Advisory Committee on Releases to the Environment

Annual report 2016

This report is published on behalf of the Advisory Committee on Releases to the Environment (ACRE) by the Department for Environment, Food and Rural Affairs (Defra)

17 Smith Square LONDON SW1P 3JR Telephone 03459 33 55 77

Website: https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment

© Crown copyright 2017

Copyright in the typographical arrangement and design rests with the Crown.

This publication may be re-used free of charge in any format or medium provided that it is re-used accurately and not used in a misleading context. The material must be acknowledged as crown copyright and the title of the publication specified.

Information about this publication is available from:

ACRE Secretariat
Defra
Area 1C, Nobel House
17 Smith Square
London
SW1P 3JR

acre.secretariat@defra.gsi.gov.uk

Contents

Foreword by the Chair, Professor Rosie Hails	4
Main activities	5
Meetings	5
Casework	5
Applications for GM releases for research purposes	5
Food and feed marketing applications	5
Medicinal marketing applications	5
Other advisory duties	6
House of Commons Science and Technology Inquiry	6
New and emerging technologies	6
Governance and transparency	6

Foreword by the Chair, Professor Rosie Hails

This is the twenty-third annual report of the Advisory Committee on Releases to the Environment (ACRE) and summarises the Committee's work in 2016. This is a new style report to reflect that our advice and other information about ACRE can be found on the relevant pages of the Gov.UK website.

ACRE is an advisory non-departmental public body, sponsored by the <u>Department for Environment</u>, Food & Rural Affairs (Defra). ACRE's main role is to give statutory advice to the UK Government and Devolved Administrations of Scotland, Wales and Northern Ireland on the risks to human health and the environment from the release and marketing of genetically modified organisms (GMOs). ACRE also advises on the release of certain non-GM species that are proposed for use as bio-control agents, and which are not native to Great Britain.

In 2016, ACRE received five applications for GM trials for research purposes; held two full committee meetings which were open to the public, issued advice on four GM products for commercial import and, or, processing, and assessed three applications for GM medicinal products. During the year Mike Bonsall and Andy Peters retired from the committee; I am very grateful to Mike and Andy for the valuable contributions and commitment they gave to the work of ACRE.

Looking forward, I am keen that ACRE continues to be open and transparent; we will continue our work to advise on applications for marketing GM products and GM research trials as required, and we will continue to open our meetings to the public. As an expert advisory Committee it is vital that ACRE continues to keep up to date with developments in new and emerging technologies such as gene drives and synthetic biology. It is important that we continue to work with our counterparts who advise on the contained use of GMOs on these issues to ensure that we are as effective as possible. I expect discussions on the regulatory status of organisms produced by new breeding techniques to escalate in 2017. While ACRE does not make decisions on whether the legal definition of a GMO applies to organisms, we will support UK regulators by providing independent advice on the underpinning science as required.

I would like to take this opportunity to express my thanks to the members, assessors and the secretariat for their dedication to the work of ACRE.

Rosie Hails

2017.

Main activities

Meetings

ACRE held two regular committee meetings during 2016. We are commitment to openness and transparency and our main committee meetings are open to the public to attend as observers. Minutes of the meetings, and details of the next scheduled meeting are published at https://www.gov.uk/government/organisations/advisory-committee-on-releases-to-the-environment/about/our-governance

Casework

Applications for GM releases for research purposes

ACRE has assessed five applications to release GMOs for research purposes under Directive 2001/18 and the Genetically Modified Organisms (Deliberate Release) Regulations 2002. The applications, ACRE's advice, and the outcome of the applications are available on the Gov.UK website as follows:

- Rothamsted Research (16/R8/01)
- Sainsbury Laboratory (16/R29/01)
- Rothamsted Research (16/R08/02)
- Oxford Vaccine Group (16/R48/01)
- Imperial College London (16/R49/01)

Food and feed marketing applications

ACRE also considered four EFSA (the European Food Safety Authority) opinions on notifications for placing GM maize, cotton and oilseed rape products on the EU market; these were for import only, and not cultivation. In each of the cases considered, ACRE was satisfied that the genetically modified products posed no greater risk to human health or the environment than their conventional counterparts. Nearly all the marketing applications that ACRE assessed are processed through Regulation (EC) No. 1829/2003. The products assessed are detailed below:

- ACRE advice: applications to market GM soybeans and maize
- ACRE advice: applications to market GM cotton and rice
- ACRE advice: applications to market GM oilseed rape

Medicinal marketing applications

ACRE was also asked to advise on the environmental risk assessment aspects of marketing applications for three human gene therapy products containing, or consisting of, a GMO. These applications are submitted to the European Medicines Agency under

Regulation (EC) No. 726/2004. Under this Regulation information on the assessment of the application is only made available as part of The European Public Assessment Report following the European Commission's decision at the end of the assessment process.

Other advisory duties

House of Commons Science and Technology Inquiry

In November, the House of Commons Science and Technology Select Committee opened an inquiry on genomics and genome editing. The Committee intends to split the inquiry into two parts, with the first looking at genomics and genome editing as it relates to human health, and the second looking at the impact of the technologies on plants, animals and ecosystems. ACRE will provide written evidence to the Committee. Details about the inquiry may be found at: https://www.parliament.uk/business/committees-a-z/commons-select/science-and-technology-committee/inquiries/parliament-2015/inquiry2/

New and emerging technologies

ACRE takes a keen and active interest in new and emerging technological developments such as synthetic biology and gene drives. Peter Lund has, for some time, been a member of both ACRE and the HSE's Scientific Advisory Committee on Genetic Modification (SAC(GM)); this supports closer links between the work of the two Committees. The Committees expect to hold a joint meeting in March 2017.

Governance and transparency

ACRE is a statutory advisory committee appointed under section 124 of the Environmental Protection Act (EPA) 1990 to provide advice to Government regarding the release and marketing of genetically modified organisms. The Committee works within the legislative framework set out in Part VI of the EPA and the GMO Deliberate Release Regulations 2002 which, together, implement Directive 2001/18/EC.

Below are links to various information relating to the work and membership of ACRE:

- Framework agreement
- Terms of reference
- Members' biographies and register of their interests