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Progress Towards the Introduction of Genetically Modified Crop Cultivars in the United Kingdom

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Introduction

In the UK the technology of genetic modification has been developing over the past 15 years or so, but recent years have seen the rapid acceleration in the practical application of genetic engineering to plant varieties. There is now in the UK a wide range of introduced characters in varieties that are well advanced through the plant breeding and selection process. Indeed, a few have entered the UK statutory testing to establish: distinctness, uniformity and stability (DUS) to enable the grant of *Plant Variety Rights*; and value for cultivation and use (VCU) to achieve National Listing and approval to market.

Approval Procedures

The UK regulatory procedures for risk assessment and consideration of applications for release of genetically modified organisms are derived from the relevant European Union Directives and enacted through the UK Environmental Protection Act 1990. Consent to release a GM organism is considered in three distinct situations: part (a) a contained release; part (b) a release to the environment for R&D purposes; and part (c) a release to the environment for marketing purposes. Part (a) releases under containment regulations are the responsibility of the Health and Safety Executive. Parts (b) and (c) releases to the environment are the responsibility of the Department of the Environment.

Under the Environmental Protection Act 1990 a statutory committee of independent experts, the *Advisory Committee on Releases to the Environment* (ACRE) has the responsibility to provide advice on risk to human health and on environmental safety to the appropriate Ministers. ACRE consists of 12 members and its deliberations are supported by the Department of the Environment Biotechnology Unit and observers from other relevant UK Government Departments. The membership is broadly based and encompasses all necessary and relevant expertise from genetics through microbiology, molecular biology, agronomy, human and animal health, ecology and environmental protection.

ACRE provides advice on both releases for research and development purposes and for marketing of GMOs and other novel organisms. In the UK the Department of the Environment, as the lead Department, has effective linkages with other Departments concerned with food safety, plant variety and seeds regulations and, where relevant, pesticide or herbicide issues. Under EU legislation each Member State can approve and implement releases for research and development purposes within its own boundaries, but consent to market has to be agreed by at least a qualified majority of all Member States.

ACRE has also devoted a major effort to rationalisation and simplification of the procedures, while still retaining full regard for safety. It has introduced, for certain combinations of introduced gene and host crop plant, where the risk to the UK environment is minimal, an accelerated *fast track* procedure. Crops like maize, tobacco, tomato, pepper, soyabean, vegetable cucurbits and sunflower are susceptible to low temperature and therefore will not survive the UK winter. Also these crops have very low seed dispersal and therefore the risk of spread of seed is minimal. In addition to these crops which have an inherent minimal risk in the UK, ACRE also considered that certain genetic modifications of potato, sugar beet and oilseed would not affect their ability to survive and spread outside the non-agricultural environment. These combinations were also considered safe in that any escape of the inserted genetic material to related species would not cause any selective advantage.

The introduction of the *fast track* procedures for defined combinations of characters and crops has allowed the relevant applications to be considered administratively. All other applications are considered by the full ACRE either by postal distribution (*streamlined cases*) or in committee (*standard cases*). ACRE keeps procedures under review and will add to or delete from the current *fast track* list over time. This stratification of both risk and the approval procedures has been of considerable advantage to all interested parties. The statutory time to reach a decision on *standard* case is 90 days. The administrative target for a *streamlined case* is 50 days, and for a *fast track* case is 30 days. The achieved turn arounds have been within these targets, and the UK system works efficiently. The UK has also strongly encouraged the very welcome moves within the EU towards simplified procedures.

Research and Development Releases

The recent rate of development and the concentration on crop plant species can be seen in the published data from the UK Department of the Environment ACRE. The following table shows the increase in approvals for R&D release in the UK and the distribution across the various crop plants. Over the last three years there have been 78 releases for R&D purposes including 70 relating to crop plants. These releases have involved 15 different genetic modifications.

Approved R&D Releases and Distribution Across Crops in the UK

	1993	1994	1995 (to end Sept)
Total number of approved releases	**16**	**23**	**39**
Releases relating to crop plants:	**13**	**19**	**39**
Oilseed rape	3	9	20
Potatoes	7	3	4
Sugar beet	1	2	5
Wheat	1	1	2
Maize	0	1	1
Chicory	0	1	1
Tomato	0	0	1
Strawberry	0	0	1
Apple	0	0	1
Tobacco	0	2	2
Eucalyptus	1	0	1

In addition to selectable markers a number of characteristics have been incorporated into oilseed rape, including: fungal resistance; herbicide tolerance; oil content; oil composition; male sterility; and restored fertility.

Within the European Union the UK is one of the most active Member States in this area and only France has handled a greater number of field R&D releases.

Marketing Approval

To date only two applications have been made to the UK authorities for approval for market release.

The first application concerned a new hybridisation system in oilseed rape with tolerance to glufosinate ammonium herbicides. This application was the culmination of many earlier small scale experimental releases by the applicant in the UK and abroad. ACRE considered that this application did not pose a risk to human health, the ecosystem or to man's property and advised approval. As required under the EC Directive, the application was sent to the European Commission with a favourable opinion in May 1994: a final EC decision has not yet been promulgated and this long

delay is a serious issue for all concerned with the safe assessment and release of genetically modified crop cultivars into commerce.

The second was for consent to market imported and subsequently processed soyabeans, modified to tolerate glyphosate herbicides. The assessment was that the risk of marketing this product in the UK would be no different from that of other conventional soyabeans marketed for processing purposes. A favourable opinion has been submitted to the EC and the review on this application continues.

Conclusions

There is an innovative and vigorous research and development programme in genetic modification of crop cultivars in the UK and an appropriate objective and practical approach to the assessment of risk. Varieties containing potentially valuable inserted characters are well advanced through the breeding and selection processes and in some cases have entered the statutory trials for *Plant Breeders' Rights* and *National Listing*. Oilseed rape dominates the applications for release to the environment with 32 out of a total of 70 submissions for all crops over the past three years. There is major concern over the long delays that are occurring within the EC officialdom over the consideration of applications for full marketing consent and release.

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