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Operating within the EU's regulatory system for GM crops – a perspective from ACRE





Advisory Committee on Releases to the Environment (ACRE)

- Advises UK Ministers on the environmental risks posed by GMOs
- Independent scientific/ technical committee operating under EU and national GMO legislation
- ‘Footprint of Agriculture Report’, 2007 – placed our advice on FSE results (GMHT crops) in a wider context.
- In 2013, followed this up with 3 reports that consider further the EU regulatory system in which we operate.



ACRE reports

(<http://www.defra.gov.uk/acre/publications/>)

- **Report 1: Towards an evidence-based regulatory system for GMOs.**
 - high-level consideration of basic principles and characteristics of the regulatory framework for controlling the deliberate release of GMOs into the environment.
 - considers whether there are fundamental problems that require the legislation to be recast.
- **Report 2: Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs.**
 - follows ACRE's report on the regulatory status of new plant breeding techniques. It explains why it is so difficult to interpret the EU's definition of a GMO from a scientific perspective.



ACRE Reports

(<http://www.defra.gov.uk/acre/publications/>)

■ Report 3: Towards a more effective approach to environmental risk assessment of GM crops under current EU legislation

- reflects on observations made during our case work and discussions at an evidence-gathering meeting we held in March 2013.
- considers how ERAs might be implemented more effectively without changing the legislation
- relevant to forth-coming EU discussions on updating information requirements for the ERA of GM crops.



Report 1

(<http://www.defra.gov.uk/acre/publications/>)

1. A regulatory system triggered by the process by which new organisms are developed (i.e. recombinant DNA technology) rather than by their novelty and potential for harm (i.e. their phenotype), cannot be justified scientifically.

- no compelling evidence that techniques used for trait manipulation have a bearing on environmental consequences.
- process-based approach results in inconsistencies, lack of regulatory clarity and inability to deregulate particular GMOs – reasons to replace the current system.



Report 1

(<http://www.defra.gov.uk/acre/publications/>)

2. Decisions on GMOs are based on risk. Potential for greater benefits for the environment and human health if more explicit risk/ benefit analysis (taking compensatory measures into account).

- Addressing important challenges e.g. ‘sustainable intensification’ of agriculture
- GM mosquitoes designed to reduce transmission of human diseases such as malaria and dengue fever
- Including risk/ benefit analysis in the assessment process requires a change in legislation



Report 1

(<http://www.defra.gov.uk/acre/publications/>)

3. The system should minimise regulatory burden and decision times to facilitate innovation without compromising safety.

- since 1998 only 1 consent to commercially cultivate a GM crop in the EU (GM potato with altered starch content; no longer grown).
- at present, 1 GM crop (insect-resistant maize) cultivated in the EU (authorised in 1998).
- ~ 20 applications to commercially cultivate GM crops submitted in the EU, more than half have been in the system for at least 5 years.



Report 1

(<http://www.defra.gov.uk/acre/publications/>)

4. "crop-by-crop" general surveillance (GS) activities that extend beyond dialogue with users and awareness of current relevant science is unlikely to be either proportionate or effective.

- Objective of GS: to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the ERA. (mandatory)
- Multi-tool approach e.g. Farm questionnaires, Literature reviews, existing surveillance networks.
- limits to sensitivity; difficulty in linking change to a specific cause.
- Recommend analyses of delivery of ecosystem services from farmland to facilitate delivery of 'sustainable intensification' more generally



Background to Report 2

(<http://www.defra.gov.uk/acre/publications/>)

ACRE's earlier report on the regulatory status of plants produced using new techniques made recommendations based on a scientific interpretation of the legal definition of what constitutes a GMO.

We concluded that:

the definition is open to interpretation (unless the organism is transgenic) and advised that a more transparent, scientifically robust interpretation be adopted if the EU continues to employ the current definition



Report 2

(<http://www.defra.gov.uk/acre/publications/>)

But... in practice, any interpretation will be flawed because the definition of a GMO captures organisms based on:

(1) the technique(s) used to produce them (process-based approach)

- *Report 1*: evidence – nature of human interventions that cause negative environmental consequences
- *Report 2*: evidence - genome studies

(2) and on the novelty of their genotypes (*‘the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination’*)

- *Report 2*: evidence – genome studies



Report 2

(<http://www.defra.gov.uk/acre/publications/>)

The GMO regulatory framework captures organisms based on:

(1) the technique(s) used to produce them and

(2) the novelty of their genotypes

- When the legislation was written, genomes of organisms were considered relatively uniform and stable; since then, extensive genome studies show a high degree of natural plasticity and variability between genomes and epigenomes of individuals of the same species as well as within any single individual
- a single nucleotide alteration (which can occur naturally) can result in a significant change in phenotype



Report 2

(<http://www.defra.gov.uk/acre/publications/>)

Report 2 concludes that:

The EU's regulatory approach is not fit for purpose for organisms generated by new techniques. This conclusion also applies to transgenic organisms produced by 'traditional' GM technology. Whilst it is clear that these will be captured by the GMO legislation, the potential for inconsistency is inherent because they may be phenotypically and genetically identical to organisms that are not regulated.

....and provides support to Report 1 in recommending that:
the EU considers adopting a regulatory approach based on novel phenotype. This would be independent of newly arising and currently unforeseen technological developments, and would focus on risks associated with phenotype.



Definition of a GMO

Article 2: an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Annex 1A lists techniques that lead to genetic modification (but this is not exhaustive):

- Vector-mediated transformation
- Direct transformation
- Cell fusion (new combinations of heritable genetic material that would not occur naturally).

Annex 1B. Organisms produced by these GM techniques are excluded as long as they do not involve the use of recombinant nucleic acids

- Mutagenesis
- Cell fusion (results could occur through traditional breeding)



New Plant Breeding Techniques

The EU identified a list of techniques – would organisms produced by them be captured by the GMO legislation?

- Cisgenics
- Reverse Breeding
- Agroinfiltration
- Grafting on genetically modified rootstock
- RNA-dependent DNA methylation via RNAi/siRNA
- Oligonucleotide-Directed Mutagenesis
- Zinc finger nucleases



Report 3

(<http://www.defra.gov.uk/acre/publications/>)

- Reports 1 and 2 make the case for a new regulatory framework that captures organisms based on the novelty of their phenotypes (and potential to cause harm) and that takes benefits into account.
- if there were an appetite for replacing the existing EU legislation, it would take a number of years
- Important to implement existing legislation optimally. Report 3 considers how ERAs could support more cost-effective, efficient and informed decision-making
- Increasing data requirements/ more prescription in data requirements will not improve ERAs.



Report 3

(<http://www.defra.gov.uk/acre/publications/>)

1. develop a more coherent understanding of what constitutes an adverse environmental effect/ harm in a broader agro-ecological context;

Several components:

- clearer, shared understanding of what constitutes harm;
 - more efficient use of broader comparisons (FSE results)
 - better appreciation of the importance of spatial and temporal scales
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- Applicants need to know the standards they need to fulfil in order to provide the relevant evidence in ERAs.



Report 3

(<http://www.defra.gov.uk/acre/publications/>)

2. focus on clearly defined hypotheses of risk rather than on either hazard or environmental exposure;

Countering tendency to:

- collect data not relevant to ERA or risk management.
- pursue the possibility of unintended effects without having a plausible risk hypothesis to test. [instead of using a weight of evidence approach to identify characteristics of a GM crop (or its use) that could be linked to harm].



focus on risk rather than on hazard or environmental exposure (risk = hazard x exposure)

Example: GM potato with altered starch content

- The applicant proposed monitoring for volunteer potatoes; accepted by regulators but the ERA did not identify a risk (or hazard) associated with the occurrence of volunteers.
- Lack of risk hypotheses - not clear if/ what level of potato volunteers would pose a risk (i.e. what to do with the monitoring results?).
- Consent stipulated monitoring for potential adverse effects on potato-feeding organisms - despite ERA concluding that no adverse effects have been observed or are likely to occur.
- No clear risk hypothesis – experimental design?



Report 3

(<http://www.defra.gov.uk/acre/publications/>)

3. environmental risk management as an integral component of ERAs.

- Use increasing understanding of how to manage environmental risks on farmland to develop ERAs that incorporate evidence-based risk management.

4. make better use of existing information.

- Structure ERAs around what is already known (including what is considered harmful) before identifying evidence gaps on a case by case basis
- adoption of a 'problem formulation' approach' will help to structure assessments and establish what evidence is required and why (previous speaker).



Acknowledgements

ACRE

Ieuan Joyce (chair of steering committee)
Chris Pollock: lead Report 1
Keith Lindsey: lead Report 2
Les Firbank: lead Report 3
Rosie Hails
Matt Heard
Jim Dunwell
Rosemary Collier
David Hopkins
Simon Kerr
Mike Bonsall
Andy Peters
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With support from the ACRE
secretariat