THE CHALLENGES OF REGISTERING AND TRIALLING GENETICALLY MODIFIED VARIETIES

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ABSTRACT

Genetically modified (GM) oilseed rape have been tested in UK registration trials since 1995. Herbicide tolerance is the major trait but modified fatty acid profiles are also under test.

GM testing and release is subject to regulation by the European Union (EU) directives and the UK authorities and is the subject of much public scrutiny. GM material must undergo the same testing requirements as conventional varieties but pollen barriers, isolation from field crops, the exclusion of produce from the food chain and post trial monitoring are some of the additional conditions and costs of the testing process. Consequently, GM trials are grown in isolation which also helps reduce the risk of vandalism to conventional trials.

Concerns about the release of GM material into the environment and the food chain have delayed introduction on the farm. At the time of writing there has been no EU clearance for commercial planting of any GM material. The debate on GM release in Europe continues to be a very live issue.

KEYWORDS: oilseed rape, hybrids, herbicide tolerance

INTRODUCTION

In the UK, genetically modified (GM) varieties of both winter and spring oilseed rape are currently undergoing registration trials and tests. There are two aspects to variety registration of GM material. First, trials and tests must comply with existing protocols within the registration process as applied to conventional varieties. Secondly, all releases of GM material must comply with additional protocols determined by regulatory authorities.

European Union (EU) regulations (Council Directive 70/457/EEC) require governments to implement a register or National List of varieties eligible for sale (EU 1970). Entry to this National List is dependant on distinctness from other varieties and satisfactory field performance over two years of trials and tests. The National List regulations are administered in the UK by the Ministry of Agriculture, Fisheries and Food, Plant Variety Rights Office (MAFF, PVRO).

DISCUSSION

There are two elements of variety testing: Distinctness, Uniformity and Stability (DUS) tests, and Value for Cultivation and Use (VCU) trials. The DUS test is performed at one location by the National Institute of Agricultural Botany (NIAB), while trials are conducted in locations throughout the Britain, by the NIAB, the Scottish Agricultural Colleges (SAC) and the British Society of Plant Breeders (BSPB). The number and type of tests vary with the crop (Table 1).

Table 1 National List VCU trials: number per year

	NIAB	BSPB	SAC	Total
Winter oilseed rape	3	3	1	7
Spring oilseed rape	1	-	1	2

The majority of oilseed rape varieties currently entered for registration exhibit modifications for herbicide tolerance (Glyphosate/Glufosinate ammonium) but varieties with modified fatty acid profiles are also under test. Both hybrid and line varieties from pedigree selection are represented.

Table 2 Winter oilseed rape: numbers of candidates entering National List trials 1995-1999

	1995	1996	1997	1998	1999
GM hybrids	-	-	-	3	3
GM non-hybrid	-	-	-	2	-
Conventional hybrid	6	17	10	22	31
Conventional non-hybrid	42	43	52	36	37

Table 3 Spring oilseed rape: numbers of candidates entering National List trials 1995-1999

	1995	1996	1997	1998	1999*
GM hybrid	2	2	1	2	4
GM non-hybrid	-	-	-	3	1
Conventional hybrid	6	5	8	4	3
Conventional non-hybrid	22	13	18	16	11

* provisional figures

The release of genetically modified organisms in the UK is controlled by *The Genetically Modified Organisms (Deliberate Release) Regulations 1992* (MAFF 1992) and *The Genetically Modified Organisms (Deliberate Release) Regulations 1995* (MAFF 1995). Together these implement Council Directive 90/220 regulating research trials (Part B release) and market introductions (Part C release). Variety testing is currently carried out under Part B restrictions and no material is cleared for commercial planting.

Applicants wishing to test GM material apply to the Department for the Environment, Transport and Regions (DETR) with details of the modifications, risk assessments and the planned programme of work. Details of the application process are given in DETR *Guidance Notes* (e.g. DETR 1994). The regulations state that all information (apart from commercially sensitive details) on the release should be made available to the public. Applicants must specify the six figure Ordinance Survey reference number which identifies each 100 m^2 of land in the UK, and these details are required to be advertised in local newspapers and placed on the public register. The applicants must also supply information on the release to English Nature (a conservation body) and, in certain circumstances, the local water authorities.

After consultation with the Advisory Committee for Release in the Environment (ACRE), environmental and conservation agencies, DETR issue a Consent detailing conditions that will apply to the release. DETR may request additional information and may refuse applications if the information supplied is insufficient or the release is thought inappropriate.

GM varieties are subject to the same trials and tests as conventional varieties including assessment of yield, agronomic, disease and quality characters (Anon 1999). However, due to the release restrictions, GM varieties are sown in separate trials. In oilseed rape, these trials are surrounded by a minimum six metre non-GM isolation barrier and a fifty metre isolation requirement from any neighbouring oilseed rape crops. These measures aim to minimise pollen spread from the trial area to neighbouring crops. The Part B release also requires that no material should enter the food chain and, for this reason, seed from the GM trials and the six metre surround is destroyed. To protect their markets, major processors may impose additional restrictions to allay consumer concerns over GM food. This is already the case for sugar beet in the UK.

Breeders and their agents are individually responsible for seeking regulatory approval for their varieties from DETR. One potential problem is that individual varieties entered for registration may be subject to differing constraints and conditions for release. In an attempt to prevent this, the National List trials are run to an agreed "Framework" document. This framework document lists the conditions that can be accommodated, such as maximum trial areas, isolation distances, crop destruction details etc. As a result, varieties within the trials may have differing restrictions, but all will fall within the scope of the trial framework. If a release application falls outside these specified criteria, the material is not accepted for trials.

The additional work setting up and conducting the separate trial series has cost implications, which has to be borne by the breeder or agent of the variety. Separate trials with few varieties impose a high financial burden on applicants but costs per variety decrease as the number of applications increase.

Applicants are required to submit a report on the release to DETR within thirty days of harvest, and trial sites are monitored for a further two year period to assess potential volunteer problems. Applicants are also required review relevant information which may affect their risk assessment, and notify DETR of any developments. To ensure compliance with the relevant consent conditions, the Health and Safety Executive (HSE), a government agency, monitor releases on behalf of DETR.

If breaches of consent conditions are discovered, HSE can advise on remedial action. In the case of serious breaches, HSE are empowered to prosecute through Health and Safety legislation.

Although some varieties entered the National List testing system in 1995 and have completed trials and tests, none have been granted National List status by Ministers. This will not take place until full marketing consents and the relevant food/feed clearances have been granted. Environmental groups opposing the introduction of GM crops have taken court action to challenge the validity of trial results in an attempt to delay the commercial introduction of such material. To date this has been unsuccessful.

Apart from the technical difficulties in running trials, sites are increasingly at threat from vandalism. The incidence of damage to GM sites increased alarmingly in 1998, reflecting public concern and resistance to GM technology. In addition, non-GM material including high value multiplication stock has been mistakenly damaged. Trials operators are working with all sectors of the agricultural industry, law enforcement and environmentalist groups to try to prevent further damage. Several research projects looking at the impact of GM crops on the environment have been commissioned, and small-scale commercial production is taking place.

SUMMARY

Despite technical difficulties, testing procedures are in place and varieties have been trialled for a number of years. The real debate now is a political one where the merits and potential problems associated with GM technology must be resolved before commercial production can become a reality. Awareness of the issues is increasing rapidly, but public concern remains high.

REFERENCES

Anon (1999). UK National List protocol - winter oilseed rape, spring oilseed rape. Ministry of Agriculture, PVRO, Cambridge.

DETR (1994). Guidance Note no.4, Guidance for experimental releases of genetically modified plants. Department of the Environment, Transport and Regions, London.

EU (1970). *Council Directive on Common Catalogue varieties of agricultural plant species* (Directive 70/457/EEC), Commission of the European Comunities, Brussels.

EU (1990). *Council Directive on the Deliberate release onto the Environment of Genetically Modified organisms* (Directive 90/220/EEC), Commission of the European Comunities, Brussels.

MAFF (1992). *The Genetically Modified Organisms (Deliberate Release) Regulations 1992*. HMSO, London.

MAFF (1995). *The Genetically Modified Organisms (Deliberate Release) Regulations 1995.*HMSO, London

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