE  
Dr Jonathan Davey           SASA

**Defra:**

Dr K Bainbridge (secretary)  
Ms G Townsend  
Ms S Brown  
Dr G Griffiths  
Mr D Sherlock

Apologies were received from Prof Pollock, Prof Bullock and Prof Peters.

**1. Minutes of the 131<sup>st</sup> meeting, 10<sup>th</sup> February 2011**

**ACRE/11/M1**

The minutes were agreed with one amendment.

**2. Matters arising**

**2.1 Votes on applications**

Votes were taken at the Standing Committee on 8<sup>th</sup>/9<sup>th</sup> February on three applications to import GM maize and use it for food and feed (excluding cultivation). These were for Bt11 x MIR604 (ref. EFSA/GMO/UK/2007/50), Bt11 x MIR604 x GA21 (ref. EFSA/GMO/UK/2008/56) and MIR604 x GA21 (ref. EFSA/GMO/UK/2007/48). ACRE's advice was that the marketing of these GMOs was unlikely to pose a greater risk to the environment or to human health compared with their non-GM counterparts in the context of their proposed use. No qualified majority was reached and these applications will now pass to the Council for a vote.

There was an Agriculture Council meeting taking place on the day of this ACRE meeting and votes were expected on the applications to import and use as food and feed of GHB614 cotton (ref. EFSA/GMO/NL/2008/51) and MON89034 x MON88017 maize (ref. EFSA/GMO/NL/2007/39) and the application for the renewal of 1507 maize for import and use as feed. ACRE's advice was that the marketing of these GMOs was unlikely to pose a greater risk to the environment or to human health compared with their non-GM counterparts in the context of their proposed use.

## **2.2 Low-level GM presence**

ACRE was informed that the UK had voted at Standing Committee on 22<sup>nd</sup> February in favour of a proposal to harmonise the treatment of low level presence of GMOs unauthorised in the EU. There was a qualified majority in favour of allowing 0.1% presence for GM events approved in countries outside the EU and zero tolerance for events not approved anywhere. This has been passed by the European Parliament and is expected to come into effect about June 2011.

## **3. Matters agreed by circulation**

### **3.1 Cibus proposal to develop herbicide tolerant oilseed rape using oligo-directed site mutagenesis**

Following discussions at the February ACRE meeting, the committee finalised its advice by e-mail on the application from Cibus to develop herbicide tolerant oilseed rape developed by Cibus using oligo-directed site mutagenesis. The committee concluded that the oligo-directed site mutagenesis technique used by Cibus was form of mutagenesis that does not involve the use of recombinant nucleic acid molecules and could therefore be excluded from the GMO Deliberate Release legislation in accordance with Annex 1B of Directive 2001/18/EC. The Competent Authority is formulating its response to the company based on this advice from ACRE along with legal advice. The secretariat will let ACRE know once this is finalised.

### **3.2 EFSA report on the environmental risk assessment of GM animals**

ACRE members commented on the report 'Defining environmental risk assessment criteria for GM mammals and birds to be placed on the EU market.' This report was commissioned by EFSA to inform its work in producing guidance on the environmental risk assessment of GM animals. The consensus was that whilst there were many parallels to the risk assessment for GM insects, there were also some differences which would be useful to consider. The committee agreed that the contractor, Fera, should present the outcomes of the report at a future ACRE meeting and that it would be useful to wait for the EFSA guidance before giving further consideration to this topic.

### **3.3 Report of the GM insects evidence gathering workshop**

The meeting report from the GM insects evidence gathering workshop was finalised by e-mail correspondence and was published on the ACRE website

#### **4. Update on notifications for authorisation under the GM Food and Feed Regulation (EC) No. 1829/2003** **ACRE/11/P2**

The secretariat informed ACRE that three new applications had been submitted under the GM Food and Feed Regulation since ACRE's meeting in February 2011. All three applications are for import and processing, food and feed use (excluding cultivation). These are DAS-68416-4 soybean (ref. EFSA/GMO/NL/2011/91), MON87708 soybean (ref. EFSA/GMO/NL/2011/93), and 1507 x 59122 x MON810 x NK603 maize (ref. EFSA/GMO/NL/2011/92).

ACRE was also informed that three applications for import and processing, food and feed use (excluding cultivation) had also been validated and that the full dossiers were now available. These are GHB614 x LL Cotton 25 cotton (ref. EFSA/GMO/NL/2010/77), NK603 x T25 maize (ref. EFSA/GMO/NL/2010/80) and MIR162 maize (EFSA/GMO/DE/2010/82).

ACRE has previously concluded that it would not consider applications to market GM crops that will result in negligible environmental exposure in detail prior to the publication of the associated EFSA's opinion. ACRE considered that the applications to import the GM soybean, maize and cotton events listed above fell into this category and did not request further information at this time.

#### **5. Application from Avebe under Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed to cultivate AV43-6-G7 potato in the EU - ref. EFSA/GMO/NL/2009/69** **ACRE/11/P8**

AVEBE have submitted an application for the marketing of AV43-6-G7 starch potato for cultivation under contract in Germany and the Netherlands. The application includes food and feed use to allow of bi-products from the starch processing industry to be used for animal feed and to ensure safety should accidental entry into the food chain occur. The potato has been genetically modified using an RNAi approach to target the GBSSI (Granule Bound Starch Synthase 1) enzyme. As a result the potato produces little/no amylose starch. Amylopectin starch, the form favoured by the starch industry, is produced.

The GBSSI RNAi construct was inserted into the starch potato cultivar Karnico using *Agrobacterium*-mediated transformation. The T-DNA does not contain an antibiotic resistance marker. At this meeting, ACRE assessed the cultivation dossier and provided comment on the molecular characterisation of the GM event, the environmental risk assessment (ERA) and post market environmental monitoring plan (PMEM).

##### *Molecular characterisation*

ACRE was content with the molecular characterisation of the GMO provided. The committee considered that sufficient evidence was provided to demonstrate a single, stable insertion. The committee noted that the T-DNA insertion was truncated, but were content that a homology search for Open Reading Frames did not show any significant homology with other toxins or allergenic proteins. An error on page 64 of Appendix 1 was noted, where the applicant had incorrectly referred to introns instead

of exons. The committee did not consider that the compositional analysis raised any issues for the environmental risk assessment and noted that alkaloid levels were lower in the AV43-6-G7 potatoes.

#### *Environmental risk assessment*

In general ACRE considered that sufficient information had been presented in the dossier to assess the risks posed by commercial cultivation of this GM starch potato. However, the committee discussed a number of specific points in detail and made recommendations for modifications to the application.

The committee discussed the risk to non target organisms. Members noted the absence of evidence regarding the potential impact of the above ground material on non-target organisms. The committee noted that the analysis of risks to non-target organisms relies heavily on the results of field trials which considered only pests of economic importance. ACRE recommended that the applicants should provide a more detailed consideration of the possible impacts on non-target organisms, making reference to specific functional groups.

ACRE agreed that the environmental risk assessment should provide a more detailed consideration of the issue of potato volunteers. Members recommended that details of the plans for monitoring for and managing volunteers should be provided by the applicants.

#### *Post-market environmental monitoring*

The committee considered the proposed Environmental Monitoring Plan which relies on the use of the "Optimeel" questionnaire. Members agreed that whilst the questionnaire provided a basis for monitoring, further modifications would be needed increase its suitability for monitoring for unanticipated effects which could result from the cultivation of a GM crop. ACRE noted that the harmonised EuropaBio questionnaire provides a more informative system for monitoring. Members suggested that the questions are restructured to prompt farmers to identify observed increases/decreases rather than the unspecific request to note whether anything unexpected had occurred. ACRE also suggested that it would be relevant to list defoliation and damage from root feeders as examples of potential crop damage. In addition the committee requested that further information should be provided as to how the farmer would inspect the crop.

*Action: secretariat to draft and circulate preliminary advice for ACRE's consideration*

### **6. Application from Syngenta under Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed to cultivate MIR604 maize in the EU - ref. EFSA/GMO/UK/2010/83 ACRE/11/P9**

ACRE considered the application for cultivation of insect resistant MIR604 maize in the EU. MIR604 produces a modified Cry3A protein, which confers resistance to the Western corn root worm (WCRW), and the phosphomannose isomerase enzyme, used as a selectable marker. This GMO received EU approval for import and processing, food and feed use in 2009. At this meeting, ACRE assessed the current MIR604 cultivation dossier and provided comment on the molecular characterisation

of the GM event, the environmental risk assessment (ERA) and post market environmental monitoring plan (PMEM).

#### *Molecular characterisation*

ACRE was content with the molecular characterisation of the GMO provided in the document. The committee considered that sufficient evidence was provided to demonstrate a single insertion, at one site in the genome and without the introduction of flanking vector sequence.

#### *Environmental risk assessment*

In general ACRE considered that sufficient information had been presented in the dossier to thoroughly assess the risks posed by commercial cultivation of this GMO. However, the committee discussed a number of specific points in detail and made recommendations for modifications to the application.

The committee noted that further information on the design of the field trials could have been provided. Details of only two treatments and three replicates are provided. ACRE recommended that the applicants should provide information on the total number of treatments and state the power of the trials.

ACRE discussed the insect resistance management (IRM) plan proposed by the applicants. The committee considered that the applicants had conducted a thorough analysis and that the plan would be suitable for delaying development of resistance to the mCry3A protein in populations of the target pest WCRW. The applicants recommend that a 20% refuge area of maize, which is not resistant to WCRW, should be planted by farmers cultivating an area of over 5ha of MIR604. ACRE commented that it was not clear whether this referred to 5ha on a per field or per farm basis. The committee also suggested that the applicants might provide further information as to how they reached their recommendation for a 20% refuge and on the sensitivity of the analysis and levels of uncertainty. ACRE noted that the applicants had not modelled the dynamics of WCRW populations in the refuge areas. Despite these limitations, the committee considered that the IRM plan proposed by the applicants was fit for purpose.

ACRE discussed the information provided on the risks to non-target organisms. ACRE considered that the applicants had conducted a thorough analysis considering a wide range of non-target organisms. The committee commented, however, that it would have preferred to see a greater focus on non-target organisms which were most likely to be affected by the mCry3A protein. In particular ACRE considered that the applicants should provide details of *Chrysomelidae* found immediately around maize fields in field borders and hedgerows. ACRE accepted the applicants analysis that MIR604 pollen contained low levels of the mCry3A protein. The committee, however, considered that the applicants should provide information on exposure to MIR604 plant material and include one *Chrysomelid* representative in Tier One laboratory studies, which could include dusting the host plant with MIR604 pollen. *Chrysomelidae* species would be the most likely non-target organism to be adversely effected by mCry3A. ACRE did not consider that further studies on mammals, birds or fish were necessary due to the mode of action of the Cry toxin, receptors for which are only found in the insect gut. The committee requested further information on the correction used in the analysis of the data presented on *Coccinella septempunctata*.

The committee noted that the resistance of MIR604 to WCRW might encourage farmers to grow maize more often in the rotation and that the applicants do not discuss the implications of this.

#### *Post-market environmental monitoring*

A key part of the post market environmental monitoring plan presented in the dossier is the gathering of data from farmers. ACRE considered that the farmer questionnaire was generally fit for purpose. The committee did, however, consider that the options for the response to some questions were unnecessarily basic and uninformative. Examples of this were the yes/no options for soil tillage practices and application of manure. The committee also considered that questions on the use of insecticides and the timing of application should be included. ACRE did not consider that more detailed questions on biodiversity could usefully be included in the farmer questionnaire.

ACRE debated whether case-specific monitoring of *Chrysomelidae* species should be required. The committee concluded that this would depend on the extent of information provided in the environmental risk assessment on the hazard and exposure of *Chrysomelidae* to mCry3A.

ACRE welcomed the information provided by the applicants on the use of existing monitoring networks for general surveillance. The committee emphasised the need for the applicant to immediately report any suspicion that unanticipated adverse effects may have occurred to the competent authority.

*Action: secretariat to draft and circulate preliminary advice for ACRE's consideration*

## **7. ACRE annual report 2010**

**ACRE/11/P10**

ACRE was asked to comment on the structure and content of the draft 2010 annual report, focussing particularly on the proposed work plan for 2011. Members were also asked to provide any updates required to their biographies or the register of members' interests. Discussing the work plan, ACRE proposed to follow up the workshop on GM insects with advice, linked to the work that EFSA was doing in this area but setting out its own thoughts. ACRE will also review when complete the desk study Defra is about to commission on advances in the area of GM medicinal products and the challenges new products would pose to the current regulatory system. This had been flagged up as a possible subject for an evidence-gathering workshop.

*Action: report to be circulated for any further comments prior to publication*

## **8. Items for information**

### **8.1 Harmonization of regulations for invertebrate biocontrol agents in Europe: progress, problems and solutions**

**ACRE/11 INF8**

Members noted this report introduced by Prof Bale, published in the Journal of Applied Entomology. The report explained there was no Directive to regulate non-native invertebrate biocontrol agents, regulation was at the discretion of individual Member States and none of them required information on the microbial symbiont content of candidate species. There were some issues here of which ACRE would need to be aware.

**8.2 COGEM comments on the EFSA guidance on the environmental risk assessment of GM plants and on the scientific opinion on the assessment of potential impacts of GM plants on NTOs** **ACRE/11/INF9**

Members noted the comments from the Dutch advisory committee COGEM on the EFSA guidance.

**9. Any other business**

None

**10. Date and time of the next meeting**

May 5<sup>th</sup>, 10.30 am in Nobel House.

**ACRE Secretariat  
March 2011**