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# Genetically Engineered Oilseed Rape:

## Agricultural Saviour or New Form of Pollution?



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some system put in place to recompense individuals or communities that suffer from adverse effects. This could be in terms of causing genetic pollution or harming ecosystems or health. One important effect of such a clause is that it would result in companies taking a more critical and realistic view of assumptions embedded in their risk assessments.

These are practical steps that the Government could take to redress the shortcomings of the present regulatory system. However, public confidence will not be gained unless it is clear that their concerns are being addressed in practice. The clearest signal would be for the UK Government to follow the example of the French Government and announce a moratorium on the commercial use of GEOs until a full public consultation has taken place and inadequacies in the regulatory framework addressed.

**At the present time, the Government should not allow the licensing of herbicides on herbicide resistant crops. Licences should only be considered when basic research has been completed which must include an assessment of multiple herbicide resistance problems and plans to avoid them. An overall policy relating to herbicide resistance must be put in place before such crops are assessed and decisions made on whether to allow marketing.**

Because there are so many gaps in the basic regulatory framework, the Government must also address the shortcomings in a more fundamental way. The review and revision of the Deliberate Release Directive gives an ideal opportunity for many of the issues to be addressed. New elements which should be introduced into the risk assessment system are:

1. **An evaluation of whether any proposed release of a GEO is in the public interest.** In this way the potential impact on other sectors of industry, the impacts on agricultural trajectories (including impacts on the genetic base of agricultural crops and monoculture), the availability of alternatives and the need for the product could be weighed up against any risks and benefits. At the moment, such assessments are made in a profoundly undemocratic way within secretive scientific committees and are based on 'taken-for-granted' assumptions. There are tools which could be used to help decision makers in evaluations of public interest, making the inclusion of such a clause a practical proposition. These include techniques such as multi-criteria evaluation, citizens' juries and consensus conferences. Although the suspicion might be that they would delay decisions, this may not be the case. Most decisions about the commercialisation of GEOs have been very contentious in Europe. The disputes come down to differing sets of value judgements about the justification for the risks in their widest sense and the acceptability of any harm<sup>99</sup>. An explicit public interest clause could result in decisions being more robust as they should more accurately represent public opinion.
2. **An overarching evaluation of the risks of different classes of GEOs, such as herbicide, insect and viral disease resistance.** This could then be used to place individual risk assessments in context and go some way to ensuring cumulative impacts are not neglected.
3. **A systematic examination of the impact of uncertainties on the risk assessments.** There should be a formal evaluation of how uncertainties in any parameter may influence the outcome if they have been over- or under-estimated. This could include the development and comparison of best and worst case scenarios.
4. **Mandatory segregation and monitoring throughout the food chain.** This is both important to collect data and to ensure that food producers, retailers and consumers are able to make choices about whether to use or eat GEOs. The costs of such a scheme should be borne by the producers of the GEOs.
5. **A system of compulsory liability for damage arising to human or environmental health as a result of the release of a GEO.** There must be

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## EXECUTIVE SUMMARY

In 1999, herbicide resistant oilseed rape could be the first genetically engineered (GE) crop to be grown commercially in the UK. Three varieties are in the final stages of plant variety approval and herbicide licensing. One was developed by Plant Genetic Systems (PGS), now owned by AgrEvo, a joint venture between the German multinational corporations Hoechst and Schering. The other two are made by AgrEvo itself. All three are resistant to AgrEvo's herbicide glufosinate. Farmers will be able to plant the seeds and then apply glufosinate to kill weeds in the crop. If the commercial exploitation of these crops is allowed, glufosinate use will increase considerably. The PGS rape also includes a system which allows manipulation of the fertility of the plants to enable hybrids to be produced and a gene giving resistance to the antibiotics neomycin and kanamycin.

Oilseed rape is grown on approximately 400,000 hectares in the UK annually and is the country's fourth most important crop. Oil from the plant is used for both food and industrial applications and is found in a wide range of products, including margarine, salad and frying oils, and biscuits. None of these products will be labelled to indicate whether they contain oil from GE oilseed rape. The cake remaining after the oil extraction is used for animal feed.

This report considers how the PGS oilseed rape was evaluated in the UK and whether all the safety issues have been properly addressed. Although the focus is on the PGS oilseed rape, the findings are also relevant to other GE crops.

### Main Findings and Conclusions:

- There will be genetic pollution of native flora following the commercial use of glufosinate resistant oilseed rape. This will be inevitable as native species are pollinated by the GE oilseed rape and the foreign genes transferred.
- This conclusion is supported by new research, published since the Government's Advisory Committee on Releases to the Environment (ACRE) considered the PGS oilseed rape in 1994. It shows that the risks of genetic pollution are greater than had been previously thought.
- Research on the ecological effects of GE oilseed rape and other crops (such as invasiveness) has been too limited to guarantee safety. Recent research has shown trials must be carried out for at least three years if they are to be reliable. Data presented on the PGS oilseed rape were derived from experiments with a duration of only one to two years.

**The Government should withdraw the consent to market PGS oilseed rape in the UK and undertake a re-evaluation of the environmental safety aspects. This should also extend to other GE oilseed rape crops.**

- Although farmers are supposed to benefit from the use of herbicide resistant oilseed rape, even those who do not use these types of crops will have to deal with complex weed control problems. The use of herbicide resistant oilseed

rape will inevitably result in herbicide resistant volunteer weeds (when seed from a crop grown one year emerges in a different crop grown the following year).

- It may not be possible to control the weed problems that arise. The authorities involved considered that volunteer weed problems arising from the PGS glufosinate resistant oilseed rape could be controlled by the use of other herbicides such as glyphosate. However, subsequent research has demonstrated that the control of volunteers may become ‘substantially more difficult<sup>41</sup>’ if they are herbicide resistant.
- Although a great number of herbicide crops could be introduced in the near future, the Ministry of Agriculture, Fisheries and Food (MAFF) has no overall policy and has not planned any precautionary measures to minimise the impact of herbicide resistant weeds. Basic research will not be completed until the year 2000.

**At the present time, the Government should not allow the licensing of herbicides on herbicide resistant crops. Licences should only be considered when basic research has been completed and this must include an assessment of multiple herbicide resistance problems and plans to avoid them. Policy must be developed which addresses the whole issue of herbicide resistant crops before individual cases are assessed.**

- Human health risks could arise through the increased use of glufosinate. Glufosinate is toxic to humans and, in poisoning cases, has been associated with neurological symptoms including memory loss and convulsions. Experiences with organophosphates suggest that any increase in exposure to neurotoxic chemicals should be avoided.
- Allergic reactions to the novel proteins in the GE oilseed rape are unlikely to arise. This is because the oil extracted from oilseed rape does not contain proteins (or only in minute amounts).
- The antibiotic resistance gene in the PGS oilseed rape is a by-product of the genetic engineering technique and serves no function in the plant, the GE plant could have been produced without it. Even though neomycin and kanamycin are not important drugs clinically, the presence of antibiotic resistance genes and any risks that could arise if the protein enters the animal food chain are not justifiable at a time when escalating antibiotic resistance is causing serious medical problems.
- Research methods to investigate the food safety aspects of GE oilseed rape have been poor. Little data has been supplied on the effect of the genetic change on the composition of the plant in the presence of the herbicide. The majority of the studies did not include the application of glufosinate.
- Safety is also compromised because the possibility of cumulative impacts is not included in assessments. The PGS oilseed rape is the first of many such crops. Case-by-case risk assessments of GE crops which form the basis of safety

## CONCLUSIONS

Glufosinate resistant oilseed rape is the first of many herbicide resistant crops that chemical companies are developing. There are some serious shortcomings in the present regulatory system which the assessment of GE oilseed rape illustrates. ‘Taken-for-granted’ assumptions about the desirability of, and justification for, genetic engineering appear to have led to conclusions which may not be valid in the light of new evidence. Lack of proactive policies or strategies on the part of regulatory authorities mean that the introduction of GE crops is being driven solely by commercial interests with little regard for public concerns. The ethical dilemmas, inherent unpredictability of the technology and justification for potential risks appear to have been neglected in the rush to commercialise.

This report shows that the commercialisation of PGS oilseed rape and other GE crops brings risks to the environment, farming and health. However, despite an apparently extensive series of regulations, there are considerable gaps. The lack of policy relating to herbicide resistant crops is also evident in other areas such as insect resistance where cumulative impacts could have important environmental effects.

In addition, research published since some of the oilseed risk assessments took place indicates that there should be a review of the environmental safety of the PGS and other GE oilseed rapes.

To redress the situation, the following specific actions should be taken in relation to PGS’ oilseed rape:

1. Since ACRE evaluated the PGS application in 1994, new data have shown that hybridisation with native flora is more likely than was thought at the time. Other research has shown that feral oilseed rape can colonise and is not exclusively transient outside the agricultural environment. Recent studies have shown that serious errors can lead to misleading conclusions if trials to determine whether ecological risks exist are not conducted for three years at a minimum. Experiments to investigate the environmental impact of the PGS oilseed rape were only conducted for 2 to 3 years. In addition, the environmental impact assessment of the PGS rape was undertaken under the assumption that glufosinate use would be restricted to the hybrid seed production and not used when grown by farmer. Following the take-over of PGS by AgrEvo this no longer appears to be the case and these changed circumstances could increase the risks involved.

**In the light of these significant new findings, the Government - under Article 16 of the Deliberate Release Directive - should withdraw consent to market PGS oilseed rape in the UK and the rest of Europe and undertake a re-evaluation of the environmental safety aspects.**

2. Recent research has also demonstrated that herbicide resistant volunteers may be considerably more difficult to control than those from conventional varieties. As more herbicide resistant crops are developed, more complex weed control problems may emerge.

*The ethical dilemmas, inherent unpredictability of the technology and justification for potential risks appear to have been neglected in the rush to commercialise.*

plants is a good strategy *'both environmentally and agronomically in the long term'*.<sup>97</sup> Whilst the Government seems content to rely on voluntary codes of practice to control weed problems the National Farmers Union believes restrictions on growing areas by zoning or other means will be unpopular with farmers and difficult to police<sup>97</sup>. Glufosinate resistant oilseed rape is the first of many potential herbicide resistant crops. Complex herbicide resistance problems may emerge but no overarching policy is in place to address this issue.

Plant variety regulations examine 'value for cultivation and use' but only in terms of how yields and other physical characteristics compare with the best varieties currently in use. Therefore, the PGS oilseed rape may be denied plant variety registration because it does not give good yields but not, in practice, because its herbicide resistance jeopardises agricultural weed control strategies (although a strong legal argument could be made that it should do so).

Also neglected has been any assessment of the use of GE oilseed rape on other sectors' business interests. Food producers may wish to avoid GE crops to provide choice for their customers. The Soil Association has already informed one organic farmer growing corn close to a GE corn test site that their crop will have to be tested to ensure no genetic contamination has taken place or their organic status may be lost<sup>98</sup>.

Farmers wishing to provide GE free supplies will be in difficulties following the commercial growing of GE oilseed rape. As no arrangements have been put in place for mandatory segregation of GE crops, increased time and expense in testing will be needed by companies wishing to secure GE free supplies. Their fields are likely to be contaminated because of the way in which pollen from oilseed rape spreads. Therefore, food producers may have to look overseas to source GE free oilseed rape and British agriculture will suffer as a consequence.

Because there are no plans in place for segregation and monitoring, it will also prove impossible to find out whether, where and how harmful events take place. Because there is such scientific uncertainty surrounding the subject, some testing of assumptions should take place if it is decided that the risks of GE crops and foods should be accepted.

However, the most striking omission from debate is whether the genetic manipulations that are being undertaken are considered justifiable or desirable by the public. Because there is no certainty regarding safety, some social, political and value judgements have to be made. Despite the considerable evidence that the public are not convinced that increases in yield justify the transfer of genes between species, the taken-for-granted assumption behind the regulations and used in their interpretation is that transgenic crops are a positive development. These qualitative aspects of the risk assessment are given little attention although they form the basis of much of the disagreements on the risks between countries in the EU.<sup>99</sup>

evaluations do not address the potential for increasing risk as many more herbicide resistant crops are introduced.

- 'Taken-for-granted' assumptions about the desirability of, and justification for, genetic engineering appear to have led to conclusions which may not be justifiable. Lack of proactive policies or strategies on the part of regulatory authorities mean that the introduction of GE crops is being driven solely by commercial interests with little regard for public concerns. The ethical dilemmas, inherent unpredictability of the technology and justification for potential risks appear to have been neglected in the rush to commercialise.

**Because there are so many gaps in the basic regulatory framework, the Government must address the shortcomings in a fundamental way.**

**All new applications to commercialise GE crops should be subject to:**

- \* **an evaluation of their public benefit**
- \* **an evaluation of the risks from each class of crop (e.g. herbicide, insect and viral disease resistance)**
- \* **mandatory segregation and monitoring throughout the food chain**
- \* **a system of compulsory liability for any resulting damage to the environment or human health from the commercialising of a GE crop.**

**The UK Government should follow the example of the French Government and announce a moratorium on the commercial use of genetically engineered organisms until a full public consultation has taken place and inadequacies in the regulatory framework addressed.**

***The most striking omission from debate is whether the genetic manipulations that are being undertaken are considered justifiable or desirable by the public.***

## INTRODUCTION

In 1999, herbicide resistant oilseed rape may be the first genetically engineered (GE) crop to be grown commercially in the UK. This oilseed rape has been developed by Plant Genetic Systems (PGS), a company owned by AgrEvo, a joint venture between the German multinational companies Hoechst and Schering. The rape is resistant to the broad spectrum herbicide glufosinate, which is manufactured by Hoechst (trade names include: *Harvest, Challenge, Liberty, Basta*). Farmers will be able to use glufosinate to kill weeds among the resistant crops. It is the first of many such GE crops which are intended to be grown and used in the production of food. Two other oilseed rape varieties, also resistant to glufosinate and developed by AgrEvo, are also in the final stages of regulatory approval and could also be grown commercially in 1999.

There has been much concern expressed about the introduction of GE crops and foods, including their impact on biodiversity, agriculture, the environment and human safety. Research has shown that the British public do not welcome GE foods but feel they are being, or will be, imposed regardless of their doubts over the justification for such foods<sup>1</sup>. In the wake of the 'mad cow' disease crisis, farmers, food producers, retailers and Governments are in a fragile relationship with their customers and electorates. In the public's mind, genetic engineering seems as dangerous and unnatural as the feeding of sheep protein to cows, which is thought to have triggered BSE. How much confidence can the British public have that mistakes will not have been made in the evaluation of GE foods?

This report evaluates the systems that are in place in Europe to assess the risks of GE crops by looking at PGS' herbicide resistant oilseed rape. This takes into account not only the physical risks to the environment and human health, but also considers the risks to business and agriculture from the use of GE crops as food.

The report first considers the risks to the environment, farming and human health that may arise from the growing and use of GE oilseed rape. It then evaluates how the various regulatory bodies have made their assessments. The report identifies shortcomings and considers the implications of these for the businesses involved. Finally, it considers ways in which the shortcomings should be addressed and, in particular, how there could be more transparency and public involvement in the decisions about whether the risks are justified. Although the focus is on the PGS oilseed rape, the findings are relevant to safety assessments of all GE crops.

GE ingredients are labelled. Thus tracking GE products will be impossible and claims to safety untestable. The same logic denies consumers any choice in the matter.

## Missing Issues

It is evident that there are problems with the existing safety evaluation systems. However, not only is there considerable scientific uncertainty and lack of data surrounding all the safety evaluations, some dimensions have been simply excluded from consideration.

There are issues concerning 'good scientific practice' that are being neglected. The whole basis of the safety evaluation is a case-by-case assessment moving from small to large scale. Considerable scientific uncertainty remains when a crop is commercialised, yet there are no sensitivity analyses conducted to determine what might be the effect of making the wrong assumption or extreme conditions arising. In the case of herbicide resistant crops there is no opportunity to consider the impact of an ever increasing number of such crops. Is it feasible that the problem weeds or volunteers from the PGS oilseed rape will be as easily managed as ACRE hopes, given the development of other glufosinate or glyphosate resistant oilseed rape, potatoes, fodder beet and sugar beet for growing in this country? Whilst the potential for harm to non-target organisms may look minimal when only one licence application for the use of glufosinate on GE crops is considered, when the number is increased the picture may look very different.

This is not only an issue for herbicide resistant crops. The same problem applies to insect resistance and other classes of modification. Whilst the presence of *Bacillus thuringiensis* toxin as an insect control mechanism in one crop may appear to carry minimal risks, if it were to be included in many crops the effects on non-target insects and the bird life that depends upon them could be serious. Yet these cumulative impacts are disregarded.

And how good are small-scale, short-term experiments likely to be at predicting the ecological impact of commercial releases? Most experimental field trials do not even consider environmental effects, being more concerned with agronomic performance.<sup>84,96</sup> Investigating the potential for weediness or invasiveness takes time and requires specialised investigation. As described earlier, transgene instability may only become evident under certain environmental conditions which field trials cannot give 100% confidence about. The rush to commercialise has appeared to compromise emphasis on studies to consider environmental impact properly and regulatory authorities have placed little emphasis on ensuring such data is supplied.

There is also a huge gap in the regulations when it comes to considering the impact on weed control. The National Farmers' Union has highlighted the increasing problems that oilseed rape volunteers are causing farmers and how herbicide resistance may compound this problem and limit crop rotations. They have also identified the lack of any assessment of whether the use of herbicide resistant

***How much confidence can the British public have that mistakes will not have been made in the evaluation of GE foods?***

***There are issues concerning 'good scientific practice' that are being neglected.***

- the frequency and impact of the transfer of GE material between crops and weeds
- the likelihood and potential impact of multiple herbicide tolerance in GE plants.

These all address important uncertainties and would supply vital information which should be taken into account in considering the PGS licence application. However, they will not be completed until the year 2000.

### Food Safety

The ACNFP considered PGS' oilseed rape and the safety of oil extracted from it in September 1994<sup>93</sup>. The conclusion of the Committee was that the composition of oil from the PGS oilseed rape was the same as oil from traditional varieties and there were no unintentional changes in the plant. Issues such as the transfer of the antibiotic resistance genes in the oilseed rape to gut flora and problems of allergenicity were thought not to be relevant because no proteins would be present in the oil after processing.

The removal of protein and DNA during processing should minimise dangers associated with them. However, the data supplied by PGS about the composition of the oil was not of ideal quality. Only three of the experiments (at four sites) examining the potential for effects on composition were undertaken in the presence of glufosinate<sup>94</sup>. No statistical analysis of experiments is presented or detailed explanation of findings presented. For example, the data presented for one experiment (FBN9302) seems to suggest that with increasing levels of glufosinate application, the levels of glucosinolate also increases, especially in the Canadian study<sup>94</sup>.

In the application, PGS stressed that:

*“for this specific use (i.e. seed production of the transgenic hybrids), the ultimate herbicide application would be at the early vegetative stage of the parents in the hybrid seed production”.*

Following the acquisition of PGS by AgrEvo, it is clear that it is no longer the case that the use of the herbicide will be restricted to hybrid production. PGS have acknowledged that licence applications for both uses have been made. However, it is not clear whether and how application rates and timings will vary for the two uses.

The ACNFP did request the company to supply data on the seed composition and fatty acid profile of oil in the future because of uncertainties surrounding the potential for 'genetic drift' to affect plant metabolism.

Like ACRE, ACNFP are considering ways in which they can test their assumptions of safety through post-commercial release monitoring<sup>95</sup>. They are finding the task extremely difficult, firstly, because there are no schemes for mandatory segregation of GE crops and, secondly, because only a small proportion of products containing

### OILSEED RAPE PRODUCTION AND USE IN THE UK

Oilseed rape (*Brassica napus*) has become a familiar feature of the agricultural landscape, producing fields of vivid yellow when in flower in late spring and summer, and is now one of the major crops in British agriculture. There has been a dramatic expansion in rape seed production in the UK since the 1970s from less than 100,000 hectares to the present day when approximately 440,000 hectares are grown annually<sup>2</sup>.

This vast expansion in oilseed rape cultivation has resulted from EU support policies and the development of varieties which produce oil suitable for human consumption and which are able to flourish in the UK climate<sup>3</sup>. Previously, food use (for animals and humans) had been restricted because of the presence of glucosinolates and erucic acid in rapeseed which are toxic and unpalatable. New varieties - the so-called '00' or 'low-low' varieties - have been bred with reduced levels of both these compounds, thus expanding their market. UK production accounts for around 20-25% of the total EU oilseed rape production<sup>2,3</sup> and over 30% of all edible oils used in this country<sup>4</sup>.

Oilseed rape is either planted in the spring or winter, depending on the variety grown. The majority of oilseed rape in the UK is winter sown and is grown widely throughout England and Scotland with smaller quantities being grown in Wales and Northern Ireland. Density of cultivation is highest in Scotland and eastern England, particularly in Lincolnshire<sup>5</sup>. Harvesting of both spring and winter varieties takes place during July and August with average yields in the UK of approximately three tonnes per hectare<sup>2</sup>. The harvested seed is cleaned, crushed and heat treated to extract the oil and, to maximise yields of oil, a solvent (hexane) extraction step is used on the remaining oilseed cake. The crude oil is then refined by neutralising, bleaching and deodorising to remove free fatty acids and impurities and the oilseed cake is toasted and dried. The UK's crushing and refining plants are located in Humberside, Merseyside and the south-east of England. Other plants around the country then blend and distribute the oil according to customers' specifications.

Oilseed rape oil is used both for food and industrial purposes. Forty per cent of edible oils are used in the manufacture of margarine, spreads, shortenings and bakery fats. Twenty five per cent are used in oils and fats for frying and salad dressings. A further ten per cent are used in biscuit manufacture and smaller amounts in crisps, frozen foods and snacks<sup>4</sup>. Oilseed rape oil is also used in industrial applications, including the manufacture of lubricants, surfactants, paints, inks, polymers and pharmaceuticals. The oilseed cake remaining after oil extraction is used as a protein meal for inclusion in feeds for cattle, pigs and poultry.

***UK production accounts for around 20-25% of the total EU oilseed rape production and over 30% of all edible oils used in this country.***

***Tracking GE products will be impossible and claims to safety untestable.***

## PLANT GENETIC SYSTEMS' GENETICALLY ENGINEERED HERBICIDE RESISTANT OILSEED RAPE

PGS was one of the first companies to successfully genetically engineer oilseed rape and bring it to the market. Their initial work involved transferring genes from two bacteria into both spring and winter varieties of oilseed rape using *Agrobacterium* as a vector<sup>6</sup>. One, the *bar* gene, confers resistance to the herbicide glufosinate by making the plant produce an enzyme, phosphothricin acetyl transferase which breaks down glufosinate. The other, the *neo* gene, confers resistance to the antibiotics neomycin and kanamycin.

PGS have also incorporated a fertility control system to be used in the production of hybrid oilseed rape<sup>7,8,9</sup>. Because oilseed rape naturally outcrosses freely, it has been very difficult to produce 100% pure hybrid seeds and finding a reliable hybrid production system is therefore seen as a desirable goal in efforts to increase yield. The PGS fertility system involves genetically engineering one line (the male sterile line) by including the *barnase* gene which codes for an enzyme which destroys the pollen producing cells in the anther<sup>7</sup>. The other line (the fertility restorer line) contains another gene, the *barstar* gene, which codes for an enzyme which inhibits the effect of cytotoxic product of the *barnase* gene<sup>9</sup>. When the two lines are crossed, a fertile hybrid is produced. Glufosinate is used in the hybrid production systems to identify those plants which have been transformed with the foreign genes - those plants fertilised by other pollen will be killed.

It is the hybrid and the two lines involved in its production which PGS have sought to commercialise in the UK. Table 1 gives details of the three lines and the foreign genetic material they contain. As this table shows, the introduced genetic material includes DNA from several different bacteria and two other plant species (tobacco and *arabidopsis*).

AgrEvo, PGS' parent company, has also been developing a glufosinate resistant oilseed rape and this may be grown commercially in 1999 or 2000. The AgrEvo oilseed rape contains the *pat* gene which was isolated from a different bacterium than the PGS *bar* gene, but which also codes for phosphothricin acetyl transferase which breaks down glufosinate. AgrEvo wishes to market the herbicide resistant oilseed rape with the herbicide glufosinate, which the company also manufactures. Following its purchase of PGS in 1996, AgrEvo now controls the two genes which have been identified and give resistance to its own herbicide.

***AgrEvo now controls the two genes which have been identified and give resistance to its own herbicide.***

The Government has made reassurances that the assessment will be thorough because the precautionary principle has to be applied<sup>90</sup>, but noticeably lacking from the evaluation under COPR is any specific requirement to address herbicide resistance in weeds and volunteers. If the application was assessed under the Plant Protection Regulations 1995 (PPR) which implements EC Directive 91/414, PGS would have to provide a management strategy designed to minimise the likelihood of tolerance emerging. This set of regulations would also require the environmental impact of multiple authorisations to be assessed rather than the individual case-by-case assessments which is the current practice. However, because glufosinate is not listed in Annex 1 of Directive 91/414, which requires an assessment of new active ingredients and a review of those already in use, the COPR will be used.

The PSD do hope some kind of resistance management strategy will be provided although this is not a statutory requirement:

*"For an application under COPR the information that must be provided would be best drawn together in a resistance management strategy as is the case in 'traditional' resistance situations. Where pesticide resistance develops so that a pesticide becomes less effective, the approval can be amended or revoked."*<sup>91</sup>

However, the underlying logic is that if a compound becomes ineffective (i.e. weeds become resistant to it), its licence would be reviewed and possibly withdrawn. In addition, no attention will be paid to the difficulties and consequences of using other herbicides instead **even though this forms the basis of ACRE's safety management plan.**

Because the responsibility for gene flow is seen by the PSD as being the Department of the Environment's and potential harm has been determined to be 'low', the pattern of use of herbicide is not seen as being of any consequence in their herbicide risk assessment. However, selection pressure for the emergence of transgenic hybrids could be considerably increased if administration frequencies rise or glufosinate is used on more and more resistant crops. ACRE's safety evaluation assumed low usage of glufosinate yet there is no link or feedback with the pesticides regulations.

The Government conducted a public consultation on herbicide resistant crops in 1997 but the response to that has not yet been published - some eight months after the consultation period closed. Indications are that they will continue to rely on voluntary control measures by farmers to avoid the problems of herbicide resistance even though the NFU do not believe this approach will succeed<sup>97</sup>. While the prevarication continues, the impetus behind the crops grows. The authorities also seem to be content to let matters progress even though they have recognised the need for, and commissioned, basic research. For example, MAFF have recently commissioned three research projects and the DETR project on<sup>92</sup>:

- quantifying the escape of GE material from GE oilseed rape in realistic agricultural situations
- the impact of the commercial exploitation of herbicide resistant oilseed rape on the agricultural environment

***Noticeably lacking from the evaluation is any specific requirement to address herbicide resistance in weeds and volunteers.***

## Herbicide Licensing

Although the UK has a policy commitment to reduce the use of pesticides<sup>88</sup>, the total area of crops treated with agrochemicals increased by 18% between 1994 and 1996<sup>89</sup>. The area planted with oilseed rape decreased by 12% during the same period, but the area treated with pesticides increased by 25%. The growing of herbicide resistant oilseed rape will allow the application of glufosinate to be extended to post-emergence use. This could increase the area of land treated and further undermine policy commitments. Although claims are made that the introduction of herbicide resistant crops will reduce the amount of herbicide used, this is only true because broad spectrum, total herbicides like glufosinate and glyphosate can kill plants at much lower doses than many other herbicides. Even this is likely to be a short term effect if herbicide resistant weeds and volunteers emerge as problems and additional herbicide treatments are then required.

How have the pesticide and herbicide weed resistance issues surrounding the PGS oilseed rape been addressed by the Pesticide Safety Directorate?

Penetrating the workings of the Pesticide Safety Directorate is rather like trying to document freemasonry. Officials will not even admit whether a company has asked to license a herbicide or to extend its conditions of use. The culture embedded in the pesticides regulations is that the commercial interest in secrecy outweighs any benefit from public scrutiny.

Because there is no access to data about a pesticide licensing application before a decision is made, the likely approach of the Pesticides Safety Directorate has to be gleaned from statements in other fora. Their published opinion is that there is no special requirement for the use of herbicide on GE crops to be treated any differently than any other application and that each can be treated on a case-by-case basis<sup>72</sup>. **Thus there is no specific policy relating to herbicide resistant crops as a whole in place under which individual crop applications can be evaluated.** In addition:

*“MAFF’s policy is that farmers should be allowed to respond to their own problems within the existing framework, choosing the appropriate solutions and approved products for the circumstances encountered”*

This *laissez faire* attitude means that MAFF are content to allow complex problems possibly involving multiple herbicide resistance to take their course. These problems may be experienced by farmers who do not even use GE oilseed rape. The only beneficiary of such an approach appears to be the companies producing the GE crops.

The pesticide licence assessment that does take place will take place under the Control of Pesticides Regulations 1986 (COPR) and will examine<sup>72</sup>:

- changes in timing of herbicide application which may affect the behaviour of the herbicide in the environment
- the exposure of non-target organisms
- residues for food and animal feed safety including the presence and effect of any residues.

**Table 1: PGS oilseed rape lines - the source of introduced genes and their intended function. Hybrids of the male sterile and fertility restoration lines will contain all the gene sequences listed.**

Line	Gene Sequence	Introduced Genes	Source	Function
All Lines	Herbicide resistance	PSuAra	Plant: Arabidopsis thaliana	promoter restricting expression to green tissue
		bar	Bacteria: Streptomyces hygroscopicus	phosphinotricin acetyl transferase
		3'g7	Bacteria: Agrobacterium tumefaciens	remnant of vector
	Neomycin resistance	PNos	Bacteria: Agrobacterium tumefaciens	promoter regulating expression
		neo	Bacteria: Escherichia coli	neomycin-phosphotransferase II production
		3'ocs	Bacteria: Agrobacterium tumefaciens	remnant of vector
Male Sterility Line	Male Sterility	PTA29	Plant: Tobacco Nicotiana tabacum	regulation of barnase gene restricting expression to tapetum cells
		barnase	Bacteria: Bacillus amylioliquefaciens	product destroys pollen producing anther cells
		3'nos	Bacteria: Agrobacterium tumefaciens	remnant of vector
Fertility Restorer Line	Fertility restoration	PTA29	Plant: Tobacco Nicotiana tabacum	regulation of barstar gene restricting expression to tapetum cells
		barstar	Bacteria: Bacillus amylioliquefaciens	restores fertility by inhibiting effect of barnase gene
		3'nos	Bacteria: Agrobacterium tumefaciens	remnant of vector

## THE REGULATORY APPROVAL PROCESS

The regulatory requirements for commercialising a genetically engineered organism (GEO) vary according to the purpose of the product. If the GEO is intended to be used intact and is capable of reproducing or transferring genetic material to other organisms in the environment, it has to be approved under the EU's Deliberate Release Directive (90/220/EEC), implemented in the UK by Part VI of the Environmental Protection Act 1990<sup>10</sup>. Products of a GEO which do not contain viable material, such as gluten made from GE corn, are not covered by these regulations. Under the Deliberate Release Directive, a company makes an application to market a GEO to one member state which then undertakes an evaluation of the environmental safety issues and recommends to the European Commission whether or not approval should be given. Other member states have the opportunity to comment and, if there is disagreement, a decision is reached on the basis of a qualified majority vote. Disagreements between countries have been a common feature of applications for the commercial use of GEOs.

In the UK, The Secretary of State for the Environment is advised by a committee composed of scientists and other experts from academia, research institutes, industry and one member from the public sector. Assessors from various other Government Departments such as the Scottish Office also participate. This committee, the Advisory Committee on Releases to the Environment (ACRE), undertakes an evaluation of the dossier prepared by the company covering the environmental impact of the proposal. ACRE then advises whether the release should be allowed.

If the proposed GEO release includes food use, it is also assessed under the EU's Novel Foods Regulation (No. 258/97), which was agreed in 1997 and covers issues of food safety and labelling. In the UK, the Advisory Committee on Novel Foods and Processes (ACNFP) advises the Minister of Agriculture whether food use should be approved. Before 1997, companies agreed to a voluntary evaluation by ACNFP.

There are other regulations which may apply to a GEO but which are not associated specifically with the method of production by genetic engineering. For example, all crops have to have plant variety approval<sup>11</sup>. This involves two seasons' growing trials to ensure the new crop variety is 'distinct, uniform, stable' and has 'value for cultivation and use'. The Ministry of Agriculture, Fisheries and Food (MAFF) has responsibility for plant variety approval and the trials are supervised by the National Institute for Agricultural Botany in Cambridge.

If a herbicide is to be used with a crop, as can be expected with herbicide resistant crops, such usage must be approved under the pesticides regulations<sup>12</sup>. Pesticide licensing is the responsibility of the Pesticide Safety Directorate (PSD), a MAFF agency which assesses herbicide usage on the basis of safety and efficacy and is advised by the Advisory Committee on Pesticides (ACP).

Therefore, PGS not only has to gain approval for its herbicide resistant oilseed rape from the perspective of environmental and food safety, but also plant variety registration and a licence to use glufosinate on the crop. Table 2 indicates the

*and revised*" (emphasis added)<sup>84</sup>.

The shortcomings of small-scale, short-term field trials are especially acute when considering ecological impacts and the considerable uncertainty surrounding this does not appear to have been given sufficient acknowledgement.

- ***The risks of herbicide use and herbicide resistant crops can be safely separated?***

Fundamental to ACRE's reassurances of the safety of the commercial use of PGS' oilseed rape is that any problems related to agricultural volunteers or resistant weeds can be controlled by management techniques including the use of other herbicides. However, on the one hand, ACRE made a judgement that 'suitable' herbicide management regimes will be able to control any problems whilst, on the other hand, that the potential environmental implications which they involve can be safely divorced and left to the Pesticides Safety Directorate, which has no specific policy relating to herbicide resistant crops.

Other European Union countries have been less sanguine about separating the interactions between herbicides and herbicide resistant crops. Denmark, Austria and Norway (applying to join the EU at the time) all raised concerns about the PGS oilseed rape application. The Danes thought the implications for herbicide use should be part of the consideration of the GE plant<sup>85</sup>. Norway<sup>86</sup> and Austria<sup>87</sup> felt that there were serious uncertainties surrounding the estimates of outcrossing with wild relatives and this prompted them to take a different view of the scale of the risks. The possibility of multi-tolerant weeds developing and becoming a complicated agricultural problem was also thought relevant, whereas the UK committee had defined this as being outside its remit but manageable anyway, at least in the short term.

To compound the problem still further, Monsanto is developing glyphosate resistant oilseed rape varieties. If these are grown in the same areas as glufosinate resistant plants, cross fertilisation, seed spillage and outcrossing mean, at worst, that multiple resistant weeds could develop or, at best, that a complex mixture of volunteers resistant to various herbicides would emerge in subsequent crops. Will volunteers remain manageable in these circumstances?.

It is the separation between the licensing of the herbicide and the GE crop which is one of the most serious and obvious disjunctures in the whole evaluation process. The two are inextricably linked. How can a conclusion of safety (or manageability) be reached based on the assumption that "glufosinate ammonium is not used extensively or plays an important role in weed control in agricultural or non-agricultural situations.." when no evaluation of the future patterns of glufosinate use has taken place and when it is clearly the intention of AgrEvo to use herbicide resistant crops as part of a strategy of increasing herbicide sales. In addition changed patterns of herbicide use could influence the likelihood and scale of the emergence of troublesome herbicide resistant weeds.

***PGS not only has to gain approval for its oilseed rape from the perspective of environmental and food safety, but also plant variety registration and a licence to use glufosinate on the crop.***

***It is the separation between the licensing of the herbicide and the GE crop which is one of the most serious and obvious disjunctures in the whole evaluation process.***

• ***Transgenic oilseed rape will not colonise the natural environment?***

In addition, the invasive potential of the PGS oilseed rape may not have been adequately researched and ACRE supplied with insufficient data with which to make to a decision. Research published in 1996, using the same data PGS relied upon to argue that their oilseed rape was not invasive<sup>29</sup>, has shown that errors due to low sampling effort are enormous and often over 100%. It concluded that:

*“In general, any sampling effort of < 3years (regardless of the number of sites) provided a very poor estimate of [oilseed rape] rate of increase. If this example portends a general trend, then experimental assessments of GEO risks will **require several years of data**, with shortcuts to speed up the process coming at high cost in terms of predictive power”.*<sup>82</sup> (emphasis in original)

None of the experimental data presented by PGS in their marketing application gives data which reaches the standards which are obviously needed to come to a proper assessment of ability to colonise or invade. Experiments were mainly conducted for only one year and the species used in studies of competitiveness were restricted to other oilseed rape varieties, wheat and white mustard. Although it might seem unlikely that only one or two genetic changes could alter the behaviour of a well known crop plant it has been noted that:

*“...[oilseed rape] exhibits a greater plasticity [than other UK crops] in the face of environment changes e.g. seed production and timing of flowering. The plasticity is more reminiscent of a wild plant than a highly bred crop.”*<sup>9</sup>

Furthermore, when ACRE considered that GE oilseed rape would not become established in the environment, or at least not outside disturbed land such as road verges, they effectively excluded part of the environment from being subject to normal assessments of harm. Constructing road verges and disturbed land as somehow distinct from the ‘natural’ or ‘agricultural’ environments is a separation which may neither recognise people’s appreciation of such land or be scientifically justifiable as it is unlikely they are valueless barren wastelands in ecological terms.

Although some studies have shown that feral populations on verges of the M25 motorway are transient<sup>83</sup>, others have shown that there are persistent populations in some areas<sup>28</sup>. Research has established that “transgene movement to non-genetically-modified fields or ‘feral’ populations is likely following commercial release”<sup>28</sup>.

In addition, there are considerable uncertainties surrounding how the pattern of feral populations may evolve depending on a variety of factors. As one study cautioned when concluding that glufosinate tolerance is unlikely to affect the survival of feral populations significantly: “This assertion takes no account of future changes in glufosinate application in non-agricultural situations, or pleiotropic effects of the transgene, or of effects on agricultural volunteers”<sup>27</sup>.

However, as one ex-member of ACRE, Professor Mark Williamson, has concluded in this context: *“Despite these demonstrations that **much of the biology of B. napus has been misdescribed**, the earlier risk assessments have not been revisited*

current status of the approvals, with final approval for food use still awaiting the signature of the French authority. A positive opinion on its food safety was given by the UK’s ACNFP in 1994 - before the Novel Foods Regulation was in place. As yet, the oilseed rape has not been placed on the plant variety list.

**Table 2: The safety regulations used to assess PGS’ glufosinate resistant oilseed rape.**

Regulation	Purpose Applied For	Approval Date
Deliberate Release Directive	Growing - via UK authority	By EU: 28th February 1996
Deliberate Release Directive	All uses including food - via French authority	By EU: 6th June 1997. Awaiting final consent to be issued by France.
Voluntary assessment by Advisory Committee on Novel Foods and Processes	Food safety	20th February 1994. Voluntary approval by UK Minister.
Plant Variety registration*	Distinctness, Uniformity, Stability and Value for Cultivation and Use	Trials completed, awaiting entry onto register.
Control of Pesticides Regulations*	Safety and efficacy of using glufosinate on PGS oilseed rape	Licence application currently being assessed by PSD

\* Not associated with GE status

Are the licensing regulations comprehensive and rigorous? The following sections consider the potential risks that may be associated with the commercialisation of oilseed rape and how well they have been addressed under the regulations in the UK.

***None of the experimental data presented by PGS in their marketing application gives data which reaches the standards which are obviously needed to come to a proper assessment of ability to colonise or invade.***

## ENVIRONMENTAL RISKS

The potentially harmful environmental effects of the use of GE crops include the transfer of the foreign gene(s) into wild native flora and the crop behaving unexpectedly and becoming a troublesome weed or disrupting ecosystems by displacing native flora. There could also be unanticipated effects on wildlife if genetic changes do not prove to be stable in the long term. All these effects could alter natural biological and genetic diversity.

With herbicide resistance there are also risks associated with the altered usage of the herbicide. As well as these direct effects, there is the potential for indirect effects on the course of agricultural practices such as continuing chemical inputs. Implications for farmers such as potential problems with herbicide resistant weeds, contractual agreements as a result of patenting of seeds, and consumer acceptance also complicate the risk picture. These risks are interwoven and interdependent. Agricultural practices, for instance, may affect the likelihood of the emergence of weed problems.

This section considers these risks and questions the extent to which they are addressed in present day regulations by using PGS' oilseed rape as a specific example.

### Gene Flow

Because GEOs are living organisms which are able to reproduce and replicate in the environment, it is possible that they could breed with native species and transfer the gene(s) which have been introduced into them. These foreign genes, which could not have entered the native gene pool through natural mechanisms, may become established and alter the genetic diversity of native flora and fauna. This is a process known as 'gene introgression' and the likelihood of its occurrence is, to a great extent, influenced by the presence of related organisms with which the GEO can successfully breed.

In the case of oilseed rape, gene flow to native flora in the UK is inevitable. Oilseed rape is one of the few major crops which originated in Europe and many related species are found in close proximity. Table 3 lists the wild related species of oilseed rape found in the UK, their distribution and their ease of hybridisation with oilseed rape. As well as the presence of compatible species, successful gene introgression also requires the resulting hybrids to be fertile and able to backcross with the native species and the gene to become stably integrated in the genome<sup>13</sup>.

*detected in this study.... Given the nature of the releases, i.e. their comparatively small scale, their isolation from other crops and use of land that had no record of growing oilseed rape for at least ten years previously, it is not surprising that the local incidence of cruciferous weeds was low and that few opportunities for cross pollination occurred".<sup>79</sup>*

No recommendations have been made that monitoring should be a condition of the commercial scale release.

### • ***Transgenic oilseed rape will not be a serious weed?***

The conclusion ACRE reached was that herbicide resistant oilseed rape will only colonise disturbed and semi-managed land to the same extent as traditional varieties of oilseed rape and that it will be no more of a problem weed than them. Is this an acceptable situation and are the assumptions surrounding the lack of weediness soundly based?

In their environmental impact assessment, PGS refer to characteristics of plants which tend to make them more or less weedy (likely to persist and be troublesome in managed or semi-managed environments) and are known as 'Baker's characteristics'. However, much work has been done that shows Baker's characteristics are poor predictors of weediness and that, in general, this is not predictable<sup>80</sup>. PGS also relies on work undertaken with one of their glufosinate and kanamycin tolerant GE oilseed rapes which showed it was no more weedy or invasive than other varieties of oilseed rape<sup>29</sup> although, this work did not consider the selection pressure that could be exerted by the presence of glufosinate. However, PGS has told GeneWatch that licence applications have been made in the UK to use glufosinate both in the hybrid production system and on the hybrids sold to farmers<sup>81</sup>. Use with the hybrids themselves is highly significant because in the application to the Department of the Environment in 1994 for commercial release of the PGS oilseed rape, the emphasis was on the hybrid system alone. The presence of the glufosinate resistance gene in the final crop was presented as incidental and unimportant. In their marketing application, PGS describe the oilseed rape as:

*".. a new hybridisation system.... Linkage of... the hybrid system to a marker - a [glufosinate] tolerance (active ingredient of e.g. Basta, Hoechst) - establishes a comfortable tool for controlled integration of the system in breeding schemes and seed production" (Part B - Information about application to be included on the public register)<sup>73</sup>.*

This use as a 'marker' gene has clearly differentiated the PGS oilseed rape from other herbicide resistant oilseed rape in the mind of ACRE<sup>72</sup>. However, the use of herbicide with the crop could materially affect the risk estimate as it could influence the rate of emergence of herbicide resistant weeds by increasing selection pressure. In their evaluation ACRE may have considered the selection pressure that would be exerted by glufosinate would be low. The changed circumstances following the takeover of PGS by AgrEvo mean there will be a much greater selection pressure for the emergence of glufosinate resistant weeds than ACRE may have thought possible because the use of glufosinate will now extend beyond the hybrid seed production stage to its growing by farmers.

***No recommendations have been made that monitoring should be a condition of the commercial scale release.***

***In the case of oilseed rape, gene flow to native flora in the UK is inevitable.***

***With the advent of GE crops, the transfer of completely novel genes into native flora seems inevitable.***

Therefore, the opinion of ACRE that “*The likelihood of any hybrids of herbicide resistant rape and wild relatives surviving and establishing was deemed to be very low, and therefore such hybrids would not pose a risk either to ecosystems or to man’s property*” now seems unreliable. When the decision was made in 1994, the requirement for information about gene flow was only just being recognised. Before that time, basic information about gene flow from crops was almost non-existent. Now that people are beginning to look, they are finding that gene flow has always taken place from non GE crops to wild relatives. For example, the frequency of marker genes from cultivated sunflowers was found to average 28% in wild sunflowers, leading the researchers to conclude that when genes were neutral or favourable in effect they would transfer and persist in wild populations<sup>76</sup>. With the advent of GE crops, the transfer of completely novel genes into native flora seems inevitable.

• ***Gene flow is unimportant?***

However, the general tenor of ACRE’s advice is that even if gene flow to wild species did occur that this is unimportant. In part, this will have arisen from the definitions of environmental harm they have been involved in developing. The relevant DOE guidance note defined harm in relation to disruption of ecosystems and population disturbances in a manner which conveys the impression that it is straightforward to categorise it as ‘severe, moderate, low or negligible’<sup>77</sup>. It also makes the assumption that genetic pollution *per se* is not harmful unless it is connected with a measurable change in species numbers or selected ecosystem parameter.

However the previous gene flow from conventional crops does not necessarily justify gene flow from unrelated species as may have been ACRE’s view. Because any harm will be irreversible, the decision about acceptable harm should be a matter for wider social debate, particularly given the considerable scientific uncertainty which affects confidence that can be placed in any present day estimate. Using a similar approach to harm, mistakes have been made with the regulation of chemical discharges. Although these are assessed on a case-by-case basis, their distribution to remote parts of the world such as Antarctica, and their accumulation in animals at the top of the food chain, were never predicted.

Whilst sounding confident that no harm to the environment will arise as a result of the commercial use of GE oilseed rape, ACRE have exposed some anxieties about their own decision. They have called for research which monitors the impacts of the crop and the Department of the Environment have funded a research project as a result of this. Advisors have admitted that commercial use would provide a large-scale experiment<sup>78</sup>.

Whilst preliminary results of the DOE work show that the reassurances that were hoped for may not be forthcoming and the scientific uncertainty remains unresolved. For example, one of the conclusions of the DOE monitoring project which has used UK National List Trials to look for evidence of gene flow to weeds was that:

*“No pollination of oilseed rape and other [related species] has so far been*

**Table 3. Native and introduced species which are related to oilseed rape, their distribution and ability to hybridise with oilseed rape** <sup>5,15,17,19,26</sup>

Species	Distribution	Ability to Hybridise with Oilseed Rape
Brassica napus - feral oilseed rape	widespread on verges, railways, gardens and other disturbed and waste land	no barriers to hybridisation as the same species
B. rapa (syn. B. campestris) - wild turnip/field mustard	as for B. napus	hybrids occur naturally and is listed in UK flora
B. oleracea ssp oleracea - wild cabbage	coastal cliffs and as short-lived local escape from gardens and allotments	difficult but reported with manual pollination
B. nigra - black mustard	locally abundant on river banks, cliffs and shingle in England and Wales	crosses reported but difficult to reproduce experimentally
Hirschfeldia incana (syn B. aprissa) - hoary mustard	sporadic throughout England	crosses in field conditions with B.napus as female
Sinapsis arvensis - charlock	abundant throughout England, Wales, Scotland and Ireland	experimental, manual crosses with B.napus as female
S. alba - white mustard	throughout England, Wales, Scotland and Ireland	limited - required ovule or embryo culture for backcrosses
Raphanus raphanistrum - wild radish	possibly native - common on roadsides in England, rarer in Scotland and Ireland	hybridisation demonstrated under natural conditions
Raphanus sativus - garden radish	widely grown in gardens and horticulture	limited - required ovule or embryo culture for backcrosses
B. juncea - mustard greens	introduced 'alien' species - infrequent throughout England and Scotland. Also grown by gardeners for food use.	crosses in field conditions with B. napus as male parent
B. tournefortii - pale cabbage	introduced 'alien' species - infrequent throughout England and Scotland	crosses using hand pollination
B. carinata - Ethiopian rape	introduced 'alien' species - rare south England	hybridisation possible but low fertility
B. elongata - long-stalked rape	introduced 'alien' species - rare southern England	hybridisation difficult
B. fruticulosa -	introduced 'alien' species - endemic to Mediterranean, recently discovered in Dublin	experimentally using ovary culture

Oilseed rape is thought to have evolved as a hybrid between the wild turnip (*B. rapa*) and the wild cabbage (*B. oleracea*)<sup>14</sup>. Feral or ‘escaped’ populations of oilseed rape are now widespread throughout the UK, especially on disturbed and waste land, thus providing one avenue of gene escape due to their complete compatibility with cultivated oilseed rape. The situation with other species varies. The production of hybrids under experimental field conditions has been demonstrated with the wild radish (*Raphanus raphanistrum*)<sup>15</sup>, wild turnip (*B. rapa* syn. *B. campestris*)<sup>16</sup>, hoary mustard (*Hirschfeldia incana* syn. *B. adpressa*)<sup>15,17</sup> and mustard greens (*B. juncea*)<sup>13</sup>. To date, in most other potentially compatible species (see Table 3), the experimental data suggests that interventions such as hand pollination or ovary culture are needed to produce hybrids<sup>18,19,5</sup>. These differences arise in part because the ability to form fertile hybrids is influenced by the ability for chromosome pairing to take place<sup>15</sup>. The variety of oilseed rape also influences its ability to hybridise<sup>20</sup>.

The fertility and fitness of any hybrids produced affects the likelihood of gene introgression. Hybrids of oilseed rape with hoary mustard perform well relative to hoary mustard itself<sup>7</sup>. Hybrids between oilseed rape and wild radish are vigorous and grow well although they are of low fertility<sup>21,22</sup>. However, although low fertility has been a feature of oilseed rape hybrids in many reports<sup>23,24</sup>, fertility can be restored on subsequent backcrosses to the parent plant. In the case of hybrids with wild turnip, wild turnip-like plants with high fertility and carrying a glufosinate transgene were produced after the first-backcross generation<sup>25</sup>. Similarly, wild radish hybrids containing the glufosinate transgene showed morphology and fertility close to the parent after four generations of backcrossing<sup>26</sup>. When wild turnip was planted in a field of oilseed rape, 91% of the germinated seeds were hybrids<sup>16</sup>.

There are other factors which increase the likelihood that low frequency hybridisation events, detected by small-scale experimental trials, will arise under conditions of commercial growth. Firstly, oilseed rape is grown on a massive scale in the UK which means that even a rare event may well occur. Therefore, the low frequency with which hybridisations take place in experiments cannot be equated with safety. As more varieties of GE oilseed rape are commercialised, the likelihood of harm will be increased.

Secondly, pollen from oilseed rape can be transported by both air and insects over long distances. Although the density of pollen concentration declines exponentially from field margins, low densities have been recorded 1.5 to 2.5 kilometres from commercial fields of oilseed rape<sup>27</sup>. These are much larger distances than were estimated from small scale field trials<sup>28</sup>. The ranges of both wild radish and turnip overlap with oilseed rape growing areas<sup>5</sup> and, in one survey in Scotland, between 31 and 42% of feral populations of oilseed rape were within 360 metres of an oilseed rape field<sup>27</sup>. Thus, there is close proximity between cultivated oilseed rape and populations of plants into which gene introgression may occur. Large amounts of pollen may not even be needed for cross-fertilisation of some species. For instance, because the wild radish is not self fertilising and relies on other plants for fertilisation, the chance of hybrids being produced actually increases even if only a few plants exist in a field of oilseed rape<sup>21</sup>.

The major uncertainties and assumptions in ACRE’s analysis of the risks and reassurances of safety are:

- that gene flow to wild species will be minimal
- that gene flow is unimportant
- that transgenic oilseed rape will not be a serious weed
- that transgenic oilseed rape will not colonise the natural environment
- that the risks of herbicide use and herbicide resistance can be safely separated.

Each of these is considered in turn.

• ***Gene flow to wild species will be minimal?***

When ACRE gave their advice in 1994, there was a great deal of ignorance about gene introgression into wild species in the UK. ACRE were in the position of having to make a judgement based on extrapolation from a very limited range of experimental studies provided in the PGS application and in the scientific literature. In their application for commercial use<sup>73</sup>, PGS concluded that “chances for successful exchange of genetic material are extremely low and practically limited to closely related species (*B. campestris*) [wild turnip] and (*B. juncea*) [wild mustard]”. They had used these two species in backcrossing experiments of their own to demonstrate the location of the foreign genes on a particular chromosome.

In addition to the PGS application, ACRE will have relied in part upon up-to-date reviews such as that co-authored by ACRE member, Philip Dale<sup>74</sup> of the John Innes Centre in Norwich as well as reviews commissioned by the DOE<sup>75,5</sup> and MAFF<sup>19</sup>. The DOE research, completed in 1992 but with additional references added later, concluded that oilseed rape fell into the category of “low probability of gene flow to wild relatives”. Hybridisation with wild relatives was thought extremely unlikely and “...the only realistic candidate species for natural hybridisation and introgression is the wild turnip *B. rapa*.... The hybrid is .. unlikely to persist. There is the remote possibility of fertility being restored” (p 42). There is no reference to the emerging work on hybridisation of oilseed rape and wild relatives under field conditions.

Whilst giving a more thorough analysis of the potential for gene introgression, the review by Scheffler and Dale<sup>74</sup> concluded that “Even where there is a possibility of hybridisation between *B. napus* and a related species growing in the vicinity of a release, poor vigour and high sterility in the hybrids will generally mean that hybrids and their progeny will not survive in either the agricultural or natural habitat”. The MAFF review, whilst less detailed, did stress the uncertainties and need for vigilance.

Since these reviews, and since ACRE made its recommendations, new research has undermined the feeling that gene flow would be unlikely. The formation, under field conditions, of vigorous hybrids between oilseed rape and hoary mustard, wild radish and wild turnip is now well described (see *Environmental Risks* section above).

***When ACRE gave their advice in 1994, there was a great deal of ignorance about gene introgression into wild species in the UK.***

***As more varieties of genetically engineered oilseed rape are commercialised, the likelihood of harm will be increased.***

effectively treats agricultural land and farming (man's property) as separate from the environment (ecosystems).

When considering herbicide resistant oilseed rape, ACRE's view was that:

*"...the herbicide tolerance gene was likely to spread in the environment through transfer of pollen to other rape crops, thereby giving rise to herbicide resistant volunteers. There was also a small chance that the gene would spread to wild relatives of rape, giving rise to herbicide resistant hybrids. Herbicide resistant volunteers could be a problem in other crops because they would compromise farmers' ability to use the particular broad spectrum herbicide to which they are tolerant for their control (assuming he would have done so in the normal course of events). However, the Committee was of the opinion that sufficient other herbicides or management practices existed for the control of volunteers, and therefore there would be no harm to man's property arising from this situation. There was also felt to be sufficient means of control should herbicide resistant volunteers spread beyond agricultural land, for instance to disturbed land or road-sides.*

*"It was thought extremely unlikely that the modified rape could cause interference with ecosystems outside the agricultural environment since rape is not known to invade natural habitats, and the herbicide resistance gene would not alter its ability to invade. The likelihood of any hybrids of herbicide resistant rape and wild relatives surviving and establishing was deemed to be very low, and therefore such hybrids would not pose a risk either to ecosystems or to man's property. This was not a unanimous view. A minority in the committee felt there were still uncertainties surrounding the extent to which the herbicide genes would spread to wild relatives, and the extent to which this could be regarded as contamination of the gene pool".<sup>71</sup>*

They have also said that:

*"the consequences in terms of harm to the environment were likely to be low...because glufosinate ammonium does not currently play an important role in weed control in agricultural or non-agricultural situations where feral oilseed rape populations or compatible weed species occur. Also, suitable alternative herbicides, and other management strategies are available for effective control if necessary".<sup>72</sup>*

The position of ACRE is, therefore, that there is little likelihood of harm arising to the environment from the use of the PGS oilseed rape as a result of the genetic engineering itself. Any harm to agriculture (man's property) could be controlled by the use of other herbicides. However, ACRE have also said that the following issues which they are concerned about are outside their remit because they fall under the responsibility of pesticides regulations<sup>72</sup>:

- the possible replacement of one herbicide with another of greater toxicity, persistence or mobility in the environment
- increased herbicide use and its effects on human health and the environment
- potential effects of metabolites on human and environmental health.

Thirdly, the effect of the introduced gene(s) may influence the likelihood of gene introgression. Foreign genes introduced into crops by genetic engineering have a major effect on the phenotype, changing it in ways not normally found in the native plants<sup>21</sup>. If the introduced gene gives a competitive advantage, a hybrid containing the gene may be better able to persist and flourish compared to the parent plant. In the absence of glufosinate, **there is no evidence that the glufosinate resistance gene gives a disadvantage** over and above the expected difficulties of hybrid formation between oilseed rape and wild turnip and radish<sup>25,26</sup>. When grown in natural habitats, the PGS oilseed rape performed as well as non-engineered varieties, suggesting that the added genes were not reducing performance<sup>29</sup>. However, if a hybrid comes into contact with the herbicide it will undoubtedly have an advantage over susceptible species.

It therefore appears that there is real potential for gene transfer from PGS' glufosinate resistant oilseed rape to feral populations of the plant, to hoary mustard, wild turnip, wild radish and mustard greens. All except mustard greens, which are grown by gardeners, are common species in the UK. Gene flow to other species seems less likely on current knowledge but further research may increase the list of species at risk. The question is, therefore, 'If gene introgression occurs - does it matter?'

There are several causes for concern over foreign gene introgression into native flora. These include matters of immediate practical importance and more intangible concerns about altering genetic diversity so fundamentally and what this means for future generations. The impacts of gene flow may not be recognised for many decades. The impacts of exotic, introduced species such as rhododendron, which is invading marginal agricultural land, decreasing grazing and displacing native flora in places such as Wales, have taken many years to become evident<sup>30</sup>.

Alterations to the genetic makeup of plants could make them 'fitter' and create problem weeds for farmers or alter local ecosystems. Natural hybridisation between crops and related flora has already resulted in the emergence of problem weeds. In Europe, for instance, hybrids between sugar beet (*Beta vulgaris*) and wild beet (*Beta vulgaris* ssp *maritima*) have led to the emergence of a weed species which causes considerable problems for sugar beet farmers<sup>31</sup>. In Canada, the wild radish is a major weed of oilseed rape and is thought to have evolved following hybridisation between cultivated radish (*Raphanus sativus*) and a weedy relative<sup>32</sup>. In India, rice growers developed a variety with a red colour to aid weeding although the advantage was short lived as wild rice, which had high selection advantage, also acquired the pigmentation gene<sup>33</sup>. Predicting how a plant will behave is notoriously difficult. Although poor fertility of hybrids has been perceived as lowering the risk, studies have shown that a genotype of the plant *Arabidopsis thaliana* with inferior seed production, could invade natural habitats as well as the wild type<sup>34</sup>.

As well as increasing the fitness of a native plant, gene introgression could have the opposite effect and lead to reduction in numbers or local extinction of a species. This is thought to have contributed to the extinction of wild rice in Taiwan where loss of seed dormancy and vegetative propagation were associated with introgression of genes from cultivated varieties<sup>33</sup>.

***The position of ACRE is that there is little likelihood of harm arising to the environment from the use of the PGS oilseed rape as a result of the genetic engineering itself.***

***The impacts of gene flow may not be recognised for many decades.***

Once gene introgression has taken place, it will be irreversible - because genetically engineered traits have major effects, the gene pool will have been changed dramatically.

## Herbicide Use

The cultivation of PGS' oilseed rape in partnership with glufosinate will alter patterns of use of the herbicide and increase its overall usage. Indeed, the development of glufosinate resistant crops to increase sales of glufosinate is considered to be AgrEvo's underlying aim in entering this market in the first place<sup>35</sup>. Increasing glufosinate usage will inevitably result in considerable damage to the environment.

Glufosinate is a broad spectrum contact herbicide with some systemic action as absorbed glufosinate is translocated through the leaves. Glufosinate acts via inhibition of glutamine synthetase leading to accumulation of ammonium and inhibition of photosynthesis<sup>36</sup>.

The persistence of glufosinate in the environment depends upon the conditions, including soil type and temperature. A half life of up to 20 days is quoted in pesticides manuals<sup>36</sup>, but much longer half lives of over 60 days have been recorded<sup>37</sup>. Because glufosinate is highly soluble in water and can be leached from soil, contamination of groundwater may occur. This is of particular concern because glufosinate is toxic to aquatic life. The UK's Advisory Committee on Pesticides have restricted the use of glufosinate to the period between March and September because "under certain conditions significant run-off or leaching could occur, leading to contamination of ground or surface water"<sup>38</sup>.

Because glufosinate is a broad spectrum herbicide, it kills all green plants and increased usage would further erode biodiversity. Until the advent of GE resistant crops, its use was restricted to pre-emergence and as a desiccant pre-harvest. By displacing more specific herbicides it may have negative effects on plant diversity in the crop and in the field margins. The use of herbicides has already caused serious harm to ecosystems. Herbicide use has been associated with the decline in ten rare or scarce arable flowers and led to alterations in flora associated with the dominance of more resistant species such as black grass (*Alopecurus myosuroides*) and cleavers (*Galium aparine*). Glufosinate has been shown to cause changes in field margin flora up to a year after spraying compared to untreated plots<sup>39</sup> suggesting that it will perpetuate such impacts.

However, the impacts of herbicides are not restricted to direct effects on plant species. The decline in some bird species has been attributed in part to the use of herbicides. The loss of invertebrate populations normally associated with weeds is considered to have led to declines in partridge breeding. Some farmland, seed eating birds such as the linnet (*Carduelis cannabina*), tree sparrow (*Passer montanus*) and skylark (*Alauda arvensis*) are thought to have declined as a result of herbicides removing grass weeds and species such as chickweed (*Stellaria media*) and fat hen (*Chenopodium album*), which form important sources of winter

## THE REGULATORY ASSESSMENT

Making an assessment of how the regulatory system copes with the risks of GE oilseed rape is often hampered by a lack of detailed justification for advice or decisions. ACRE and ACP only supply short descriptions of their judgements although the ACNFP supplies greater detail. Documents unrelated to particular decisions give some indication of general thinking and social science research which has involved interviewing members of some of the committees also sheds some useful light. In general, however, the system is rather impenetrable and difficult for outsiders to challenge. It is also obviously fragmented in rather inexplicable ways which makes evaluation difficult. This report first looks at the environmental impact assessment by the Department of the Environment (DOE) before considering MAFF's evaluation of food safety and pesticide licensing.

### Environmental Impacts

The European Deliberate Release Directive covering the release of GEOs to the environment aspires to being precautionary. Before testing or commercial use GEOs must be assessed according to certain criteria laid down in the Directive. Information is gathered by a gradual increase in scale of experiment from laboratory to greenhouses to field trials. By examining each proposed release of a GEO in turn in this way, it is hoped that harm will be prevented. It is the characteristics of the GEO and an assumption that each individual genetic change will alter the whole organism in a largely predictable, deterministic and manageable way that underpins the rationale. However, the systems of use (both agricultural and food production) are often less rigorously addressed, tending to rely upon a set of value judgements about these systems that are debatable. It is this 'out of context' approach and lack of regard for the uncertainties involved that undermines the confidence that can be placed in regulations.

### ACRE's view of herbicide resistant oilseed rape

In the UK, the Minister of State for the Environment is advised by ACRE on the environmental safety of commercial releases of GE crops. ACRE considered the PGS application in the first half of 1994. They recommended (with one expert dissenting - Julie Hill) that the use of the oilseed rape should be allowed for hybrid seed production and growing subject to the following conditions:

- only the varieties described in the application could be grown
- that they must not be used for human or animal feed unless given approval by relevant authorities.

Under Section 107(6) of the Environmental Protection Act 1990, "harm means harm to the health of humans or other living organisms or interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property". In their evaluation, ACRE tend to split harm into two categories - ecosystems and man's property. This

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genetic engineering, there are also questions about the safety of any metabolites remaining in the plant.

Glufosinate resembles one of the brain's chemicals, glutamine, which transmits nerve impulses. Glufosinate also inhibits glutamine synthetase in mammalian cells and particularly in the liver. Laboratory studies of acute effects show that glufosinate is neurotoxic to a range of mammalian species with dogs in particular being among the most sensitive to its effects<sup>37</sup>. Chronic effects include neurological signs in dogs and effects on blood cells and coagulation in rats<sup>37</sup>. In humans, using glufosinate to attempt suicide, neurological symptoms including convulsions and short-term memory loss are seen<sup>67</sup>. Based on animal studies, glufosinate is generally considered not to be teratogenic or carcinogenic, but recent studies have shown that it can have teratogenic effects on rat and mouse embryo cultures<sup>68</sup>

Formulations often include compounds which increase penetration into the leaves of plants and these can also act to increase uptake through the skin and cause irritation. It was this concern, among others, that led the ACP to allow only a provisional licence for glufosinate compounds<sup>38</sup>. The surfactant in preparations also causes circulatory collapse in attempted suicide cases and is probably responsible for deaths which occur<sup>67</sup>.

It is farm workers who will be most at risk from these sorts of toxic effects if their exposure rises as a result of increased use of glufosinate. Experiences with chronic exposure to organophosphates cautions against increasing exposure to even low levels of other neurotoxic chemicals.

In glufosinate resistant oilseed rape, glufosinate is metabolised to N-acetyl-L-glufosinate. Adverse effects of this compound have been studied by AgrEvo who attributed toxic effects in short term and subchronic experiments on rats, mice and dogs to contamination of the test material with 4.5% of the parent compound, glufosinate<sup>69</sup>. The same studies showed that when administered orally to rats, approximately 10% of N-acetyl-L-glufosinate was converted back to glufosinate, presumably by the gut flora. Thus, if residues of N-acetyl-L-glufosinate are found in the PGS oilseed rape, it will be important to consider the toxicity of both the compound itself and glufosinate. This issue will be important not only for human consumers but also for any animals fed on the product. Glufosinate is currently licensed for use as a desiccant with oilseed rape and other crops such as potatoes, peas and wheat. The licence conditions state that it must not be used if straw is to be used for animal feed or bedding<sup>70</sup>. Residues will be much lower in seed but there are obviously important questions to be addressed.

seeds for these birds<sup>40</sup>. When herbicide inputs are reduced in conservation headlands, increased populations of butterflies and other invertebrates clearly demonstrate the harmful effects they are having.

***Experiences with chronic exposure to organophosphates cautions against increasing exposure to even low levels of other neurotoxic chemicals.***

## AGRICULTURAL RISKS

The introduction of GE crops will change the face of modern agriculture. Although the benefit for farmers from using GE crops is claimed to be increased yields, this may come at a sizeable cost and be short lived. Farmers will have less room for independent choices as they purchase packages of seeds and chemicals from agrochemical companies and agree to specific licence agreements on patented seeds. Controlling herbicide use will become more complex as records will need to be kept of which crops were grown where and what volunteers may be resistant to. This section considers the possible risks for farmers accompanying the use of PGS' herbicide resistant oilseed rape.

### Weed Control

There are two ways in which weed problems may increase as a result of using herbicide resistant oilseed rape - herbicide resistant volunteers or the emergence of herbicide resistant weeds. Herbicide resistant volunteers are considered inevitable:

*“Herbicide-tolerant rape will undoubtedly become part of established volunteer weed populations that occur in many cereal rotations...”<sup>41</sup>*

Volunteer weeds arise when seed from one crop survives and emerges in different crops grown in the following year or years. It has been estimated that over 750,000 hectares of cereal rotations in the UK are infested with oilseed rape volunteers as weeds and that, because cereals do not always follow rape, over half the volunteers must have come from seed dormant in the soil for at least two years<sup>42</sup>. Not only may volunteers cause yield losses in the following crop, but if varieties intended for industrial uses emerge in oilseed rape intended for food use, they may become contaminated with erucic acid or glucosinolates.

The appearance of herbicide resistant volunteers from GE oilseed rape could arise in one of three ways. Firstly, seed will be shed in the field at harvest time and volunteers emerge in the same field the following season(s). Up to 10,000 seeds per square metre may be left after harvest<sup>42</sup>. Secondly, there may be spillages of seed during transport on the same farm or between farms as the use of contractors for harvesting is common practice. Thirdly, a field of GE oilseed rape may pollinate plants in neighbouring fields so the seed they produce is herbicide resistant. Research in Germany has shown that the glufosinate resistance gene can be transferred to crops in fields 200 metres away<sup>43</sup>.

One of the most important factors in predicting the impact of herbicide resistant volunteers is the dynamics of the seed bank. The natural seed bank is the soil's buried seed which may germinate in the future. If the seed bank contains high levels of viable oilseed rape, it is more likely that volunteers will emerge and be problematic. The dynamics of the oilseed rape seed bank depend critically on the density dependent fecundity of the seed and management practices<sup>41</sup>. However, knowledge of density dependent fecundity is very limited and experimental studies have had difficulty replicating the persistence of oilseed rape seed which clearly

crop which is used for human consumption and only trace amounts of protein (if any) remain in the oil after the extraction process. But, whilst many of the basic characteristics which tend to make a protein allergenic are known, there are always exceptions<sup>63</sup>. Laboratory tests will never be foolproof. So, although very little protein should enter the food chain, if it does, it will not be possible to be completely certain it will not prove to be allergenic in the future. The same proteins will be found in other crops which AgrEvo are also engineering for glufosinate resistance. When eaten, these could sensitise people to proteins found in trace amounts elsewhere. A large food producer has told GeneWatch that they avoid peanut oil in their products because of the *remote* risk that trace amounts of peanut proteins could find their way into products and trigger dangerous and possibly life threatening allergic reactions in susceptible individuals.

### Antibiotic Resistance

Whether the neomycin/kanamycin resistance gene (coding for the NPT-II protein) could be transferred to bacteria in the gut and lead to increased resistance in pathogenic bacteria is also an important safety question. The resistance gene is a remnant of the genetic engineering technique and serves no function in the oilseed rape. Because of their toxic effects on the kidney and hearing, the use of neomycin and kanamycin has largely been superseded by newer antibiotics in human medicine. It is only in very rare cases of multiple drug resistant tuberculosis that kanamycin would be used. In veterinary medicine, neomycin is more widely used in topical creams and for treatment of intestinal infections<sup>64</sup> although its use is discouraged<sup>65</sup>. The main site where gene transfer could occur is in the intestine of animals fed oilseed rape meal as a protein supplement. The treatment processes used in production of oilseed meal should result in the degradation of most of the NPT-II gene. However, if genetic material does survive these processes, it is possible for gene transfer from the meal to gut bacteria to occur as genetic material may escape degradation in the stomach if protected by other food ingredients.

The potential for such transfers to take place was the basis of the UK Government's objection to an application for a commercial licence for a maize plant which contained an ampicillin resistance gene. Although ampicillin is a much more important antibiotic clinically than neomycin and kanamycin, why any risk of this nature should be tolerated is unclear. ACRE have recently recommended that 'it is good practice not to insert into plants unnecessary genes which have no purpose in the GM plant'<sup>66</sup>.

### Glufosinate Use

If the use of glufosinate increases as a result of the use of the PGS oilseed rape, this could have consequences for human health if exposure increases because glufosinate is not only toxic to plants, it can also affect humans. Increased worker and consumer exposure could arise if application frequencies and residues rise. However, because the glufosinate is metabolised in the plant as a result of the

***A field of GE oilseed rape may pollinate plants in neighbouring fields so the seed they produce is herbicide resistant.***

***Increased worker and consumer exposure could arise if application frequencies and residues rise.***

## HUMAN HEALTH RISKS

Another area where considerable concern has been expressed is whether the products of GE crops will be safe to eat. When a foreign gene is introduced into a plant, it produces a new protein coded for by that gene. The new proteins produced by the PGS oilseed rape are shown in Table 4.

**Table 4. Novel proteins produced by PGS' oilseed rape.**

Gene	Protein	Action
neo	neomycin phosphotransferase II - NPTII	breaks down neomycin and kanamycin and thus confers resistance to them
pat	phosphothrinocin acetyl transferase	breaks down glufosinate and thus confers resistance to it
barnase	a ribonuclease	prevents pollen production
barstar	ribonuclease inhibitor	inhibits the ribonuclease and thus allows pollen production to take place

These give resistance to neomycin, kanamycin and glufosinate together with those giving male sterility and fertility restoration. The presence of these proteins has raised safety concerns for two reasons. Firstly, the incidence of food allergies is increasing and this is thought to be associated with the growth in production and consumption of processed foods and the novel proteins they contain<sup>61</sup>. The presence of more new proteins from GE crops has raised the possibility that they will perpetuate this trend. Secondly, the presence of an antibiotic resistance gene means that antibiotic resistance problems could be increased if the gene is transferred to gut flora.

In addition the increased use of chemical herbicides could lead to higher residues in food and increased worker exposure.

### Allergies

Testing for new allergens is extremely difficult and never foolproof. If genes from well known allergenic species such as nuts are transferred, testing is more straightforward as it is possible to conduct tests using human volunteers known to be allergic. This has already proved to be the case when a brazil nut protein gene was transferred into soybean to improve its methionine content<sup>62</sup>. Development of the crop was halted. This was only possible because the source of the gene, the brazil nut, is a well known allergen.

In the case of the novel proteins in the PGS oilseed rape, very few are likely to reach the human food chain in large amounts. This is because it is the oil from the

takes place in practice<sup>42</sup>. It has been concluded that "sensitivity to management practices suggests that seed bank levels will be *substantially more difficult to control* if the efficacy of the herbicide is compromised" (emphasis added)<sup>41</sup>.

Problematic weeds may also arise if there is gene flow to wild species which then become troublesome or more troublesome weeds in crops. The potential for gene introgression has been discussed above. Although, on current knowledge, gene introgression into charlock (*Sinapsis arvensis*) seems less likely than for other weed species such as wild turnip, if it did arise it could cause particular problems. Charlock commonly grows within oilseed rape crops and flowers simultaneously<sup>19</sup>.

The increased use of glufosinate will also add a selection pressure for the natural evolution of resistance in weeds. In 1997, about 20% (over 800,000 hectares) of the oilseed rape grown in Canada was glufosinate resistant (known as 'Liberty Link' canola)<sup>44</sup>. If a similar scale of use was seen in the UK, the pressure for emergence of herbicide resistant weeds would be enormous.

### Yield, Stability and Unexpected Effects

It is important that farmers feel they have a reliable crop that will perform well. Little data is in the public domain about the performance of the PGS oilseed rape in Europe. That data which is available comes from a joint European Commission, PGS and AgEvo project known as FACTT (Familiarisation with and Acceptance of Crops incorporating Transgenic Technology in modern agriculture). The EC has invested over 1.5 million Ecus in this project with slightly less coming from the partners<sup>45</sup>. The trials under this project show that yields of the transgenic varieties are no better than those of conventional oilseed rape hybrids. Therefore, farmers may have little to gain, especially if seed prices are higher as is expected.

There may also be practical problems if the wrong fields are inadvertently sprayed with glufosinate. This problem has arisen in Canada where there is widespread use of glufosinate resistant varieties<sup>46</sup>. Detailed record keeping will become more important.

Farmers may even have to contend with unexpected events concerning the stability of the herbicide resistance under varying environmental conditions. A body of research shows that when a gene is transferred into another organism a complex set of internal and external factors can influence how and whether it is expressed. If multiple copies of genes are transferred or if the gene is transferred into an area of high methylation<sup>47</sup> the gene may not be expressed or expression may be impaired. The PGS oilseed rape contains only one glufosinate resistance gene and does not appear to be in a hypermethylated region. However, even single genes transferred into unmethylated areas can be methylated with ageing and under conditions of environmental stress<sup>48</sup>.

Backcrosses of a PGS oilseed rape have been shown to lose expression of glufosinate tolerance occasionally<sup>49</sup>. Tobacco which was genetically engineered to be resistant to the herbicide sulfonylurea lost resistance when planted out as

***Trials show that yields of the transgenic varieties are no better than those of conventional oilseed rape hybrids.***

***Testing for new allergens is extremely difficult and never foolproof.***

seedlings<sup>50</sup>. In petunias, the expression of a single maize gene was influenced by age and environmental factors<sup>51</sup>.

These may appear remote risks, but experience with GEOs is so limited that they cannot be ruled out. There have been worrying signs from the commercial use of GE cotton in the USA which show that, despite extensive testing, things can still go wrong in the wider environment. In 1997, farmers in some parts of Mississippi had problems with their GE Roundup Ready cotton which produced deformed bolls or dropped them before harvest<sup>52</sup>. In 1996, Monsanto's GE insect resistant cotton performed badly in some parts of Texas<sup>53</sup>. These cases may or may not have resulted from the instability of the foreign gene(s), but clearly demonstrate how field trials over relatively short periods cannot guarantee a crop's performance. When a major change has been made to a crop, as is the case with genetic engineering (in contrast to traditional breeding where the time scales are longer and change is more gradual), any unexpected effects or lack of expression of a key gene could prove disastrous for the farmer.

### **Contracts With Agrochemical Industries**

Genes, cells, seeds, plants and their offspring are all being patented by the agrochemical industries developing GE crops. A patent gives the patent holder a right to the exclusive use of the invention for seventeen years in exchange for making knowledge about the invention available. Agrochemical industries are used to having patent protection for the chemicals they produce and use this as a way of gaining a protected monopoly for their products. Now, the same companies claim they have 'invented' genes, cells and living organisms and, with the assistance of patent offices in Europe and the USA, are attempting to establish monopoly rights over them.

The implications of patents for farmers is that they will have to pay royalties to the company owning the patent if they wish to keep seed to sow in future years. They may also be asked to enter into legal agreements with the company producing the seed in order to ensure they comply with the monopoly control. Soybean farmers in the USA have been amongst the first to experience such contracts directly. When it was introduced in 1996, farmers had to sign contracts when purchasing Monsanto Roundup Ready soybean seed, promising to use only Roundup on the crop, not to use cheaper non-brand versions of glyphosate, not to keep seed for their own future use, and to allow Monsanto access to their farms for three years after the crop was grown. Since then Monsanto have reduced the inspection requirements because of farmer objections. However, Monsanto is policing the agreement not to keep seed for sowing in future years very closely. Over 100 soybean farmers are reported to have been 'caught' by Monsanto and required to destroy the crop, to make cash payments to Monsanto, and/or to agree to several years of inspections to ensure that saved seed is not planted again<sup>54</sup>.

PGS has taken out patents both for its oilseed rape's herbicide resistance and hybrid production system with the European Patent Office, which give patent protection throughout Europe<sup>55</sup>. Although Greenpeace made a successful

challenge to one PGS patent for glufosinate resistance, restricting the patent to the first generation of seeds produced rather than to all subsequent generations, PGS hold other patents on the final hybrid plant. Hybrid seed is not usually kept for re-sowing, but farmers can expect to have to enter into agreements on other management practices with PGS or AgrEvo when they buy seeds. Judging by the US experiences, these seem likely to restrict farmers' freedom to make choices in how they farm.

### **Consumer Rejection**

Another risk farmers will take if they choose to grow PGS oilseed rape is that there is considerable consumer resistance to GE crops in Europe. The same resistance has not been seen in North America and so the uptake of GE crops there should not be taken as a positive sign for farmers here.

The problem for farmers is twofold. Firstly, public opinion surveys and other research have shown that people are concerned about the use of genetic engineering in food production. They feel it is unnatural and unjustified. This, coupled with the experiences of 'mad cow' disease, has left the European public feeling uneasy about GE crops<sup>56,57</sup>. Secondly, neither the European Union nor the British Government have put a process of segregation in place. Therefore, food producers, retailers and consumers have little choice over whether they use or eat the products of genetic engineering. Labelling schemes are confusing and not comprehensive<sup>58</sup> and unless action is taken before PGS oilseed rape is grown, the situation is likely to get worse. This may lead to a backlash against farmers growing such crops.

Field trials have already been targeted by activists in the UK. The arrival of Monsanto's GE soybean was met with a storm of protest. Conflict is likely to continue as public concerns have largely been disregarded in regulations<sup>59</sup>. Farmers growing the PGS oilseed rape may find they have a confrontation on their hands at worst or, at best, a product that food producers say they simply do not want. Iceland, the UK supermarket chain, has already announced its intention to avoid GE products<sup>60</sup> and others may follow suit.

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