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ACRE meeting. ACRE/12/M1

**ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT  
MINUTES OF THE 135<sup>TH</sup> MEETING OF ACRE AT NOBEL HOUSE, LONDON,  
THURSDAY, 9<sup>TH</sup> FEBRUARY 2012**

**Present:**

Prof Chris Pollock (chairman)  
Prof Jim Dunwell  
Prof Keith Lindsey  
Prof James Bullock  
Prof David Hopkins  
Prof Rosie Hails  
Dr Ieuan Joyce  
Prof Les Firbank

**Assessors:**

Dr Jonathan Davey	SASA
Mr Chris Chesterton	NE
Mr Anthony Hicks	WG

**Defra:**

Dr L Ball (secretary)  
Ms S Brown  
Dr P Costigan  
Dr S Popple  
Dr K Bainbridge  
Mr D Sherlock

Apologies were received from Prof Peters, Mr Orson, Prof Bale, Prof Bamford and Dr Bonsall.

The Committee welcomed Dr Kath Bainbridge back from her career break and noted Sarah Brown was leaving to work as a seconded expert in the European Commission.

**1. Minutes of the 134<sup>th</sup> meeting, 1<sup>st</sup> December 2011**

**ACRE/11/M4**

The minutes were agreed with one amendment.

**2. Matters arising**

**2.1 Votes on food and feed applications**

Since the December ACRE meeting, Member States had voted on applications for 356043 soya beans (EFSA-GMO-UK-2007-43) and MON87701 soya beans (EFSA-

GMO-BE-2010-79) to import and use as food and feed, excluding cultivation. As there was no qualified majority, the applications were referred to the new Appeals Committee which considered them on 17 January. A5547-127 soya bean (EFSA-GMO-NL-2008-52) and a renewal of 40-3-2 soya bean (EFSA-GMO-RX-40-3-2) were also considered at the same meeting. The Appeals Committee failed to deliver an opinion on all four authorisations, with the predominant position being in favour of each of these. The College of Commissioners will now decide how to proceed, with adoption a formality.

## **2.2 Decisions on food and feed applications**

Commission Decisions were issued on 22 December authorising the import and processing of 3 types of maize and 1 of cotton, excluding cultivation. The maize events were Bt11 x MIR604 x GA21 (EFSA-GMO-UK-2008-56), Bt11 x MIR604 (EFSA-GMO-UK-2007-50) and MIR604 x GA21 (EFSA-GMO-UK-2007-48), and the cotton was 281-24-236 x 3006-210-23 (EFSA-GMO-NL-2005-16).

## **2.3 Diamondback moths**

On the basis of legal advice and scientific advice received from ACRE (and SACGM), Defra and HSE have sent a joint letter to Oxitec Ltd with guidance on the regulatory controls likely to be associated with its proposal to trial a 'genetically sterile' diamondback moth.

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

### **3.1 T25 maize**

ACRE agreed its advice on Bayer CropScience's application to cultivate T25 maize and this was sent to EFSA in December

### **3.2 Application for a trial of GM vaccines against prostate cancer – ref. 11/R44/01 and 11/R44/01/W**

ACRE finalised its advice on an application to trial GM vaccines against prostate cancer (PROSTVAC V/F). Separate consents have been issued for England and Wales.

### **3.3 Application to market a veterinary medicinal product under Regulation (EC) No. 726/2004**

ACRE advised on an application to market a veterinary medicinal product and this was sent to the UK's Veterinary Medicines Directorate

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

**ACRE/12/P1**

ACRE was informed that there had been one new application submitted since ACRE's last update. This is a GM potato with resistance to late blight, PH05-026-0048 for uses including cultivation (EFSA-GMO-.UK-2011-102). Once this application has been validated by EFSA, ACRE will be asked to consider the application

One application (that is relevant to ACRE) has been validated by EFSA since the last ACRE meeting. This is for a GM cotton, GHB119, that is insect-resistant and herbicide tolerant (EFSA-GMO-NL-2011-96). The application is for food and feed, import and processing but excludes cultivation. As ACRE did not ask to see this application when it was notified, the committee's advice will be sought once EFSA's opinion has been published.

#### **5. Draft final report of ACRE's Post-market Environmental Monitoring Sub-group**

**ACRE/12/P2**

Professor Rosie Hails gave a presentation to update ACRE on the work of the subgroup on Post Market Environmental Monitoring (PMEM). This group, chaired by Professor Hails, was established in March 2011 to provide scientific advice on options for implementing PMEM of GM crops. ACRE discussed a draft of the final report. The committee was broadly content with the report's recommendations, but agreed to return further comments on this draft by e-mail. The committee was also informed of a recently commissioned research project<sup>1</sup>, which will look in more detail at the power of existing surveillance networks to detect change. The results of this project are expected to be available in April of this year.

*Action: Secretariat to circulate an electronic copy of an updated version of the draft PMEM report for ACRE to comment on.*

#### **6. EFSA Scientific Opinion on an application under Regulation (EC) No. 1829/2003 for authorisation to cultivate MON88017 maize – ref. EFSA-GMO-CZ-2008-54**

**ACRE/12/P3**

EFSA had published its scientific opinion on two GM maize events – MON88017 and GA21 that have been notified for cultivation, import, processing and use as food and feed in the EU. The next formal step in the regulatory process is for Member States to vote on whether to authorise these GMOs. The secretariat informed ACRE that currently, the EU Commission is not bringing forward draft decisions on applications that include cultivation in their scope. However, ACRE was asked to begin formulating its advice on these two applications.

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<sup>1</sup> Determining and increasing the sensitivity of existing environmental surveillance monitoring networks to detect unanticipated effects that may occur in the environment in response to the cultivation of genetically modified crops. Defra project CB0304. <http://randd.defra.gov.uk/>

MON88017 maize contains a modified Cry3Bb1 protein that confers tolerance to certain coleopteran insect pests, including members of the corn rootworm complex. This includes the Western corn rootworm, which is a pest in some parts of the EU. This GMO is also tolerant to glyphosate herbicides (it expresses a modified version of the CP4 EPSPS protein).

At this meeting, ACRE was requested to review its comments/ concerns when this application was submitted in 2008 in the light of the further information provided by the applicant (Monsanto) and in response to EFSA's opinion.

Previously, ACRE considered that Monsanto had not investigated the hazard to non-target chrysomelids (leaf beetles) satisfactorily. EFSA and the competent authority leading on the assessment of this application (Belgium) requested more information from the company on this aspect and on the potential impact on non-target organisms more generally. ACRE noted that EFSA had carried a very detailed consideration in its opinion. ACRE agreed with EFSA's conclusion that 'the risk to valued chrysomelid species is likely to be minimal'.

ACRE also discussed the advice of COGEM, its Dutch counterpart. COGEM has concluded that Monsanto has not demonstrated that the risk to non-target arthropods is negligible. This is because Monsanto has used MON863 maize or Cry3Bb1 protein from MON863 maize in its studies on non-target organisms (in addition to studies with MON88017 maize). The Cry 3Bb1 protein in MON863 maize is a variant of that produced by MON88017 maize (there is a change in one amino acid). EFSA considers that Monsanto has demonstrated the functional equivalence of these proteins, whereas COGEM has recommended that further studies on susceptible insects are required. ACRE agreed with EFSA's conclusion that the evidence demonstrates that the Cry3Bb1 protein produced by MON88017 is unlikely to harm populations of non-target arthropods.

With respect to the potential for herbicide regimes used in association with this GMO to have greater indirect effects on biodiversity compared with conventional systems, EFSA has advised that the company recommend stewardship schemes to farmers, the implementation and efficacy of which are tested. EFSA has suggested testing these through questions on herbicide/ crop management practices and weed populations in the farm questionnaire and a strictly limited number of 'more specific and focussed multi-annual scientific studies at sites where baselines have been established'. ACRE agreed with the use of farm questionnaires but was not convinced that further studies would necessarily inform the existing risk assessment. It discussed the use of post-market environmental monitoring to identify locations in the EU where the biodiversity in conventional maize fields may be relatively high. This is because it is feasible, at least in theory, that altered weed management practices in these particular situations could have an ecologically-relevant impact on biodiversity. ACRE noted that EFSA had not taken the biodiversity value of maize into account to the extent that ACRE has done in its advice on T25 maize.

EFSA had identified the evolution of pest resistance as an environmental risk. However, this is not discussed in any detail in the opinion and it is not clear what the basis for this view is. EFSA notes that pesticides are used currently to control the Western Corn Rootworm in maize. If the biological control function of MON88017

were eroded, the expectation is that farmers would resort to conventional methods of pest control. A principle established in the legislation is that 'characteristics that have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations'. ACRE agrees that it is important to take measures to prevent or to slow down the erosion of biological control measures such as the adoption of Bt crops but was not convinced that this was within the scope of the legislation. The secretariat confirmed that this was for the regulatory authorities to determine. ACRE welcomed EFSA's view that insect resistant management practices, including the use of refugia should be continually updated in the light of new evidence and new innovations.

ACRE considered the case specific monitoring of MON88017 maize in the light of the conclusions on the environmental risk assessment. It was then asked to consider the general surveillance plan for MON88017 maize. Monsanto had outlined a multi-tool approach that EFSA and ACRE have agreed with. ACRE discussed the recommendations from EFSA on improving the general surveillance plan. ACRE agreed with some of the points; for example, with respect to the farm questionnaire - the provision of more information on herbicide applications and clarity about what comparators respondents were using. ACRE considered that in cases where comparisons were made with non-GM maize fields on the same farm at the same time, this may address the need for specific research trials. However, ACRE considered that some of the EFSA's suggestions may not be proportionate or practical. In particular, it was concerned about recommendations to modify existing monitoring networks. ACRE also thought that questions in the farm questionnaire on ease of working the soil, surface ponding and soil pan formation should be included.

*Action: Secretariat to draft ACRE advice on Monsanto's application to cultivate MON88017 maize on the basis of ACRE's discussions.*

## **7. EFSA Scientific Opinion on an application under Regulation (EC) No. 1829/2003 for authorisation to cultivate GA21 maize – ref. EFSA-GMO-UK-2008-60 ACRE/12/P4**

GA21 maize has been genetically modified so that it is tolerant to the herbicide glyphosate. As ACRE discussed EFSA's opinion on the environmental implications of adopting altered weed management practices involving glyphosate under the previous agenda item, the committee did not need to repeat it under this item. However, ACRE noted that the applicant, Syngenta, had developed a structured approach to characterising the environmental risk. ACRE also noted that the general surveillance plan provided in this application was more detailed than that for MON88017 maize; in particular, ACRE was positive about the proposed farm questionnaire included in the plan. It considered that the farm questionnaire proposed by Syngenta was better than the questionnaire produced by Monsanto. EFSA's recommendations on the PMEM plan in this application were consistent with those for GA21 maize, which ACRE discussed under the previous agenda item.

*Action: Secretariat to draft ACRE advice on Monsanto's application to cultivate GA21 maize on the basis of ACRE's discussions.*

**8. EFSA scientific opinion on the 2009 PMEM report from Monsanto on the cultivation of MON810 maize.** **ACRE/12/P5**

EFSA has recently published an opinion on Monsanto's 2009 PMEM report for MON810 insect resistant maize. ACRE discussed the report and the EFSA opinion. ACRE supported the logical framework taken by EFSA in analysing the report, but in some cases were not convinced that requests for additional information could be scientifically justified. The Committee agreed to provide further comment on this by email correspondence, taking the recommendations of the ACRE PMEM report into account.

*Action: ACRE to submit further comments by email correspondence.*

**9. EFSA Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified 1507 maize for cultivation** **ACRE/12/P6**

ACRE was asked to comment on the EFSA opinion updating the environmental risk assessment for maize 1507. The Committee was asked to consider the robustness and suitability of a model that had been used to estimate the risk of mortality to European non-target Lepidoptera via ingestion of maize 1507 pollen and the efficacy of mitigation measures.

ACRE concluded that the model is sound as is the basic idea of investigating density effects on non-target Lepidoptera through modelling. However, the committee considered that the outputs were highly theoretical because of the extreme parameter values used in the model and that these did not provide a sound scientific basis to inform risk management measures.

**10. Implementation of recommendations from the revised Code of Practice for Scientific Advisory Committees and framework agreement on the relationship between Defra and ACRE** **ACRE/12/P7**

ACRE took note of the new recommendations in the revised Code of Practice, including various actions which the chair and secretariat will take forward. The committee also noted the revised agreement on the relationship between Defra and ACRE.

Discussion focussed on the requirement for performance assessment of the committee and of individual members. It was agreed that ACRE's performance should be dealt with by the annual report and that the secretariat should draft two alternative proposals for a light-touch system to be discussed at the next meeting.

*Action: secretariat to draw up proposals for appraisal system*

## **11. Items for information**

### **11.1 ACRE meetings in 2012**

**ACRE/12/INF1**

Members agreed to move the September meeting from the 6<sup>th</sup> to the 12<sup>th</sup>, to avoid any congestion associated with the Paralympics. The August meeting date has been left, though this clashes with the Olympics, but this will be cancelled unless there is unavoidable urgent business.

A large conference room in Nobel House has been booked for the October and November meetings so one of these dates can be used for an open meeting.

Members agreed that the May meeting should be held outside London.

*Action: secretariat to set up arrangements for May meeting*

### **11.2 Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making**

**ACRE/12/INF2**

Members noted this paper.

### **11.3 Rapporteur's assessment report on an application to market a GM veterinary product under Regulation (EC)No. 726/2004**

Members noted this report and agreed with the assessment

## **12. Any other business**

None

## **13. Date and time of the next meeting**

Thursday, 22<sup>nd</sup> March at 10.30am in Room 501, Ergon House (come to Nobel House reception as usual).

**ACRE Secretariat  
February 2012**

