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# GM CROPS, BIODIVERSITY AND THE EUROPEAN AGRI-ENVIRONMENT: REGULATORY REGIME LACUNAE AND REVISION

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The introduction of genetically modified (GM) crops for commercial planting approval and importation under the European Union's (EU's) regulatory process has led to an increasingly visible political debate over the potential impacts of these crops upon the European agri-environment. The potential impacts of GM crops upon biodiversity and farming in the wider European agri-environment are presented, and related to the gaps in the EU's regulatory regime under Directive 90/220. The current revision of the regulatory Directive 90/220 up to the Common Position stage, as agreed by the Council of Ministers, offers some important changes to the environmental risk assessment of the impact of GM crops upon biodiversity and farming. However, the inclusion of wider socio-economic impacts upon agriculture remains incomplete, and such impacts are likely to remain on the political agenda. Copyright © 2000 John Wiley & Sons, Ltd. and ERP Environment.

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## INTRODUCTION

### GM crops and lacunae in the EU regulatory regime – from low to high politics

The introduction of genetically modified organisms (GMOs) into European agriculture moved from experimental field trials to the approval of commercial planting of genetically modified (GM) crops in the mid-1990s. The European Union's (EU) regulation of these releases into the agri-environment (Directive 90/220/EC) has generally failed to take adequate account of the possible wider ecological effects of the release of GMOs, in particular with regard to the potential impacts upon local and regional biodiversity in Europe. In addition, the agricultural impacts of particular GM crops (e.g. modified for herbicide resistance) have often been ignored in the risk assessment process under the regulatory regime's procedures. The boundaries for risk assessment under the directive have been continually contested as new products have been put forward for EU-wide marketing approval, or importation from overseas, under the directive's case by case process (Levidow and Carr, 1996). Debates over the risk assessment boundaries for GM crops have highlighted the need for clearer risk assessment steps to be included in the regulation. The debates have also featured epistemic tensions between the differing perspectives offered by molecular biologists and

ecologists. Certain GM varieties of maize and oilseed rape have gained regulatory approval under the EU process but have been denied market access in individual member states, putting further stress on the regulatory regime. In part, there has been an inherent contradiction to this regulatory regime, that is the attempt to treat differing crop ecosystems within European agriculture as a single environment in order to meet the needs of a single economic market.

GM crop varieties are subject to regulations at all stages of development in the EU. Both EU varieties seeking large scale commercial release and imported varieties can only be released into the European environment if granted marketing licences agreed at Community level under Part C of Directive 90/220/EEC on the deliberate release of GMOs into the environment. The member state that received the initial application notifies breeders of licences. Releases for research and development are granted at national level under Part B of this directive.

Farmers in large crop producing areas, notably in North America and Argentina, grew commercially an estimated 27.8 million hectares of acres globally of GM crop varieties in 1998, and 39.9 million hectares in 1999 (Gene Watch, 2000). These GM crops have been cleared by their government authorities for field characteristics determined by bacterial genes such as tolerance to the broad spectrum herbicides glyphosate and glufosinate ammonium and insect resistance due to the insertion of genes from the soil bacterium *Bacillus thuringiensis* (*Bt*). GM varieties invariably contain selectable gene markers used to identify successful gene transfer, which may be resistant to antibiotics, herbicides or other substances, and gene promoters to enhance gene performance. Transferred genes (transgenes) added to a variety's usual gene content are normally located in its cell nuclei though they may be placed in other cell structures such as chloroplasts. Transgenes are normally derived from other natural organisms like *Bt*, but artificially constructed genes could be used in the future. In addition, the crossing of existing GM varieties by plant breeders will produce varieties containing multiple (or stacked) transgenes.

In 1996 Monsanto's Roundup Ready soybean, containing bacterial genes for glyphosate tolerance and a marker gene resistant to the antibiotic ampicillin, received an EC marketing licence for grain importation, storage and use in agriculture. Novartis' Maximiser GM *Bt* maize with alien genes for resistance to the European corn borer, with marker genes for tolerance to glufosinate and resistance to the antibiotic ampicillin, and with the cauliflower mosaic virus gene promoter, was licensed in 1997 for importation and agricultural use. Subsequently, in 1998 some 15 000 hectares of *Bt* maize were grown in Spain and 1000 hectares in France (NFU, 1998). Releases granted at national level for experimental field trials, under Part B of 90/220, include varieties of fodder beet, sugar beet, oilseed rape and potatoes (ACRE, 1998).

The importation of large amounts of GM grain mixed in with conventionally bred imports of soybean and maize, from the first large scale North American harvests in 1996, proved to be something of a turning point in the politicization of GM crops. The importation of the non-segregated grain for diffusion through the animal and human food and processing chains in Europe sparked off widespread and ongoing public protest. The safety implications of GM crops moved from an issue of technical concern, amongst environmental policy-makers and interest groups, to a prominent issue for food consumers and so other key players along the food chain, notably the large retailers and processors. The GM crops had been modified for improvements in terms of inputs for growers rather then outputs for consumers, offering the public no visible benefit. The next generation of crops modified for outputs remain, for the most part, some way from commercialization. The increased public visibility of the issue crossed over to the high politics of international trade, notably between the EU and the USA (De Jonquières, 1999). In addition, the revision has overlapped with international diplomacy over an International Biosafety Protocol under the 1992 Convention on Biological Diversity (CBD). The protocol negotiations over the transboundary movement of any living modified organisms resulting from modern

biotechnology (i.e. GMOs) were ongoing during this period, from their origin with the Jakarta Mandate in 1995 to the conclusion of the Cartegena Agreement in January 2000 at Montreal.

The political and regulatory conflicts led, in June 1999, to the EU's Council of Ministers imposing a *de facto* moratorium on the approval of any further commercial releases of GMOs until the successful passage and introduction of the revised deliberate release directive. This *de facto* moratorium was the result of a declaration signed by the governments of Denmark, France, Greece, Italy and Luxembourg, providing a blocking minority vote on any new approvals in the Council of Ministers (FoEE, 1999a).

The revision of the European regulatory regime, which began within the Commission back in 1994, and more visibly with the presentation of the Commission's revision in 1998, has occurred within this changing political context. During this period the imperative for revision has changed from one of producing a more harmonized and speedy commercial approval process to one that has sought to broaden and deepen the scope of the directive.

A major concern about herbicide tolerant and insect resistant GM crop plants is their potential effect on farmland biodiversity at ecosystem, species and genetic levels. Adverse environmental effects may result from the management of GM crops and from transgene spread into other sexually compatible species. The vulnerability of conventionally produced crop varieties to genetic contamination by sexually compatible GM varieties can also engender management and economic liabilities for growers.

## GM CROPS AND BIODIVERSITY CONCERNS

The evaluation of the ecological impact of GM crops is still in its infant stage as early evidence from the first field studies are only now emerging for public dissemination (BCPC, 1999). The European environment already has a biodiversity landscape severely damaged by the intensity of past agricultural management (Krebs *et al*., 1999). There have been calls for the wider and indirect impacts of GM crop production on the environment and on crop ecosystems to be brought into the risk assessment procedures for marketing GMOs under 90/220 (English Nature, 1998a; ACRE, 1999). Currently, there is a paucity of adequate field research findings as to the environmental and biodiversity effects of these GM innovations (English Nature, 1998a).

### Herbicide tolerant GM crops

Farmers aiming at increased and more efficient weed control see the benefits of managed inputs of glyphosate or glufosinate on GM tolerant crops as providing increased performance due to more flexibly applied and lower herbicide rates, thus reducing crop management and production costs (PSD, 1998). The manufacturers are able to market their own herbicide as an integrated package with the GM seed, maintaining a market advantage for the herbicide.

The introduction of GM crops to agriculture can be portrayed as an extension of the crop management applications that, since the 1940s, have reduced the biodiversity of crop and farmland ecosystems and produced the demise of some weed species, notably in parts of the UK (Stoate, 1996). Such losses, in turn, have reduced the availability of key invertebrate and seed foods for birds (Wilson *et al*., 1999) and affected birdlife levels across Europe (Pain and Pienowski, 1997; Krebs *et al*., 1999).

Studies into the decline of the grey partridge illustrated that crop weeds provide herbage and seeds for bird feed and act as hosts to insects, an important food source in rearing young chicks (Potts, 1997). Pesticide free crop borders demonstrated how to increase weeds, insect densities and wildlife support (Rands, 1985). The UK Government's conservation agency, English Nature, called for a moratorium on the use of herbicide tolerant GM crops to arrest further wildlife food losses and decline in farmland birds caused through the dislocation of food chains and webs in crop ecosystems (English Nature, 1998b).

Although glyphosate is rapidly degraded in the soil there is concern that its repeated use on GM tolerant crops would increase pollution of the water environment and costs of water purification for human use (UK Water, 1999), and affect aquatic wildlife. Widespread use on crops could increase glyphosate levels in foodstuffs. A successful application by Monsanto to the EU has raised the maximum residue limits (MRLs) on imported soya from 0.1 to 20 mg/kg (Dibb, 1999). Repeated use could also produce genetic change from glyphosate susceptibility to resistance in weeds, as reported for wimmera ryegrass in Australia (Guterman, 1998), and for other herbicides used in the UK and monitored by the Weed Resistant Advisory Group (WRAG/HGCA, 1997).

### Cross-pollination and the disruption of genetic diversity

Pollen grains dispersed by all plant species are deposited close to their source though some pollen may be carried long distances by wind or bees; however, the viability of pollen for some crop species may be brief (Proctor and Yeo, 1973). Dispersal may reach 4000 m in oilseed rape (Thompson *et al*., 1999), and 500–700 m in maize (Emberlin *et al*., 1999). Such widespread pollen distribution increases the risk of a GM crop cross-pollinating a wild counterpart or closely related wild species to produce biodiversity and genetic effects. This is of special genetic concern, as it would normally involve transgenes from unrelated species such as bacteria being introduced into the gene pools of plant populations, which could not occur by natural means. For example, transfer of toxic producing *Bt* genes into weed populations, where insects limit the weed population numbers, could give hybrids with the alien genes advantage over weeds without these genes (Dale, 1994). Gene flow between cultivated and wild forms of the same species occurs across the world: maize with teosinte, sugar beet with sea beet and rice with wild rice (Dale, 1994). Such gene flow would not occur in GM maize and GM soybean in Europe as no wild relatives are present, but would occur with GM sugar beet and GM brassicas as there are wild relatives present.

Oilseed rape is widely grown in Europe and is one of the cultivated forms of the swede species (*Brassica napus*), which evolved from a cross between the turnip (*B. campestris*) and cabbage (*B. oleracea*), two species growing wild in Europe (McNaughton, 1995). In Denmark, spontaneous hybrids were reported between GM glufosinate tolerant oilseed rape and wild turnip, one of its parents. In the field herbicide tolerance was found in the first hybrid back-cross, suggesting good gene flow between the species (Mikkelsen *et al*., 1996). Conversely, gene flow into local populations of wild turnips from nearby oilseed rape crops in England was considered likely to be relatively slow in comparison to the Danish example (Scott and Wilkinson, 1999).

In France, hybrids have been reported between GM oilseed rape and hoary mustard (Lefol *et al*., 1995) and between oilseed rape and both hoary mustard and wild radish, whose seeds survived for several years in the soil (Chadoeuf *et al*., 1998). Four generations of study between oilseed rape and wild radish showed 20% of the hybrids retaining the glufosinate tolerant transgene (Chèvre *et al*., 1997).

The species crossing with GM oilseed rape occur within the plant family *Brassicaceae* that contains many wild species in Europe. Europe can be considered one centre of its biodiversity where constituent species could be genetically polluted by widespread cultivation of sexually compatible GM crops. This issue was addressed in the CBD, and GMO releases in centres of origin and diversity were included in the terms of reference for the drawing up of the International Biosafety Protocol (UNEP, 1995). Concern over the impact of compatible GM crops upon local biodiversity led the French national competent authority for GMO releases to withhold the formal notification to PGS, Belgium, of a marketing licence granted to its GM oilseed rape (in order to postpone the commercial planting). The French Government announced a two year moratorium in 1998 on the release of GM oilseed rape and sugar beet pending more research, as both crops could cross with wild species indigenous to France (FoEE, 1999b).

The beet species (*Beta vulgaris*) contains a range of inter-fertile forms including the wild sea beet of maritime habitat, biennial sugar beet and fodder beet crops, and the annual weed beet that has evolved in beet growing areas. Weed beet is kept under control in beet crops by machines that wipe its tall stems with glyphosate above the crop canopy. The viability of this method will depend on preventing crosses between new GM glyphosate tolerant beet varieties and the weed (*Farming News*, 1997). Such crosses illustrate the risk where a GMO could cross with a weed of the same species and enhance its invasiveness in the agri-environment (Vigouroux *et al*., 1999).

### Antibiotic resistant marker (ARM) genes

Large scale planting of transgenic crops containing antibiotic resistant marker genes will massively amplify these genes in the biosphere (Tomlinson, 1999). Some GM crop products containing these marker genes, such as fodder beet roots and maize grain, will be fed to farm animals. ARMs of bacterial origin could be taken up into the genetic make-up of the animal's gut bacteria. There is already a high incidence of resistance to antibiotics in micro-organisms, which could be enhanced by uptake of ARM genes, leading to calls for ARMs to be replaced by alternative markers in the modification of crops (ACNFP, 1994).

When Novartis's *Bt* maize was declared safe for use in processed human food, reservations were made about the presence of ampicillin resistant markers when grains were fed unprocessed to farm animals as they could cause therapeutic problems for veterinarians (ACNFP, 1996). In 1998, Austria and Luxembourg enacted an import ban on Novartis's *Bt* maize over this issue under Article 16 of 90/220, which remained in place despite the subsequent opinion of the European Commission's Standing Committee for Plants that there was no justification for the ban (Agra Europe, 1999).

### Trophic level effects

In crop ecosystems natural predators do much to hold light insect pest attacks in check and delay the need for insecticide use. Laboratory studies have shown that transgenic crops expressing *Bt* toxins affect not only the target insect pests but also the survival of beneficial predator insects feeding on them. Examples include, the two-spotted ladybird (Birch *et al*., 1997) and lacewing (Hilbeck *et al*., 1998). These findings were considered inadequate to abandon use of *Bt* crops in the UK but highlighted the need for field research on the biodiversity impacts at the different food chain (trophic) levels in GM crop ecosystem populations (ACRE, 1998). The completion of such field research would be useful to aid strategies for pesticide minimization and for greater sustainability in cropping systems.

Impairment of the survival of parasitic wasp larvae from eggs in crop pest larvae feeding on *Bt* crop material has also been demonstrated (Schuler *et al*., 1999). Reports from the USA that larvae of the monarch butterfly were impaired by *Bt* maize pollen dusted onto their wild food plants added to these biodiversity concerns (Losey *et al*., 1999), as have findings on toxin root exudates into the soil from *Bt* corn (Saxena *et al*., 1999).

### Monitoring of biodiversity impacts

The implications for biodiversity of GM crops led to the UK seeking a voluntary moratorium with industry on widespread commercial planting, pending a controlled series of large farm scale trial plantings. The trials were to be monitored to compare the effect of herbicide use on the diversity and abundance of plants and invertebrates in GM herbicide tolerant and non-GM crops on the farm, over a four year period (ACRE, 1999; Gene Watch, 1999). A managed introduction was seen as an alternative to calls for a complete moratorium of GM crop planting over the medium term (Gene Watch, 1998; ENDS, 1999a). In addition, pressure has increased for an effective system of post-release monitoring to be included in the legislative revision of the regime. While it is impossible to define the totality of biodiversity in the agri-environment, which results from a mixture of farmed and non-farmed habitats (PSD, 1998), post-release monitoring of the ecological effects of

a GM crop should be based on as comprehensive a biodiversity site audit as possible. Hitherto, audits have been confined to single components of sites such as weeds, insects or pathogens, according to the subject of study, with little reference to vertebrates, soil flora and fauna and other abiotic factors.

## GM CROPS, FARM MANAGEMENT AND SOCIO-ECONOMIC CONCERNS

### Farm management and genetic pollution concerns

Socio-economic pressures affecting farmers producing non-GM crops will arise from genetic contamination by cross-pollination with neighbouring compatible GM varieties in the field and by seed admixture during cultivation, harvest, transport, storage and processing.

Organic farmers in the UK are forbidden to use GMOs and their derivatives by the United Kingdom Register of Organic Standards (Elm Farm, 1995). Organic crops will be very vulnerable to cross pollination by GMOs (Moyes and Dale, 1999). Contamination from GM crops will result in products losing organic accreditation and associated financial premiums (Masood, 1998). Contracts for supplying organic and other GMO free products will have to be routinely analysed at extra cost to be verified as free from GM material, or have to be within the EU's threshold standards, to ensure unwanted spread of modified material into relevant human and animal food chains.

Farmers introducing GM crops will be a liability to neighbouring farmers by affecting their farm management planning as well as enterprise profitability, in addition to adverse environmental impacts. For example, if non-GM crops were cross-pollinated by glyphosate tolerant GMOs then some shed seeds could produce volunteer plants. These volunteers would not be controlled by glyphosate used as a non-selective broad spectrum herbicide to clean crop stubble or new seed beds, so causing managerial problems (Leahy, 1999). Crosses involving several GM varieties tolerant for different herbicides could produce volunteers with stacked genes for herbicide resistance and extend weed control problems.

Shed or spilled seed can produce feral populations on field borders, wasteland and roadsides that can be sources of transgene contamination. Flowering in feral oilseed rape overlaps with that of winter and spring sown rape, which could give gene flow into both forms (Charters *et al*., 1996). Shed seed from GM plants may also remain dormant in the soil to germinate and contaminate other rape crops in later years. In the UK a national register of farm sites growing GM varieties has been recommended due to concern that polluting residues will affect land values and leave tenant farmers liable to compensate land owners (RICS, 1999).

Isolating seed production by distance from sexually compatible sources of genetic contamination is one way of limiting cross-pollination (OECD, 1992). Under UK legislation, minimum isolation distances for producing certified and basic standard of seed purity in oilseed rape are 200 and 400 m respectively (NIAB, 1990), which look to be inadequate for absolute prevention. Seed production protocols for seed for sale to farmers or for food processing must ensure quality and traceability. The Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), an industry based body, has produced guidelines for growing GM herbicide tolerant crops and a code of practice for crop management from seed to primary end product (SCIMAC, 1999a,b). Alternatively, zonation of farmland for the separation of GM crop production from non-GM cropping areas would help to reinforce avoidance of genetic contamination by cross-pollination. In the UK, the organic certification bodies are in discussion with government departments and SCIMAC to attempt to develop protocols acceptable to all parties (Blake, 2000).

The European demand for reliable and traceable GM free supplies for use in animal and human food chains grew from 1996. The labelling provisions under 90/220 were tightened in 1997. Labelling was made compulsory on all submissions to market a GMO (CEC,

1997). The management problems of adventitious contamination of non-GM food supplies by GMOs were recognized by the EU with the introduction of a *de minimus* threshold set at 1%, below which level a foodstuff could declare itself as non-modified (CEC, 2000a). However, these labelling changes did not ensure an integrated system of traceability for GM crops.

A novel way of preventing transgene spread from GM plants involves placing the transgenes in the genetic material of chloroplasts instead of the cell nuclei of plants. This would function in those species that do not transmit plastids in pollen, but transmit uniparentally through the female reproductive cells (Daniell *et al.*, 1998). A second GM application involves the production of sterile seeds through the so-called terminator technology, which, its originators claim, prevents seeds germinating in the next generation. Conversely, other potential escape problems may occur, since the genetic information for sterility is also contained in the pollen, and so cross-pollination and gene transfer to adjacent crops could accidentally spread sterility (Lehmann, 1998). Moreover, the technology has socio-economic implications for poorer farmers who traditionally save seed for future planting.

### Broader regulatory management concerns

Both the socio-economic and biodiversity concerns around GM crops have led to further gaps in the regulatory regime being highlighted. There is a lack of clarity over who would be legally liable for the impacts of pollution from GM crops. Such concerns were voiced by MEPs when the original directive was formulated in the late 1980s. The European Commission had responded then that the issue would come under a proposed general directive on environmental liability. The Commission, over a decade later, is still promising the same general directive in response to current concerns (ENDS, 1999a).

The current absence of clear scientific proof concerning the safety dimension of these ecological and regulatory concerns provides a compelling case for continuing to apply a precautionary approach to the deliberate release and management of GM crops in order to avoid serious environmental damage. The precautionary principle had been explicitly included in the environment section of the Treaty on European Union in 1992. The European Commission put forward a communication further defining its position on the meaning and criteria for the operation of the principle in February 2000 (CEC, 2000b). A more explicit incorporation of the principle within the deliberate release directive has also been debated during the revision.

## THE COMMON POSITION ON THE REVISION OF DIRECTIVE 90/220/EEC

Directive 90/220 was adapted to technical progress for the first time in April 1994 when the notification requirements for the release of GM higher plants, such as GM crops, were separated from those of other GMOs (in Annex IIIB). The Commission announced its intention to comprehensively review the directive in 1994. In February 1998 the European Commission published its proposal for extensive revision of the directive, which being the subject of co-decision allows the European Parliament a greater say in relation to the Council of Ministers over its ultimate revision. The subsequent report of parliament's first reading of the proposal contained over a hundred amendments and was finally voted on by parliament in February 1999. The Commission then published its amended proposal for 90/220, which rejected most of the amendments. The Council of Ministers Proposal for amending 90/220 in view of a Common Position was reached in June 1999, and formally adopted the following December. This analysis focuses on the changes incorporated in the Common Position, which provide the first clear indication of the likely scope and shape that the new directive will eventually take (Council of the European Union, 1999).

The Common Position has strengthened the biodiversity and ecological components of the risk assessment and the notification

procedures beyond the position originally taken by the Commission. The European Parliament, through their amendments, also sought to strengthen some of the socio-economic dimensions of the regulation. However, the Council of Ministers has been less revisionist in these areas. Nonetheless, the ministers have gone further than the Commission in relation to labelling, traceability and monitoring, and in the weight accorded to the precautionary principle. The Council of Ministers and the European Parliament have in their different ways responded to the social and political concerns that have arisen in parallel to the revision of the directive. The original impetus for the revision, which was in response to the wishes of industry and the EU's trading partners, notably the USA, for a more streamlined and quicker approval process, has not been realized.

### Environmental risk assessment and notification revisions

The notification procedures for deliberate release, which contain requirements relevant to biodiversity in Annex IIIB, have been strengthened. To the information required on a GMO's sexual compatibility to other cultivated or wild species is added 'including the distribution in Europe of the compatible species' (IIIB, 2b). Again to the requirement on distances from compatible species is added from 'both wild relatives and crops'. Moreover, consent to market a GMO can now specify 'conditions for the protection of particular ecosystems/environments and/or geographical areas' (Article 18).

The original directive does not contain specific details for conducting an environmental risk assessment of GMOs. The Commission's revision includes a new Annex II covering the principles and methodology for environmental risk assessment of GMOs that must be carried out as part of the notification process. The environmental risk assessment has been further strengthened in the Common Position.

The scope of the risk assessment covers the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed. The Common Position has defined these terms and so widened the scope of the risk assessment. Indirect effects are those affecting human health and the environment through mechanisms such as interactions with other organisms, transfer of genetic material or change in a GM crop's use or management. It expands that 'such indirect effects are likely to be delayed'.

The risk assessment describes the objective of case by case assessment of GMOs and the general principles to be used in accordance with the precautionary principle. Guidance is also provided on the step by step analysis of risk factors. The items to be used in drawing conclusions on the potential environmental impact from marketing a GM higher plant are listed separately from those for non-plant GMOs. For GM higher plants these items include some of the concerns raised previously about the biodiversity and socio-economic impacts of GM crops. The potential for gene transfer to the same or other sexually compatible species, potential impact from direct and indirect interaction with target and non-target organisms and effects on animal health and the food chain from consumption of GM crops are all included. In addition, the impacts of farm management practices where these are different to those for non-GM crops have to be identified, allowing for assessment of the potential impact upon the agricultural system. All of these items become requirements of the notification process.

This more prescriptive approach to the principles for risk assessment and for notification should facilitate a more harmonized regulatory approval process while allowing for the variability of crop ecosystems and biodiversity within the EU to be taken into account.

Antibiotic resistant genes are not withdrawn from use under the Common Position, as the European Parliament has sought. Rather, it is proposed that GMOs containing genes for resistance to antibiotics used in medical and veterinary medicine be taken into consideration in an environmental risk assessment of GMOs, with a view to phasing out those that may adversely affect human health and the environment (Article 4).

Similarly, the risk assessment principles affecting GM crops call for similar consideration where such genes may compromise medical and veterinary therapy.

### Labelling, traceability, monitoring and broader regulatory revisions

The Common Position required that a notification for marketing consent (which can be granted for a ten year maximum) must state the genetic modification incorporated into a new GMO together with the means by which it can be used to identify the crop variety and its progeny (Annex IV). A labelling proposal was also required (Article 20). In addition, notification requires a plan for post-release monitoring, which the notifier is to be responsible for carrying out (Article 12 and Annex VII). The linking of identification, labelling and monitoring will facilitate a more integrated system for the traceability of GM crops. The monitoring plan must reflect the risk assessment criteria, and record any adverse effects not anticipated. However, these criteria fall short of a full biodiversity audit of a release site.

The precautionary principle is emphasized in the Common Position under the general obligations of the directive (Article 4), and in the general principles for the environmental risk assessment. A legal liability provision, desired by the parliament, is absent, although member states can determine penalties applicable to breaches of national provisions under the directive that should be effective, proportionate and dissuasive (Article 31).

Parliament had passed an amendment to allow for socio-economic factors to be included in the risk assessment steps applied to GMO releases. While this was rejected by the Council of Ministers, a report from the Commission on experiences gained with implementation of the directive, scheduled for 2003, must contain any socio-economic implications of the deliberate release and market placement of GMOs (Article 30). The social impact should allow for the effects upon organic farming to be assessed, although there is still a compelling case for specifically including the impact upon organic farming in the risk assessment. The Commission's report will also consider a more centralized approval system, as favoured by industry as a way to attempt to de-politicize the process, and more streamlined procedures for approvals in order to lift the regulatory burden on industry and the regulators as applications increase (ENDS, 1999b).

## CONCLUSIONS

The regulatory regime for the release of GM crops into the environment has revealed a number of important lacunae. Gaps have become evident in the risk assessment and notification criteria under the directive, leading to disputation between member states over the specific risks associated with the commercialization of GM crops as exhibited in the case by case approval process. In particular, there has been a lack of recognition of the varied ecosystems and their biodiversity within the EU. Also, disputes have arisen over the impact upon farming and crop management of the spread of transgenes. An examination of the potential environmental impacts upon biodiversity and upon farm management serves to highlight the need for regulatory revision. It also reveals the lacunae in scientific knowledge, where much needed research is ongoing. The horizon for establishing a more comprehensive ecological knowledge base remains long term.

The revision of the directive has begun to address some of these gaps. The Common Position agreed by the Council of Ministers in 1999 has seen a widening and specification of the risk assessment principles and criteria that need to be addressed in applying to market a GM crop. The biodiversity criteria, in particular, are being improved. In terms of broader regulatory management, the proposals for post-release monitoring are welcome, but they do point to the need for effective implementation, and effective systems of inspection and control. The issue of legal liability remains to be resolved.

While the Common Position is not the completion of the revision process, it is a key

stage and shows that the Council of Ministers has become a more progressive force in the revision than the European Commission, reflecting the movement of the issue onto the agenda of high politics. The other participant, the European Parliament, remains more responsive and open to social concerns than its institutional partners. The inclusion of socio-economic factors in the risk assessment process remains outside the Common Position. However, in areas of scientific uncertainty the boundaries between risk assessment and risk management become unclear, and so debate over the role of socio-economic factors will probably remain on the agenda after the legislative revision of the directive has been completed (Barling *et al*., 1999).

## REFERENCES


Advisory Committee on Novel Foods and Processes (ACNFP). 1994. *Report on the Use of Antibiotic Resistance Markers on Genetically Modified Food*. ACNFP: London.

Advisory Committee on Novel Foods and Processes (ACNFP). 1996. *Advisory Committee on Novel Foods and Processes Annual Report 1995*. Ministry of Agriculture, Fisheries and Food: London.

Advisory Committee on Releases to the Environment (ACRE). 1998. Advisory Committee on Releases to the Environment Annual Report (4) 1996/7. London.

Advisory Committee on Releases to the Environment (ACRE). 1999. The Commercial Use of Genetically Modified Crops in the United Kingdom: the Potential Wider Impact on Farmland Wildlife, Discussion paper prepared by the Secretariat to ACRE. Department of the Environment, Transport and the Regions: London.

Agra Europe. 1999. EU scientists reject Austrian GM maize ban. *Agra-Europe* **1872**: EP 4–EP 5.

Barling D, de Vriend H, Cornelese J, Ekstrand B, Hecker E, Howlett J, Jensen J, Lang T, Mayer S, Staer K, Trop R. 1999. The social aspects of food biotechnology: a European view. *Environmental Toxicology and Pharmacology* **7**: 85–93.

Birch A, Geoghegan I, Majerus M, Hackett C, Allen J. 1997. Interactions between plant resistance genes, pest aphid populations and beneficial predators. Scottish Crop Research Institute: Annual Report 1996. Invergowrie; 68–72.

Blake A. 2000. Support for GM buffer zone. *Farmers Weekly* **11**(February): 66.

British Crop Protection Council (BCPC). 1999. *Gene Flow and Agriculture: Relevance for Transgenic Crops* (Proceedings/Monograph Series 72). BCPC: Farnham.

CEC. 1997. *Official Journal of the European Communities L* **169**: 72–73.

CEC. 2000a. *Official Journal of the European Communities L* **6**: 13–17.

CEC. 2000b. Communication from the Commission on the precautionary principle. COM (2000) 1. Commission of the European Communities: Brussels.

Chadoeuf R, Darmency H, Mallet J, Renard M. 1998. Survival of buried seeds of interspecific hybrids between oilseed rape, hoary mustard and wild radish. *Field Crop Research* **58**: 197–204.

Charters Y, Robertson A, Crawford J, Squire G. 1996. Investigation of feral oilseed rape populations. Scottish Crop Research Institute: Annual Report 1995/6. Invergowrie; 40.

Chèvre A-M, Eber F, Baranger A, Renard M. 1997. Gene flow from transgenic crops. *Nature* **389**: 924.

Council of the European Union. 1999. Common position adopted by the Council with a view to the adoption of a directive of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council directive 90/220/EEC, Interinstitutional File 98/0072 (COD). Council of the European Union: Brussels.

Dale P. 1994. The impact of hybrids between genetically modified crop plants and their related species: general considerations. *Molecular Ecology* **3**: 31–36.

Daniell H, Datta R, Varma S, Gray S, Lee S-B. 1998. Containment of herbicide resistance through genetic engineering of the chloroplast genome. *Nature Biotechnology* **16**: 345–348.

De Jonquières G. 1999. Genetically modified trade wars. *Financial Times* **18 February**: 15.

Dibb S. 1999. Glyphosate residue limits in soya relaxed to accommodate GM crops. *Pesticide News* **45**: 5.

Elm Farm. 1995. Revised UKROFS statement on GMOs. *Bulletin Elm Farm Research Centre* **20**: 1.

Emberlin J, Adams-Groom B, Tidmarsh J. 1999. *A Report on the Dispersal of Maize Pollen*. National Pollen Research Unit and the Soil Association: Worcester.

ENDS. 1999a. Sustainable farming agenda makes no mark on policy for GM crops. *ENDS Report* **291**: 34–35.

ENDS. 1999b. Overhaul of EC regime for regulating GMOs. *ENDS Report* **294**: 50–52.

English Nature. 1998a. *Position Statement on Genetically Modified Organisms*. English Nature: Peterborough.

English Nature. 1998b. Press Release. Government wildlife adviser urges caution on genetically modified organisms – the new agricultural revolution. English Nature: Peterborough.

*Farming News*. 1997. GMO sugar beet offers reduced crop damage. *Farming News* **7 February**: 17.

FoEE. 1999a. EU Environment Council adopts *'de facto'* moratorium on GMOs. *FoEE Biotech Mailout* **5**(5): 1–3.

FoEE. 1999b. Commission starts legal action against France. *FoEE Biotech Mailout* **5**(5): 7.

Gene Watch. 1998. Genetically engineered crops and food: the case for a moratorium. Gene Watch UK Briefing 4. Gene Watch UK: Tideswell.

Gene Watch UK. 1999. Farm scale trials of GM crops: answering the safety questions? Gene Watch UK Briefing 8. Gene Watch UK: Tideswell.

Gene Watch UK. 2000. GM crops and food: a review of developments in 1999. Gene Watch UK Briefing 9. Gene Watch UK: Tideswell.

Guterman L. 1998. How to handle a herbicide. *New Scientist* **15**(August): 7.

Hilbeck A, Baumgartner M, Fried P, Bigler F. 1998. Effects of transgenic *Bacillus thuriengiensis* corn fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysophidae). *Environmental Entomology* **27**(2): 480.

Krebs J, Wilson J, Bradbury R, Siriwardena G. 1999. Commentary: the second silent spring? *Nature* **400**: 611–612.

Leahy S. 1999. First GM tolerance transfer is feared in Canadian OSR. *Farmers Weekly* **15 January**: 52.

Lefol E, Danielon H, Darmency H, Buocher F, Maillet J, Renard M. 1995. Gene dispersal from transgenic crops. 1. Growth of interspecific hybrids between oilseed rape and hoary mustard. *Journal of Applied Ecology* **32**: 803–808.

Lehmann V. 1998. Patent on seed sterility threatens seed saving. *Biotechnology and Development Monitor* **35**: 6–8.

Levidow L, Carr S (eds). 1996. Special issue on biotechnology risk regulation in Europe. *Science and Public Policy* **23**(3): 133–200.

Losey J, Rayor L, Carter M. 1999. Transgenic pollen harms monarch larvae. *Nature* **339**: 214.

Masood E. 1998. Organic farmer takes gene battle to court. *Nature* **394**: 8.

McNaughton I. 1995. Swedes and rapes. In *Evolution of Crop Plants*, Smartt J, Simmonds N (eds). Longmans: Harlow; 68–75.

Mikkelsen T, Anderson B, Jorgesen R. 1996. The risk of crop transgene spread. *Nature* **380**: 31.

Moyes C, Dale P. 1999. *Organic Farming and Gene Transfer from Genetically Modified Crops*. John Innes Centre: Norwich.

NFU. 1998. *Written Evidence of the NFU of England and Wales to the House of Lords' European Communities Committee Enquiry into EC Regulation of Genetic Modification in Agriculture*. National Farmers Union: London.

National Institute of Agricultural Botany (NIAB). 1990. Growing oilseed rape for seed. Seed Growers Leaflet No. 10. NIAB: Cambridge.

Organisation for Economic Co-operation and Development (OECD). 1992. *Safety Considerations for Biotechnology*. OECD: Paris.

Pain D, Pienowski M (eds). 1997. *Farming and Birds in Europe: The Common Agricultural Policy and its Implications for Bird Conservation*. Academic: London.

Pesticide Safety Directorate (PSD). 1998. Scientific review of the impact of herbicide use on genetically modified crops, Report produced by PSD. PSD: York.

Potts R. 1997. Cereal farming, pesticides and grey partridges. In *Farming and Birds in Europe: The Common Agricultural Policy and its Implications for Bird Conservation*, Pain D, Pienowski M (eds). Academic: London; 150–177.

Proctor M, Yeo P. 1973. *The Pollination of Flowers*. Collins: London.

Rands M. 1985. Pesticide use on cereals and the survival of partridge chicks: a field experiment. *Journal of Applied Ecology* **22**: 49–54.

Royal Institution of Chartered Surveyors (RICS). 1999. *Government Review of the Framework for Overseeing Developments in Biotechnology: Comments from the Royal Institution of Chartered Surveyors*. RICS: London.

Saxena D, Flores S, Stotzky G. 1999. Insecticidal toxin in root exudates from *Bt* corn. *Nature* **402**: 480.

Schuler G, Pott N, Denholm I, Poppy G. 1999. Parasitoid behaviour and *Bt* plants. *Nature* **400**: 825.

Scott S, Wilkinson M. 1999. Low probability of chloroplast movement from oil seed rape (*Brassica napus*) into wild *Brassica rapa*. *Nature Biotechnology* **17**: 390–392.

Stoate C. 1996. The changing face of lowland farming and wildlife, part 2: 1945–1995. *British Wildlife* **7**(3): 162–172.

Supply Chain Initiative on Modified Agricultural Crops (SCIMAC). 1999a. *Guidelines for Growing Newly Developed Herbicide Tolerant Crops*. SCIMAC: Ely, UK.

Supply Chain Initiative on Modified Agricultural Crops (SCIMAC). 1999b. *Code of Practice on the Introduction of Genetically Modified Crops*. SCIMAC: Ely, UK.

Thompson C, Squire G, Mackay G, Bradshaw J, Crawford J, Ramsay G. 1999. Regional patterns of gene flow and its consequence for GM oilseed rape. In *Gene Flow and Agriculture: Relevance for Transgenic Crops*. British Crop Protection Council (BCPC): Farnham; 95–100.

Tomlinson N. 1999. Letter from ACNFP to US Food and Drug Administration (FDA) on guidance for industry. 1998. In *Advisory Committee on Novel Foods and Processes Annual Report 1998, ACNFP*. Ministry of Agriculture, Fisheries and Food: London; 64–68.

UK Water. 1999. Press Release: UK Water Industry Statement on Genetically Modified Crops. UK Water: London.

UNEP. 1995. Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity, UNEP/CBD/COP/2/9. Jakarta.

Vigouroux Y, Darmency H, Gestat de Garambe T, Richard-Mollard M. 1999. Gene flow between sugar beet and weed beet. In *Gene Flow and Agriculture: Relevance for Transgenic Crops*. British Crop Protection Council (BCPC): Farnham; 83–88.

Weed Resistant Action Group/Home Grown Cereals Authority (WRAG/HGCA). 1997. *Revised Guidelines for Preventing and Managing Herbicide-Resistant Grass Weeds*. WRAG/HGCA: London.

Wilson J, Morris A, Arroyo B, Clark S, Bradbury R. 1999. A review of the abundance and diversity of invertebrate and plant foods of granivorous birds in Northern Europe in relation to agricultural change. *Agriculture, Ecosystems and Environment* **75**: 13–30.