

Advisory Committee on Releases to the Environment

These minutes are subject to approval following formal adoption at the next
ACRE meeting ACRE/16/M1

Minutes of the 150th meeting of ACRE held at Nobel House, London, on Wednesday 23 March 2016

Present

ACRE members:

Prof Rosemary Hails (Chair)

Dr Rosemary Collier

Simon Kerr

Dr Andy Wilcox

Dr Ben Raymond

Prof Ian Crute

Dr Peter Lund

Dr Kathy Bamford

Prof David Hopkins

Prof Mike Bonsall

Prof Jim Dunwell

Prof Andy Peters

Assessors:

Dr Karen Pearson SASA

Chris Chesterton NE

Defra:

Dr Louise Ball (secretary)

Dr Martin Cannell

Renaud Wilson

Ivy Wellman

Apologies were received from Dr Matt Heard.

One member of the public attended this meeting.

1. Defra staff changes

Sarah Cundy has left the GM team. Heloise Tierney is the new head of the GM (and EU crops) team. David Sherlock has retired. Ivy Wellman has joined the secretariat.

2. Membership of ACRE

ACRE welcomed two new members: Dr Andy Wilcox from Harper Adams University and Dr Ben Raymond from Exeter University. Kathy Bamford has returned to the committee having successfully re-applied for the medical microbiologist post.

3. Minutes of the 149th meeting, 4 September 2015

ACRE/15/M2

The date at the end of the minutes was incorrect. Subject to making this amendment, the minutes of the last meeting were agreed.

5. Policy update

Renaud Wilson of the Defra GM Team updated the Committee on policy developments at EU and UK level:

There has been no progress towards EU decisions on the outstanding applications to approve the commercial cultivation of GM crops

The European Commission has published information relating to the potential impact of its legislative proposal that would allow national bans on EU-approved GM food and feed products for non-safety reasons. The Commission's paper is not expected to change the Member States' largely negative reaction to the proposal which, combined with its formal rejection by the European Parliament, means that it is unlikely to be adopted.

The Government has issued its formal response to the report published by the House of Lords Science and Technology Committee on GM insect technology. The Committee made a number of recommendations to Government, of which perhaps the most noteworthy were that it should commission trials of GM insects in the UK, and seek to revise the EU regime for GMOs so that, inter alia, non-safety impacts (benefits/dis-

benefits) are taken into account alongside potential risks. In its response the Government has noted the difficulty of trying to secure beneficial changes to the EU legislation.

The Commission's long-awaited paper on the regulatory status of organisms produced by new genetic breeding techniques is now not expected to be published before the summer at the earliest.

6. Matters arising

6.1 Authorisations

The Commission has authorised 7 GM events for import and use in the EU since September 2015. These are 4 GM soybean events: MON87705 x MON89788; MON87708 x MON89788; MON87769 x MON89788 and FG72 and three GM maize events: Bt11 x MIR162 x MIR604 x GA21; MON87427 and NK603 x T25.

Monsanto has withdrawn four GM events containing MON863 maize that were authorised for import and food/ feed use. These are: MON863 x MON810 x NK603; MON863 x MON810 and MON863 x NK603 maize.

Syngenta has withdrawn two of its GM maize events that were notified (but not authorised) for commercial cultivation. These are MIR604 and Bt11 x MIR604 x GA21.

6.2 Reviews

The secretariat informed ACRE of current reviews that are relevant to ACRE:

6.2.1 General review of Defra's expert advisory bodies

Defra's ministers and Chief Scientific Advisor have requested a review of all Defra's expert evidence advisory bodies against a backdrop of declining resources.

Defra's Science Advisory Council (SAC) is conducting a review of the structure, function and operation of existing groups. This will advise the Chief Scientific Advisor on options for how these groups could be structured and operate to optimise efficiency and better meet Defra's evidence needs. The SAC Secretariat is also reviewing the governance and administrative aspects of the committees to ensure consistency in approach and adequate reporting.

The Secretariat will update ACRE on the review's findings when they are made available.

6.2.2 Cabinet office Review

The Cabinet Office is taking a two tier approach that develops the current triennial review policy. The first tier has involved cross-government functional reviews, covering several arm-length bodies (ALBs) in similar or related areas of government and the second tier is a programme of Department-led tailored reviews into individual ALBs, so each ALB is reviewed at least once per parliament. ACRE will be reviewed in 2017 as part of this process.

6.2.3 National Audit Office audit

6.3 Chair meetings

The chair met with Defra's CSA, Ian Boyd, on 16th September. The CSA passed on his thanks to ACRE for its efforts. The chair met with other Defra chairs on 29th September.

7. Matters agreed by circulation

7.1 . Applications for authorisation under the GM Food and Feed Regulation (EC) No. 1829/2003

Three EFSA opinions on food and feed applications have been circulated to the committee since the last meeting and ACRE advice has been published on all of them (MON87769 x MON89788 soybean; MIR604 and Bt11 x MIR604 x GA21 maize). None of these applications include cultivation in their scope.

In each case, ACRE agreed with EFSA that the GMO was as safe as conventional varieties and it agreed to add them to ACRE's advice for GM crops that have a limited potential to grow and flower outside of agricultural conditions in the UK.

7.2 Applications for marketing medicines containing or consisting of GMOs

As these products are regulated under medicinal products legislation, they could not be referred to in public session. The public can refer to the European Medicines Agency website where 'European Public Assessment Reports' are published once a product is authorised by the EU Commission.

7.3 GM insect inquiry

ACRE discussed the evidence it would submit to the inquiry at its September meeting. This was finalised through email correspondence and then submitted to the House of Lords' Science and Technology Select Committee. It was published on the parliamentary website on October 6th. The chair was asked to appear before the committee on November 20th. A transcript of the session is available on the parliamentary website.

8. Update on applications for authorisation under the GM Food and Feed Regulation (EC) No. 1829/2003

ACRE/16/P1

The Secretariat informed ACRE of new applications to import GMOs for food/ feed use. None of these included cultivation in their scope.

EFSA/GMO/NL/2015/127: 1507 x MIR162 x MON810 x NK603 maize. This maize is resistant to certain Lepidopteran pests, tolerant to glyphosate and glufosinate-herbicides and has a selectable marker gene that allows the GM plants to metabolise mannose.

EFSA/GMO/NL/2016/128: MON87751 x MON87701 x MON87708 x MON89788 soybean. This soybean is resistant to certain Lepidopteran pests, tolerant to glyphosate and dicamba herbicides.

EFSA/GMO/NL/2016/129: MON87751 x MON87701 x MON89788 soybean. This soybean is resistant to certain Lepidopteran pests and tolerant to glyphosate.

EFSA/GMO/DE/2015/130: VC0-01981- 5 maize. This maize is tolerant to glyphosate.

ACRE advised the Secretariat that it was content to wait for EFSA's opinions on these applications before it needed to consider them further.

One application (EFSA/GMO/BE/2015/125) had been validated since ACRE's last meeting. As this is a new trait (increased ear growth and grain yield at harvest) that ACRE had not considered before, ACRE asked for more details after validation. The secretariat agreed to circulate this information by email.

9. Application from the Rothamsted Research for consent to field trial GM Camelina plants expressing Omega-3 long chain polyunsaturated fatty acids and the pigment astaxanthin (Ref 16/R8/01).

ACRE16/P3

Rothamsted Research have submitted an application to carry out a research trial which involves the growing of genetically modified Camelina plants under field conditions. ACRE are required to assess the environmental risks and provide advice to Defra ministers, to help them make decisions on authorisation and consent. The purpose of the trial is to test the agronomic and yield performance of the GM camelina under field conditions.

ACRE's Professor Ian Crute declared a potential conflict of interest in that he was the Director of Rothamsted Research when the research that underpins this application was initiated. The chair concluded that whilst the minutes for the meeting should record this information, this there was no need for Ian to be excluded from ACRE's considerations.

The research trial involves growing GM Camelina plants which are modified in a very similar way to those grown previously at Rothamsted, in GM trials that took place in 2014 and 2015. ACRE had also provided advice on these previous trials.

In the trial proposed for 2016/17, three individual events (constructs) and one 'stacked' event (which combines two of the individual events) will be grown (four plant 'lines' in total). Two of the constructs each encode seven genes responsible for making omega-3 long-chain polyunsaturated fatty acids. All these genes originate either from algal, moss or fungal gene sequences. Together, they confer the ability to produce one or both of the omega-3 LC_PUFA eicosapentaenoic acid and docosahexaenoic acid in the seed oil of the plant. The third construct encodes genes which direct the synthesis of the ketocarotenoid astaxanthin which is used as a pigment in feed. It also encodes the selectable marker gene BAR, which confers resistance to glufosinate-ammonium herbicides.

ACRE discussed the molecular characterisation of the three lines and concluded that the information provided by the applicant was adequate for the purposes of carrying out the risk assessment. Members noted that information on the presence or absence of vector 'backbone' sequence in the plants was not required for the risk assessment in this case. ACRE proceeded to discuss the issue of the presence of sexually compatible relatives in the vicinity of the trial and the risk of potential gene transfer to such relatives.

ACRE concluded that since there was a theoretical risk that such out-crossing could occur, implementing the measures proposed by the applicant to minimise this eventuality would be prudent. Finally ACRE discussed the measures proposed by the applicant for dealing with waste and monitoring of the site after all the material had been harvested. ACRE concluded that with respect to inactivation and disposal of waste material, the same measures as proposed for the 14/15 trial remained appropriate. However ACRE also suggested that autoclaving of waste material should be added to the list of options available to the applicant since this is an effective and convenient method. With regard to monitoring, ACRE was satisfied that the measures proposed for the 2014/15 trials remained appropriate, namely that the applicant should monitor for the presence of volunteers for a minimum of two years and that monitoring may cease a) if no volunteers are identified in the second year of monitoring or b) after the first volunteer-free year after year 2.

Action: Secretariat to draft advice based on this discussion and to circulate it to ACRE for agreement.

10. ACRE annual report for 2015

ACRE/16/P4

The annual report is mostly a summary of ACRE's activities from last year taken from minutes and advice. The secretariat asked ACRE members to check their biographies and interests.

11. Government Response to House of Lords Science and Technology Select Committee Report on GM insects

ACRE/16/P5

ACRE received the House of Lords' select committee recommendations on GM insects ahead of the meeting. The Government's response to these recommendations was tabled. The Government's response had been introduced briefly during the policy update earlier in the meeting. ACRE was asked to consider the implications for its future work plan. The use of 'gene drives' was of interest to the select committee and this topic has received a lot of attention more generally. This had led to a number of initiatives. ACRE noted the USA's National Academies project on gene drives in non-humans, a forthcoming ILSI work shop in Washington and a recent report from the Dutch GMO office.

The UK's Scientific Advisory Committee on Genetic Modification (under contained use) has also discussed the issue. SACGM has invited ACRE to hold a joint workshop on gene drives. ACRE discussed the possibilities and the timing. ACRE's view was that it would be more valuable to consider gene drives within the broader topic of gene editing.

Action: Secretariat to liaise with the SACGM secretariat about next steps.

12. Application from the Sainsbury Laboratory for consent to field trial GM potatoes to screen for improved field resistance to potato late blight (Ref 16/R29/01).

ACRE/16/P2

Defra's Minister of State, George Eustice, listened to this agenda item. He welcomed the new members onto ACRE and thanked the committee for its detailed consideration of this application and for the quality of its work more generally. He also highlighted the constructive, well-referenced contribution made during the public consultation of this application by a group of interested organisations.

Professor Ian Crute declared a potential conflict of interest. He was a member of The Sainsbury Lab's governing council but this is no longer the case. The chair concluded that whilst the minutes for the meeting should record this information, there was no need for Ian to be excluded from ACRE's considerations.

The Sainsbury Laboratory (TSL), has requested consent from Defra to grow GM potatoes in a field trial. The purpose of the trial is to screen for field resistance to potato late blight (*Phytophthora infestans*).

TSL is applying to field trial GM potato plants (*Solanum tuberosum*) containing one of six resistance (*R*) genes. These confer resistance to different isolates of *P. infestans*. The *R* genes are derived from wild potato relatives *S. venturii* and *S. americanum* and from the *S. tuberosum* variety *Sarpo Mira*. ACRE noted that *R* genes from wild potato relatives had been bred into commercial potato to develop *Sarpo* varieties.

The GM line containing the *R* gene from *S. venturii* was authorised for use in a previous trial (which took place in 2010- 2012).

ACRE noted that this application was unusual in that TSL had only made GM lines containing two of the *R* genes. This meant that ACRE had to specify the molecular

characterisation information it would need to see to ensure that its advice on risk assessment/ management applies to the new GM lines that are produced. ACRE considered that TSL had provided a comprehensive, high quality molecular characterisation of the existing lines but noted that some of these data were not necessary for characterising the risk posed by this particular trial. ACRE discussed the need for data on copy number, transgene expression, genotypic/ phenotypic stability and nuclear transformation. TSL had analysed whether vector backbone DNA had been inserted into the genome of the existing GM potato lines. As TSL had not assessed the potential risks of genetic elements from the vector backbone being inserted, ACRE considered that lack of backbone DNA would need to be demonstrated for all transgenic potato lines planted in this trial. ACRE considered that the analyses that TSL had carried out for the existing lines was fit for this purpose.

ACRE considered that TSL's environmental risk assessment was comprehensive and did not identify any risks. ACRE then reviewed the site management conditions associated with TSL's previous GM potato trial to determine whether they were fit for this trial. If consent for the field trial is issued, it will not allow for material to enter the food/ feed chain and as such, the consent will need to stipulate measures for minimising the persistence of GM material at the site and dispersal from it.

The public consultation on this application closed the day before the meeting. ACRE members read a representation submitted by twenty two NGOs before discussing the application. The secretariat also tabled individual representations. These raised three main points that were discussed by ACRE: 'pollen and seed escape', transfer of the antibiotic resistant marker gene to disease-causing bacteria and unexpected effects. ACRE noted that some of the issues raised were not relevant to the risk assessment of this particular trial. These included concerns about whether the trial should have been funded, whether it would be successful and whether there are existing non-GM varieties with resistance to potato blight.

The NGO representation suggested that the properties of Maris Piper (one of the parental varieties used in the trial) increase the potential for pollen movement and for the presence of true seed and volunteers/ ground keepers at the site. ACRE noted that there are no wild relatives or ornamental species that can hybridise with potatoes in the UK. Therefore, ACRE focussed on the possibility of cross-hybridisation with non-GM potatoes. ACRE discussed the biology of potatoes and research on gene flow and agreed that the 20 metre

separation distance proposed by TSL was appropriate. ACRE also noted that a number of R genes of this type are present naturally in potatoes and other food crops.

ACRE discussed the potential for true seed to persist at the site. Its view was that there is little evidence that true seed will cause a problem. However, it discussed precautionary measures that would keep any true seed near the soil surface and measures that would encourage it to germinate so that any plants could be destroyed. ACRE considered that most plants would derive from tubers/ fragments of tubers left in the soil after harvesting. ACRE considered that hand-pulling plants would lead to higher numbers of ground keepers compared with the use of machinery. ACRE noted that the trial would be fenced, which would minimise dispersal.

ACRE has discussed the use of the *nptII* antibiotic marker gene in GM plants on a number of occasions. It re-iterated its previous reasoning that (i) this gene is already present in soil bacteria (ii) transfer of this gene is far more likely to occur between bacteria than between plants and bacteria (iii) in order for the gene to be expressed it would have to be transferred intact from plant cells (iv) selective pressure (e.g. the presence of associated antibiotics) in the environment affects the frequency of antibiotic resistant bacteria. Excessive and inappropriate use of antibiotics has increased antibiotic resistance in disease-causing bacteria. Therefore, ACRE concluded that the plants containing the *nptII* gene in this trial would not contribute to the problem of antibiotic resistant disease-causing bacteria.

ACRE also discussed the possibility of unexpected effects associated with the genetic modification. If the GM potatoes were for food/ feed use, TSL would be required to provide data on glycoalkaloid levels to ensure that they do not contain unacceptably high levels of these natural toxins. ACRE noted that TSL will monitor the site during the trial for unexpected effects but did not identify any particular characteristics that TSL should look out for.

ACRE considered how plant material from the site should be disposed of and post-trial monitoring. ACRE advised that all material from the site (GM and non-GM potatoes) should be treated the same. It considered that its previous advice on monitoring was fit for purpose i.e. that the trial plots should be monitored until there have been two successive years where no volunteers or ground keepers have been found.

Action: Secretariat to draft advice based on this discussion and to circulate it to ACRE for agreement.

13. Papers for information

10.1 synthetic biology: relevance to ACRE

10.2 Parisi C., Tillie P. and Rodriguez-Cerezo E (2016). The global pipeline for GM crops out to 2020. *Nature Biotechnology* **34**: 31- 36.

14. Date of the next meeting

The next scheduled meeting is on 26 May at 10.30am in Room 806 Nobel House.

ACRE Secretariat

April 2016