Advisory Committee on Releases to the Environment

These minutes are subject to approval following formal adoption at the next ACRE meeting ACRE/20/M1

Minutes of the 155th meeting of ACRE held on 14th May 2020.

The meeting was held online.

Present

ACRE members:

Prof Jim Dunwell (Chair)
Dr Andy Wilcox
Dr Peter Lund
Dr Kathy Bamford
Dr Ben Raymond
Prof Andy Peters
Prof Alan Raybould

Assessors:
Dr Laura Bowden SASA
Dr Elspeth Ransom
Dr Sabrina Roberts
Dr Hoa Chang
Debbie Kessell

Defra:
Louise Ball (Secretary)
Martin Cannell
Sean Simpkins

Apologies were received from Prof. David Hopkins.

1. Minutes for the 154th meeting, March 23rd, 2018.

ACRE adopted these minutes subject to a minor change. They will be published as formal minutes on the gov.uk website.

2. Matters arising

Professor Rosie Hails has retired from ACRE after 13 years of service, including 6 years as chair. Members noted Prof Hail's significant contribution to the committee both in terms of her expertise and her leadership. Prof Hails also provided expertise to the European Food Safety Authority during this time, which included contributing to risk assessment guidance. Professor Jim Dunwell from the University of Reading has been appointed as the new chair of ACRE.

The ACRE secretariat has a new member.

3. State of play on GMO regulatory processes

The secretariat provided a short run-through of the different GM regulatory processes relevant to ACRE. EU exit has not, and will not, change ACRE's work significantly in the near future.

Applications to trial GMOs are, and will continue to be, regulated on a national basis. Applications to market GM medicines are dealt with under legislation on medicinal products and as such, ACRE will continue to comment in the same way and within the same timeframes as it does now.

The approach ACRE has developed to assess the environmental risks associated with the import and use GM food and feed will need to change as this depends on reviewing European Food Safety Authority (EFSA) opinions. ACRE discussed this in more depth under the next agenda item.

UK regulators are not expecting applications to cultivate GM crops in the near future. Any application for GM crop cultivation is likely to be submitted under the GM food and feed regulations, for which the Food Standards Agency (FSA) is responsible. ACRE will be asked for advice on the environmental risks and this will be combined with advice from the Advisory Committee on Novel Foods and Processes (ACNFP) on food and feed safety.

ACRE discussed briefly the implications of the UK Government revisiting its approach to GM regulation and what ACRE's role in this will be. The devolved administrations have signalled that they do not want to diverge from the EU's approach. Defra would consult ACRE on any proposed change to its GM legislation. Whether, how and when changes are made will depend on a number of factors. Public trust is an important issue and Defra does not want to signal that decisions on a new regulatory framework have been made, when they have not.

4. ACRE/2020/P2: ACRE's approach to advising on the environmental risks associated with applications to import GM food and feed into the UK.

ACRE's current approach for developing its advice on the environmental risks associated with applications to import GMOs for food and feed use involves checking whether the application fits with one of the three categories of existing advice. If it does, it is added to a list of applications at the end of that advice. The agronomic characteristics of the unmodified crop and whether the novel trait alters its potential to persist in the agricultural setting or invade new habitats determines this categorisation. ACRE confirms that EFSA has not identified any unexpected issues before issuing its advice.

After the Transition Period has ended, the UK will make authorisation decisions independently of the EU. The outcome of negotiations with the EU on our future relationship should confirm this. In any circumstance, ACRE cannot rely on EFSA opinions from January 2021.

The FSA is responsible for the regulation of GM food/ feed and as such, ACRE's assessment will need to fit into the FSA's risk analysis process. The plan is for ACRE's advice on the environmental risks to slot into the ACNFP's advice on food/ feed safety aspects. The FSA has not confirmed timeframes or how technical information will be shared at this point. ACRE discussed whether it wants to consider the full complement of information in applications initially with the aim of filtering-out information that does not inform its assessment of the environmental risks or whether it wants to continue to base its advice on a limited amount of targeted information (for most applications). In the case of the latter, ACRE could specify further detailed information it needed to address any plausible risks identified from the limited amount of information.

ACRE concluded that it would prefer to start with information that would enable it to identify environmental risk. If there is a plausible risk, it will ask the secretariat to provide information that will allow ACRE to investigate and characterise it.

5. ACRE/2020/P3: The consequences of Defra's intention to remove temporarily the requirement for post-trial monitoring due to COVID-19 restrictions.

The consent conditions of GM field trials require monthly post trial monitoring. This is to monitor for and remove plants on the site that could result in GM material persisting on or around the site in years to come (and potentially ending-up in the food chain).

Due to the Covid-19 outbreak, Defra temporarily removed the requirement to make monthly monitoring visits. Some of the consent-holders will carry them out; for others visits might be less frequent. ACRE was provided with information on each trial, including the results of monitoring from previous years. The secretariat will inform

ACRE about the visits consent-holders were able to make during this period and the results of monitoring.

Defra has stipulated that it will not terminate these consents until it is convinced that the trial sites have been managed effectively. ACRE was asked to consider what additional monitoring or management measures might be needed on the sites where monthly monitoring visits were not possible.

ACRE advised that consent-holders should visit the trial sites if they could and, if possible, in June before any volunteer plants on the sites could flower. The secretariat will inform ACRE on whether this occurred at all the sites and ask for its advice on what, if any, additional management measures are required. This would depend on the crop-type and specific information on site management.

ACRE's existing advice on these trials does not flag any risks to human health or the environment.

Action: Secretariat to provide ACRE with information on consent-holder visits to the trial sites over the period of Covid-19 restrictions and to seek advice on any additional risk management measures required.

6. ACRE/2020/P4: Gene drive international discussions

This information paper was presented to highlight to committee members certain discussions taking place within the Convention on Biological Diversity (CBD) and other international fora. These discussions concern the risk assessment and risk management of synthetic gene drive organisms and whether additional guidance may be needed concerning their release into the environment. The paper acknowledged that ACRE had recently responded to a related public consultation on EFSA guidance on the risk assessment of genetically modified animals.

7. ACRE/2020/P5: EFSA consultation: Applicability of the EFSA opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis

The EU Commission has asked EFSA to revisit its opinion on site-directed mutagenesis-3 (SDN-3) to determine whether its conclusions also apply to SDN-1 and 2.

EFSA has advised that off-target changes associated with SDN-3 are likely to be fewer than most traditional mutagenic techniques (which are excluded from GMO regulation as a result of 'having conventionally been used in a number of applications and have a long safety record'). It also considers that where they do occur, they will be of the same type as those generated by traditional mutagenesis. EFSA concludes that this is true for plants produced using SDN-1 and 2. It notes that

information on off-targets effects associated with oligo-directed mutagenesis (ODM) is more limited. However, it considers that as ODM is also based on site-specific site recognition, that off-target effects will also be negligible compared to traditional mutagenic techniques. Therefore, EFSA concludes that 'the analysis of potential off-targets would be of very limited value for risk analysis'.

EFSA notes that SDN-1 and 2 can result in unintended on-target or off-target integration of exogenous DNA. EFSA recommends that applicants should demonstrate absence of this DNA in final products, if its inclusion was not intended.

EFSA's opinion on SDN-3 plants considered the assessment of the transgene that is inserted. This is not relevant to plants developed using SDN-1 and 2 or to ODM.

ACRE made a few minor comments but had no substantive concerns about the opinion.

8. ACRE/2020/P6: EFSA consultations on risk assessment of plants and micro-organisms produced using synthetic biology

This paper highlighted an EFSA consultation regarding Scientific Opinions on synthetic biology developments in plants and micro-organisms. These opinions were commissioned by the European Commission to evaluate whether existing guidance on GMO risk assessment is adequate to deal with current and near future synthetic biology developments or whether there is a need for updated guidance. EFSA conclude that its GMM Guidance (EFSA GMO Panel, 2011) is a useful basis for the ERA of products containing living SynBioMs, because living GMMs were also foreseen in this Guidance. For microbial characterisation, environmental risk assessment and PMEM of SynBioM, guidance and knowledge need to be developed in a number of areas. The draft EFSA Opinion on synbio plants concluded that no alterations to existing guidelines are required but that depending on future developments in synbio there may be a need to update guidance accordingly.

ACRE made a few minor comments but had no substantive concerns about either opinion.

9. Next meeting

To be confirmed.

ACRE Secretariat