3.9. Genetically modified organisms

Main findings

All releases of GMOs to the environment in the EU have to be authorised under the Deliberate Release Directive, 1990, which operates through a 'step-by-step' progression and uses data from earlier experiments to inform decisions about the safety of future field trials. This procedure may not deal satisfactorily with cumulative impacts of many releases in the complex situation of the natural and agricultural environments. Risk assessments of releasing GMOs across the EU need to take account of the diversity of agricultural practice and of potential effects on biodiversity, taking into account Member States' commitments to conservation.

There are serious disagreements between Member States on the main potentially adverse effects of GMOs and there is very little public confidence in or support for the current development and regulation of GMOs. Public concern about the use of GMOs includes issues of trust, control, information (via labelling etc.) and the related benefits and justification of the effects of the technology for particular applications. Attitudes to medical applications for example are much more sympathetic than to the use of the technology in food.

Efforts are increasing to inform, involve and consult the public about GMOs, in order to reach a consensus on GMO regulation. Further research into potential environment and health impacts, and approaches to risk assessment, as well as more comprehensive monitoring are needed help fill the knowledge gaps and inform the risk evaluation system.

Achieving the right balance between risk and innovation with GMOs may help resolve generic issues surrounding new technologies, such as the management of scientific uncertainty, application of the precautionary principle, public information, monitoring, liability, informed consent to imports, and the resolution of trade and environmental/health issues.

1. GMOs in the European Union: setting the scene

This chapter focuses on applications of genetic modifications (GM) with the greatest potential for environmental effects: in agricultural production, food processing and animal feed. It does not consider medical applications, apart from listing GM vaccines which have been approved under environmental regulations.

1.1. Experimental and commercial releases of GMOs licensed in the European Union

Deliberate experimental releases to the environment of GM crops have been conducted in Europe since 1985-86. At present there is very limited experience in the EU of cultivation of GM crops, although there have been over 1 300 experimental field trials with genetically modified organisms (GMOs), involving over 60 species of plants and microorganisms, and some 18 marketing approvals have been given for GM crops and vaccines. It is therefore not possible to evaluate the environmental effects of GMOs, such as the transfer of inserted genetic materials to related wild species. Assessment and management of risks in this area are beset by complexities and uncertainty (Royal Society, 1998), despite recent scientific advances (see the case study of GM oilseed rape in section 2 below).

Genetically modified foods are now starting to be sold commercially. In the United States almost 30 varieties of crops have been given approval for commercial planting and use. In contrast, in the EU only four commercial

Box 3.9.1. Basic definition

Genetic modification involves the transfer of genetic material between species (the use of recombinant DNA technology to transfer genes), a technology which was developed using microorganisms in the 1970s and applied to plants and animals during the middle and late 1980s.

The transferred gene(s) from the donor organism then functions in a specific way in the host organism, altering both its genetic makeup and its biological behaviour. There is usually more than one donor organism, as DNA sequences from bacteria or viruses are needed to facilitate the transfer of genetic material (as vectors), as control mechanisms (e.g. promoter genes); and as markers to demonstrate that the genetic modification has been successful (e.g. antibiotic and herbicide resistance).

food crops (oilseed rape, maize, soybean and chicory) have been approved (Table 3.9.1) and only one, Novartis's GM insect-resistant maize, has been grown commercially during 1998 in France, Spain and Germany. Some varieties of GM maize and soybean can be imported into, but not grown in, the EU. One oilseed rape variety has been given approval for importation and a GM chicory has also received approval. Zeneca's GM tomato paste has been sold in the UK since 1996 but because this is grown and processed in the US it is not considered a living GMO, and therefore not regulated under the EU's Deliberate Release Directive. Certain GM vaccines, a test kit for antibiotic residues and a GM herbicide-tolerant tobacco have also been approved for commercial use. However, Member States have not given approval to four products (two cotton, one tomato and one maize) and the European Commission will now have to decide about these.

Box 3.9.2. Disputed GMO marketing authorisations

Austria and Luxembourg banned the sale of the Novartis GM maize in 1997 because of concerns about the presence of a marker gene conferring resistance to the antibiotic ampicillin, the absence of a resistance management plan for insect resistance and concerns about herbicide resistance.

France used Article 16 in December 1998 to restrict the use of two varieties of herbicide-resistant oilseed rape made by Plant Genetics Systems and AgrEvo. France has also not signed the consent license for another Plant Genetics Systems oilseed rape which has completed the authorisation process. France is concerned about the potential for gene flow to its native flora.

Greece used Article 16 in October 1998 to ban the import of AgrEvo's herbicide-tolerant oilseed rape because of environmental and health concerns; and has recently called for a moratorium on GM crops in Europe.

The European Parliament's Environment Committee called for a moratorium on all new GM crop varieties in October 1998.

Products can take a number of years to obtain marketing consent, and as Table 3.9.1 shows, there has so far only been unanimous approval for three GM carnations. Even when given approval, Marketing consents can remain controversial. Several EU Member States have imposed restrictions on GM crops which have already been given marketing consent under Article 16 of the Deliberate Release Directive. Box 3.9.2 lists the Article 16 objections currently in place.

Table 3.9.2 gives details of the numbers of experimental trials carried out in EU countries and in other European countries for which data is available. In EU trials, herbicide tolerance and insect resistance have been the most common traits tested. Over 60 species of GM plants have been tested in Europe with four crops making up 75% of the trials: maize accounted for 28%; oilseed rape 22%; sugar beet 15% and potato 10%, reflecting the importance of these crops in European agriculture. The majority of early research focused on herbicide tolerance in crops and this is reflected in the first products coming to market. Insect resistance has also been a common subject of research and is marketed in the form of Novartis' insect-resistant maize. On the evidence of developments in the US (where more GM crops are available because the market opportunities are greater) and the experimental field trials conducted in Europe, forthcoming commercial applications are likely to include: viral disease resistance in crops such as potatoes, altered starch characteristics in potatoes to improve processing, altered oil composition in oilseed rape to reduce reliance on other sources and fruit that ripens more slowly.

1.2. Policies

The main EU legislation covering environmental safety of the release of GMOs is the 'Deliberate Release Directive' (90/220/EEC). Genetically modified microorganisms that are released accidentally or incidentally from research and production facilities are regulated under the Contained Use Directive (90/219/EEC), with a view to protecting health and the environment. Food safety aspects are covered by the Novel Foods Regulation (258/97). This chapter concentrates on the Deliberate Release Directive as it most directly affects environmental safety; its approach is summarised in Box 3.9.3. The decision-making tree is shown in Box 3.9.4. Crucially the approach is intended to be precautionary – the possibility of serious, irreversible harm is acknowledged, justifying preventative action without scientific proof of harm.

Products approved under the Deliberate Release Directive 90/220/EEC to 31 December 1998 Table 3.9.1.

Product	Use	Notifier	Conditions	Date of Commission Decision*/ Member State Consent**
1. Vaccine against Aujeszky's disease	Pigs	Vemie Veterinär Chemie GmbH	According to veterinary product licenses	18.12.92
2. Vaccine against rabies	Foxes	Rhône-Mêrieux	Hand or aerial dropping twice annually	19.10.93
3. Tobacco tolerant to bromoxynil.	Herbicide tolerance	SEITA	Growing and use by tobacco industry	08.06.94
4. Vaccine against Aujeszky's disease (further uses)	Pigs	Vemie Veterinär Chemie GmbH	According to veterinary product licenses	18.07.94
5. Oilseed rape resistant to glufosinate ammonium	Herbicide tolerance and hybrid production	Plant Genetic Systems	Seed production only	06.02.96
6. Soybeans tolerant to glyphosate	Herbicide tolerance	Monsanto	Importation for food and feed	03.04.96
7. Male sterile chicory tolerant to glufosinate ammonium	Herbicide tolerance	Bejo-Zaden BV	Growing	20.05.96
8. Bt-maize tolerant to glufosinate ammonium	Herbicide tolerance	Ciba Geigy	Growing, animal feed and food use	23.01.97
9. Oilseed rape tolerant to glufosinate ammonium	Herbicide tolerance and hybrid production	Plant Genetic Systems	Growing	06.06.97
10. Test kit to detect antibiotic residues in milk	Agriculture	Valio Oy	Use in test kit only	14.07.97
11. Carnation lines with modified flower colour	Horticulture	Florigene	Cut flowers and plants	01.12.97 (MS consent)
12. Swede rape tolerant to glufosinate ammonium	Herbicide resistance	AgrEvo	Growing	22.04.98
13. Maize tolerant to glufosinate ammonium (T25)	Herbicide resistance	AgrEvo	Growing	22.04.98
14. Maize expressing the Bt cryIA(b) gene (MON 810)	Insect resistance	Monsanto	Importation for animal feed and human food uses	22.04.98
15. Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene	Herbicide and insect resistance	Novartis (formerly Northrup King)	Importation for animal feed and human food uses	22.04.98
16. Carnation lines with improved vase life	Horticulture	Florigene	Cut flowers and plants	20.10.98 (MS consent)
17. Carnation lines with modified flower colour	Horticulture	Florigene	Cut flowers and plants	20.10.98 (MS consent)

* where objections were raised by Member State authorities

** in the absence of objections by Member State authorities

Bt = *Bacillus thuringienis*

Table 3.9.2. **Numbers of experimental-release notifications of GMOs to the EC (from 1 January 1992 to 1 September 1998)**

Country	Plant	Micro-organisms	Vaccines	Total
Austria	3			3
Belgium	91		1	92
Bulgaria	3			3
Denmark	32			32
Finland	16	1		17
France	385	5	4	391
Germany	92	2		94
Greece	12			12
Ireland	4			4
Italy	201	12		214
Netherlands	100	2	1	103
Portugal	11			11
Russian Federation	4			4
Spain	115	8		123
Sweden	36			36
Switzerland	2			2
United Kingdom	165	7		172
Total	1269	37	6	1312

A notification may relate to several different species at several sites. Therefore this data only gives a guide to the relative numbers of experiments in different countries.

Source: European Commission's Joint Research Centre 'Biotechnology and Environment' database: http:/biotech.jrc.it) and those in other European countries where available (from OECD Biotrack Online database: http:/www.oecd.org).

There is also provision for GM products to be assessed under product regulations alone as long as these include a risk evaluation which is equivalent to that required under the Deliberate Release Directive. For example, in December 1998, the Council adopted amendments to the Directives relating to the marketing of seeds (66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/457/EEC, 70/458/EEC) aiming among other objectives, at integrating the process of environmental risk assessment with the procedure of variety acceptance.

The EU now faces a challenge, with the revision of the Deliberate Release Directive, to reconcile these commitments with the need for rigorous assessment of the environmental risks of GMOs, taking account of commitments to environmental protection under legislation such as the EU's Habitats Directive and the Biodiversity Conventions (see section 3 below).

1.3. Applications of genetically modified organisms

Conventional crop breeding has produced large agricultural and other benefits, some of which have been monetised. For example, the crossing of a perennial Mexican corn able to grow in marginal soils at high altitudes, and which is resistant to seven major corn diseases, with modern corn varieties,

Box 3.9.3. Regulating the releases of GMOs in the European Union

- ALL environmental releases of GMOs must be licensed under the Deliberate Release Directive (90/220).
- The approach is intended to be precautionary.

Experimental releases are covered by Part B of the Directive (following the general provisions of Part A):

- Safety is assessed by a 'step-by-step', progression using data from earlier experiments to inform decision about safety of future field trials.
- At each stage it is assumed the presence or absence of effects will be identified thus allowing for a decision to be made on whether a lower containment level can be allowed.
- Simplified procedures can be introduced for some crop species where the characteristics of both the inserted gene and the host organism are well known.
- Approvals can be given either for a single release or for a programme of releases taking place over several years and at several sites.
- The risk assessment includes the conditions of release and the receiving environment, and interactions between the GMOs and the environment such as characteristics affecting survival, multiplication and dissemination, and interactions with the environment.

Marketing authorisations are covered by Part C of the Directive and Europe-wide approval for marketing may be given following a risk assessment which considers:

- Information about the GMO – the recipient and donor organism, the vector and the GMO.
- Conditions of release and the receiving environment.
- Assessment of potential health effects.
- Interactions between the GMOs and the environment – characteristics affecting survival, multiplication and dissemination, interactions with the environment and potential environmental impact.
- Information provided derives from earlier field trials either in Europe or elsewhere.

If new information becomes available that a product may be a risk to human health or the environment, a Member State may temporarily restrict its use or sale, pending a decision at EU level.

Box 3.9.4. Current practice in the decision-making process for marketing authorisations of GMOs

1. Application to Member State (MS).
2. Opinion given to the European Commission.
3. Other MSs comment and consent granted if no disagreement between MSs.
4. Commission may consult expert EC scientific advisory committees.
5. Decision based on a qualified majority voting procedure if disputes between MSs.
6. If no qualified majority possible, then the Council is asked to decide.
7. If failure to agree, the Commission makes a final decision.
8. MS where initial application made issues consent for placing on the market.

had generated some $4 400 million a year in potential benefits by 1990 (UNEP, 1990). It is the ability to alter crops in more clear-cut and particular ways, together with a much greater scope for alteration without the long time-scales involved in conventional breeding, that has attracted industry to GM technology.

The main applications of GMOs are shown in Box 3.9.5.

Future applications include cold tolerance (in plants and animals, especially fish); specialised products such as new fibres and oils; 'functional foods' and 'nutraceuticals' which claim health advantages such as lowered cholesterol or raised vitamin levels; and the production of vaccines and other pharmaceuticals in plants. Designing GM products to meet the needs of certain markets, such as farming or food processing, may provide significant business and employment opportunities. However, there may also be costs (Box 3.9.6). Although traditional crop breeding also has costs, they are better known, slower to arrive, and generally are easier to manage than some of the potential costs of GM technology.

In addition to the jobs and profits potential, there are other socio-economic implications, such as the information rights of consumers, and the property rights of GM producers and farmers.

1.4. Key issues associated with the release of genetically modified organisms

The direct environmental risks from GMOs have been examined by a number of expert groups (including the UK's Royal Commission on Environmental Pollution (1989) and the US's Ecological Society in the same year (Tiede *et al.*, 1989)), as have the perceived risks to human health from eating GM foods (see for example Clydesdale, 1996; Advisory

Box 3.9.5. GMOs: main applications

Food crops

- Herbicide tolerance – allows crops to resist non-selective weedkillers.
- Insect resistance – allows crops to resist insect attack by producing an insecticidal toxin.
- Male sterility systems – for production of hybrid crop giving enhanced yield
- Disease resistance – prevents crops developing viral and fungal diseases.
- Delayed softening in fruits – prolonging storage life.
- Altered oil characteristics – to fit processing needs.
- Nitrogen fixation – to transfer this ability to non-nitrogen fixing crops.

Non-food crops

- Flowers with modified colour and extended vase life.
- Trees with altered characteristics to make paper production easier.
- Plants to produce plastics and pharmaceuticals.
- Plants to assist in bioremediation of polluted sites.

Animals

- Increased growth rates – to reduce time to reach mature weight.
- Therapeutic substances in milk – to provide sources of medicines which are difficult to produce by other means.

Microorganisms

- Production of enzymes or drugs – for use in food processing or as medicines.
- Degradation of pollutants – to clean up contaminated sites.

Box 3.9.6. The main potential benefits and costs attributed to GMOs

Potential benefits:

- promoting efficiency in farming – for example by reducing labour costs of herbicide or insecticide spraying and less tillage;
- increased yields – by reducing losses from pests and disease, hence reduced pressure for more farmland;
- providing altered product characteristics to aid in food processing – such as tomatoes which soften more slowly and therefore have lower water content facilitating processing into paste;
- controlling fertility – to improve the purity of hybrid seed, hence higher yields;
- reducing fertiliser inputs through nitrogen fixation;
- reduced pesticide use.

Potential costs

- **Direct environmental effects**:

- if there is gene transfer from the GMO to native flora or fauna – leading to new pests as a result of hybridisation;
- unexpected behaviour of the GMO in the environment if it escapes its intended use and becomes a pest;
- disruption of natural communities – through competition or interference;
- food web effects through harm to non-target species – for example, if the host range of a virus was increased it may affect beneficial as well as the targeted species or there may be secondary effects of the insect toxin contained in a crop on the food web;
- harmful effects on ecosystem processes – if products of GMOs interfere with natural biochemical cycles;
- squandering natural biological resources if, for example, the use of a genetic modification to bring pest resistance in many difference species induces the emergence of resistance and loss of efficacy.

- **Indirect environmental effects**:

- continuation of intensive agricultural systems – as a result of the requirement for high levels of external inputs;
- impacts on biodiversity as a consequence of changes in agricultural practice – for example by altering patterns of herbicide use, effects on flora may be seen;
- cumulative environmental impacts from multiple releases and interactions;
- alterations in agricultural practices, for example, to manage any direct environment impacts such the evolution of insect, herbicide or disease resistance in weeds.

- **Health:**

- new allergens being formed through the inclusion of novel proteins which trigger allergic reactions at some stage;
- antibiotic resistance genes used as 'markers' in the GM food being transferred to gut microorganisms and intensifying problems with antibiotic-resistant pathogens;
- the creation of new toxins through unexpected interactions between the product of the GM and other constituents for example.

Committee on Novel Foods and Processes, 1994; Royal Society, 1998).

Official regulatory processes (see section 4 below) are based on a risk assessment of the potential for direct environmental effects of GMOs. These assessments have been criticised for failing to take proper account of indirect effects: an early example of this critique was of GM herbicide-tolerant crops, *Biotechnology's Bitter Harvest* published in 1990 (Biotechnology Working Group, 1990) and there have since been similar criticisms from various non-governmental organisations (NGOs) and scientific advisory bodies (Box 3.9.7). US growers have recently proposed to limit the cultivation of Bt insect-resistant crops such as cotton and maize on GM crop lands to 80% of the area in order to prevent the build up of insect resistance (FOE, 1999).

Ethical issues concerning GMOs (see Grove-White *et al.*, 1997) have been more clearly articulated in relation to patenting (Box 3.9.8) and animal welfare (see O'Brien, 1995) than to environmental implications. There has also been considerable debate on implications for developing country agriculture – whether the technology will assist food security or increase poverty and hunger (see for example the differing views of Monsanto, 1998; Action Aid, 1998; Shiva, 1999). Concern has recently arisen over the so-called 'Terminator Technology' which prevents use of seeds from a previous crop, and which in the event of cross pollination might lead to the formation of non-viable seeds in neighbouring non-GMO crops. The 4th Conference of the Parties to the Convention on Biological Diversity has requested its Subsidiary Body on Scientific, Technical and Technological Advice to consider and assess any

consequences for the conservation and sustainable use of biological diversity from the use of this new technology.

1.5. Industrial and public opinion about GMOs

1.5.1. Industrial opinion

There is no single industrial position on GMOs and their use. While developers of GMOs see them as a huge market opportunity, food producers, although interested in new technological developments, are under pressure from consumers who wish to avoid GMOs. According to their impressions of public opinion some companies have had different positions in different parts of the EU. For example, a major food company in Germany avoids the use of GM ingredients in all its products but in the UK and the Netherlands the company uses GM ingredients in some products, with labelling.

Food retailers have come under pressure to label and segregate GM products containing GMOs. Some supermarket chains in various European countries have taken the step of ensuring only GM-free sources are used in their own brand products.

Box 3.9.7. Some indirect effects of GM products on wildlife

'There are concerns that the current regulatory regime may fail to identify long-term indirect effects on biodiversity resulting from commercial use of GM crops in agriculture, if production management methods, such as herbicide use for weed control, are encouraged … Whether or not the crop itself was considered to pose a low risk to human health and the environment, widespread commercial uptake by farmers could result in declines in certain wildlife species.' (ACRE, 1997)

'The specific issue that faces ACRE is that, while the decision to grant licenses to introduce genetically modified seeds for one crop may have a very small impact on insect populations and so on bird populations, as licenses are granted to introduce genetically modified varieties of more and more crops then the impact on insect and bird populations becomes more severe. The only policy instrument that is required is a subsidy to the growing of non-modified crops. We determine both the optimal number of technologies to introduce, and the optimal usage of each technology. These decisions in turn determine the amount of food available for insects to feed on and hence the number of species of insects and birds that survive. This subsidy should be introduced even before the new technology becomes available, and then should be raised over time so as to choke off the demand for further crop modification' (Sianese and Ulph, 1998).

The attitude of the conventional farming industry is not yet clear. Because GM crops and food are not allowed under organic standards, the attitude of organic farmers across Europe is firmly opposed. They are worried that if cross-pollination occurs between GM and organic crops that they will lose their organic status.

Box 3.9.8. Patenting

Patenting is one form of intellectual property protection (others include copyright, plant breeders' rights, trademarks, etc). In exchange for disclosure of the invention, the inventor is given a right to exclude others to commercially exploit the invention for a period of time, usually 20 years from the filing date. The intention of patent protection is to encourage further innovation by making information available whilst allowing for the costs of research and development to be recouped by allowing only the innovator to market the product of their investment in R&D.

There are three requirements for an invention to be patentable in Europe:

- novelty (not known before);
- inventiveness (not obvious to one skilled in the art; more discoveries are not patentable);
- capable of industrial application.

Businesses have applied for patent protection on the genetic material, useful micro-organisms, cells, plants and seeds they have produced using molecular techniques. The objections include that:

- patent protection should not be extended to living material;
- genes, cells, plants and seed are the products of natural process and therefore cannot be claimed to be inventions;
- it is unethical to allow monopoly control over such materials: 'life is not patentable';
- farmers will have to pay royalties to companies if they keep seed from their own crop to resow in subsequent seasons.

The EU has tried to resolve these conflicting positions through the introduction of a Directive on the Patenting of Biotechnological Inventions. Directive 98/44/EEC was introduced by the Commission in 1996 and was agreed in 1998. Some safeguards such as the clarification of inventions which would be considered contrary to public order and morality, and the inclusion of a 'farmers' privilege' (to allow seed to be kept for future years) helped secure the agreement of the European Parliament, which was also concerned about possible delays in medical applications.

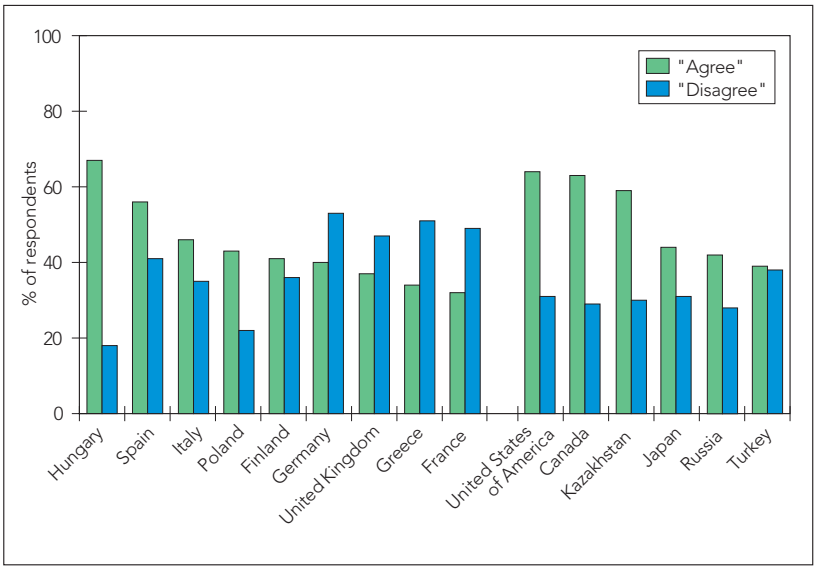
However, the European Patent Convention (EPC) excludes patenting on plant varieties and case law to date at the European Patent Office (EPO) has led to patents being refused for GM plants, a situation which conflicts with the patenting Directive. The Enlarged Board of Appeals at the EPO is reconsidering the exclusion of plant varieties.

Internationally, the European approach to patenting biotechnological inventions also has to be consistent with the TRIPS agreement (Trade Related Aspects of Intellectual Property Right) which was negotiated as part of the Uruguay Round of the GATT. The TRIPS agreement met opposition of 45 indigenous, peasant and non-governmental organisations from 19 countries who agreed on the so called Thammasat Resolution (December 1997). It is their conviction that the TRIPS agreement will 'result in new and further monopoly rights over plant varieties'. The TRIPS article is to be reviewed in 1999.

1.5.2. Public opinion

Public opinion across Europe has tended to be sceptical about GM foods, a development which has proved contentious (Figure 3.9.1).

Figure 3.9.1 **Public opinion on GMOs**



The population of respondents who agree/disagree with the statement that the benefits of using this technology to create GM foodcrops that do not require pesticides and herbicides are greater than the risks.

Source: International Environmental monitor 1998

The GM soybean imported from the US since 1996, amongst growing controversy, is now found in a large range of processed foods in the EU. However, neither citizen nor consumer acceptance are at all certain. There has been opposition from a broad range of environmental and consumer organisations, and GM crops have suffered direct-action destruction in several EU Member States including the UK, Germany, the Netherlands and France.

Public opposition to GM foods has been seen by some as reflecting a lack of knowledge about the technology, but comparing the results of Eurobarometer surveys in 1991, 1993 and 1996 shows that whilst basic knowledge about the technology has increased, optimism about its ability to improve the quality of life has decreased (Biotechnology and the European Public Concerted Action Group, 1997). The 1996 Eurobarometer results confirmed other research showing that on GM foods, environmental and consumer groups were much more trusted sources of information than public bodies or companies. Eurobarometer also demonstrated that 74% of the European public supported the labelling of GM foods; 60% believed there should be public consultation about new developments; and just over half, 53%, felt current regulations are insufficient to protect people from the risks of the technology.

Relying on opinion poll information alone does not provide a good basis for measuring public attitudes as it reveals little about underlying concerns and can be heavily biased by the way in which a question is asked. Qualitative research has shown that, for example, the British public have considerable mixed feelings about GM foods and the adequacy of present systems of regulations and of official 'scientific' assurances of safety, especially given the knowledge gained during the BSE crisis (Grove-White *et al.*, 1997). The same study also claimed that *consumer* acceptance in terms of purchasing a product such as tomato paste made from GM tomatoes which soften more slowly, should not be equated with *citizen* acceptance as there is often an underlying lack of support for such interventions even from people who behave pragmatically in the marketplace.

This and similar research from the Netherlands (e.g. Hamstra, 1995) also showed that the public are discriminating in how they judge GM technologies, looking more favourably on applications, especially in the medical domain, where a clear social benefit is seen. Applications which give benefits to, say, food processors are viewed less favourably since benefits appear restricted to certain financial interests. The public also displays awareness – and negative evaluation – of the interests driving GM innovations which are slanted to the affluent markets of the developed world rather than the needs of poor countries. The ultimate trajectory of the technology also plays in the public mind, with the concern that apparently innocuous uses may lead to misapplication in the future which they may be unable to control.

Thus the public appears to bring together issues of trust, control, the controlling purposes and the particular costs and benefits of the application when evaluating the effects of GM technology. Public expressions of concern also show ethical judgements to be part of risk judgements. The public are therefore making rather complex and sophisticated judgements in forming their attitudes towards GMOs. Some local authorities reflect the publics concerns; for example, in Germany and the UK they have recommended GM-free foods in schools and other institutions, and the city of Munich has recommended GM-free crops on its leased allotments (FOE, 1999).

2. Investigating the risks of gene flow: a case study of gene transfer from oilseed rape to related wild plants

Research programmes developed over the past 10 years have allowed identification of the crops where gene flow to weedy relatives can occur. One environmental concern associated with the release of GM crops is the risk of dispersal of the transgene within cultivated and wild populations. Such genetic transfers may have already occurred from traditionally bred plants, so the risk here relates to the nature of the transgene rather than the transfer as such. Such transfer could enhance the invasiveness of the wild populations and modify the pressures on agriculture as well as agricultural practices, with consequential environmental impacts of their own, depending on the transgene concerned.

With crops such as sugar beet, radish and alfalfa, gene flow will undoubtedly occur because weeds belonging to the same species as the crop are present in the cultivated areas. There are also crops, such as maize in Europe, for which gene flow is impossible because of the absence of wild weeds which are related to the cultivated plant; however, even in such cases it remains essential to assess pollen dispersal because cutivated crops can cross-pollinate, affecting the ability to produce non-GM crops. Other crops, such as oilseed rape, are in an intermediate situation. Many different, related weeds are present in or close to the crop fields but they have different abilities to cross-pollinate. Research programmes have still to be developed to provide information on the genetic mechanisms of recombination according to the location of the transgene or on the occurrence of new weeds.

Oilseed rape (*Brassica napus*) is therefore particularly suitable for a case-study of gene transfer to illustrate the complex problems of environmental assessment. Gene dispersal can take place via pollen and seeds and there are numerous weedy species more or less related to oilseed rape with an overlapping flowering period within the cultivated area. Furthermore, commercial GM varieties of oilseed rape are already available. However, this case study is not intended to define the range of possible effects of GMOs but to illustrate the issues surrounding the investigation of direct effects. Gene transfer may be more or less important than some other possible impacts such as altered patterns of herbicide use or insect resistance if a crop was modified in this way. However, the complexity that is revealed in the relatively straightforward question about gene flow demonstrates how difficult unravelling secondary effects may be.

So far research programmes have focused mainly on the frequency of gene transfer rather than the impact. Gene dispersal within the same species always causes problems in conventionally bred crops as it can interfere with the purity of hybrid seeds if cross pollination by other crops or wild species occurs. However, there is little data available about gene flow from crops to related species. To be successful, gene transfer from one species to another involves the following steps: (1) production of viable hybrids from crosses between the two species, (2) occurrence of fertile plants in the successive generations, (3) gene transmission through the different generations, (4) effective gene establishment within the natural populations and maintenance of the new trait.

2.1. Development of research over the past 10 years

Research programmes have focused on the crop's ability to disseminate genes spatially and temporally and on the risk of gene introduction into the weedy relatives.

2.1.1. Gene dispersal from the crop

Oilseed rape is partially self-fertilising with, on average, a third of its pollen contributing to out-crossing. Pollen, carried by wind and insects, is the main route of spatial dispersal. Experiments to determine over what distance pollen can move have given different results depending on the assumptions and methodologies used (Box 3.9.9). So the isolation distance which would totally prevent pollen dispersal remains highly speculative.

Seeds contribute to temporal dispersal. One to 10% of the seeds are lost at harvest and result in volunteers (where seed from one crop survives and grows in different crops in following seasons) which may emerge in following years (Price *et al.,* 1996). The ability of such seeds to survive under natural conditions and to contribute to feral populations seems to be low (Crawley and Brown, 1995) but little experimental data is available.

2.1.2. Gene flow to weeds

The occurrence and frequency of gene flow from crops to weeds can be studied by two methods: either by researching genes specific to the crop within the weedy

Box 3.9.9. Whither pollen?

- How far pollen can travel is important for assessing the risks of genetic pollution by GM crops of non-GM crops, such as organic produce, with attendant safety and economic implications. An opinion from the UK government's Advisory Committee on Releases into the Environment (ACRE) stated that 'at a standard separation distance of 200 metres between the organic sweetcorn and the GM maize, the likely cross-pollination frequently would result in no greater than 1 sweetcorn kernel in every 40 000 being a GM hybrid.' However, a recent report by the UK Nature Pollen Research Unit (NPRU) concluded that 'in conditions of moderate wind speeds, the rates of cross-pollination at 200 meters would be in the order of 1 kernel in 93.' The NPRU report observed that the ACRE report failed to 'even consider cross-pollination of the organic sweetcorn by bees' despite the presence of several beehives adjacent to the disputed experimental site, and that its dismissal of long-range transport was noncompatible with the 'substantial evidence' on the 'long-range transport of considerable numbers of pollen grains… . Maize pollen remains viable under normal conditions for approx. 24 hours giving potential for pollination by grains that had travelled many hundreds of kilometres on the air flow.' (Emberlin, 1999).
- Cross-pollination can result in the crops in neighbouring, non GM farms producing GM seed. As the GM company forbids seed saving from year to year or exchange between farmers, enforcement of such agreements will be difficult if there is accidental genetic pollution by GM crops on non-GM farms, which is already happening in the US (FOE, 1999).
- Timmons et al. (1995) studying pollen movement between different fields showed that pollen can be dispersed over 1 km. In contrast experiments looking at pollen movement from a small plot within a field indicated that the majority of the pollen fell within the first meters around the plants (Scheffler et al., 1993). Comparison with global pollen dispersal suggests that measurements for individual plant pollen understate the area covered by medium- and long-distance dispersal (Lavigne et al., 1998).

populations or by producing hybrids between the GM crops and wild species (interspecific hybrids).

The first method is difficult because the weed species belong to the same botanical tribe as oilseed rape and have a common ancestor; consequently, there are no agreed specific marker genes to use in the study of gene transfer. Following the second approach, data for laboratory-developed interspecific hybrids (Scheffler and Dale, 1994), and the relative importance of the different species as weeds within the cultivated areas, has been used to target studies of gene flow from oilseed rape to related weeds under natural conditions (see Jorgensen and Andersen, 1994; Bing *et al.*, 1996; Eber *et al.*, 1994; Chèvre *et al.*, 1996; Lefol *et al.*, 1996a, b; Darmency *et al.*, 1995).

Although studies show that hybrids can be formed between oilseed rape and some related species under field conditions, there are many other factors which will influence how likely it is that gene transfer will occur and the new gene(s) become established in the weed population. The outcome is affected by:

- use of oilseed rape as female, which generally produces more seeds (Kerlan *et al.*, 1992; Jorgensen and Andersen, 1994; Jorgensen *et al.*, 1998);
- the genotype of both parent plants (Jorgensen and Andersen, 1994; Baranger *et al.*, 1995);
- variability in the weeds (Lefol *et al.*, 1996a ; Darmency *et al.*, 1998);
- the spatial relationship between the crop and the weed species (Jorgensen *et al.*, 1998; Lefol *et al.*, 1996a ; Darmency *et al.*, 1998).

Studies using herbicide-tolerant oilseed rape varieties have shown that, if genes are carried on a genome common to the weed and crop, their transfer to the weed is relatively easy. Mikkelsen *et al.* (1996b) showed that only two backcrosses to the wild species were needed for gene introgression from oilseed rape to field mustard. However, although these studies indicate that gene flow to closely related species can be rapid, studies with a less-related species, the wild radish, indicated that, at the third backcross generation, none of the herbicide-tolerant plants had the same chromosome number as the weed. So, the transgene was not established in the genome of the weed (Chèvre *et al.*, 1997; 1998). However, hybrid plants with both sets of parental genes have been detected at the first generation stage and are under further study.

The results of all these studies show that gene transfer from GM oilseed rape to related plants is possible under field conditions and that its frequency is dependent on many factors including the biology of the weeds. As research has progressed over the past decade, it now seems that this is more likely for some species than was at one time believed. How-

ever, the many interrelated factors affecting gene flow, ranging from variations in the genetic composition of weeds to spatial relationships between plants and agricultural practices mean that prediction with any certainty how, when, where and with what outcome remains extremely difficult.

The case study raises several critical methodological issues (Box 3.9.10).

3. Evolving regulations on the release of genetically modified organisms

3.1. Revision of the Deliberate Release Directive in the EU

One of the primary intentions of the Directive's revision (European Commission, 1998), driven by single market trade imperatives, is to harmonise risk assessments across the EU and to facilitate agreement on marketing authorisations in particular. Other aims are to improve transparency and introduce a monitoring mechanism to detect any effects on the environment or human health arising from the release of GMOs.

The main elements of the Commissions' original proposal are shown in Box 3.9.11. One area involves the implementation of a risk assessment which explicitly includes direct and indirect, as well as immediate and delayed effects. It also recognises how important disagreements about the scope and nature of unacceptable effects have been in the past. Such disagreements amongst Member States can result in them using Article 16 of the Directive which allows countries to ban the use of a GMO, if new evidence emerges which indicates that harm may have been underestimated.

Box 3.9.10. Critical methodological issues in gene transfer research

Some of the shortcomings of present knowledge on gene transfer for risk assessments are outlined below.

– Experiments are on a small scale providing limited evidence on:

- the effect of the parental genotypes – a large diversity exists amongst oilseed rape varieties cultivated over Europe and gene flow will vary according to genotype;
- the effect of the relative positions and density of the parental species – close to large oilseed rape fields, weedy plants can be present as isolated plants or as clusters within the field, in the border of the field or in fallow ground and this will influence how likely it is that cross-pollination can occur and at what frequency;
- the effect of time and repeated oilseed rape pollen flow from fields or volunteers which also influences the likelihood of gene flow as it affects contact time and opportunity for cross pollination;
- the fitness of the plants, according to their genomic structure along the different generations, which may increase or decrease over time and in varying environmental conditions affecting the long-term likelihood of successful gene flow;
- the impact of different agronomic practices such as the use of herbicides to control volunteers.

– Few predictive models and insufficient data for validation

– Few transgenes analysed

Most of the research programmes have been performed with herbicide-tolerant GM crops because herbicide tolerance was the first trait of agronomic interest widely used and because this trait is easy to screen on large populations. However, the results may not be directly relevant to other GM crops and thus other studies will be needed. For example, other GM traits such as pest- or fungi- or stress-resistance, and modification of oil quality, may affect the fitness of the hybrid plants differently than herbicide tolerance, and little data is available.

Other risks

Because oilseed rape is pollinated by insects, whether there are any effects on beneficial insects such as honeybees has to be assessed under product authorisation regulations. Effects of gene products at both individual and colony levels under confined conditions were analysed from different transgenic oilseed rape lines expressing pest and fungi resistance. The three proteins tested were shown to be non-toxic at the doses tested (Picard-Nizou et al., 1997). The bioassays developed will be useful in testing new transgenic lines. Potential opportunities for reducing the risks of gene flow include:

- identification of a 'safe insertion site' for the transferred gene because it has been shown that gene flow is dependent on the location of the genes in the donor species (Lukaszewski, 1995);
- modifications which reduce the dispersal of pollen (e.g. self-fertilising varieties) and seeds (e.g. reducing seed loss at harvesting and dormancy);
- adaptation of agronomic practices (e.g. management strategies for herbicide-tolerant volunteers); a multi-year monitoring study is already in progress with different GM crops (corn, sugar beet and rapeseed) tolerant to glufosinate, glyphosate or bromoxynil (Messean, 1997).

Box 3.9.11. Revision of the Deliberate Release Directive – main features of the Commission's proposals

- Maintain precautionary approach.
- Aims to promote consistency in risk assessment across the EU.
- Direct and indirect, immediate and delayed environmental impacts to be explicitly included in risk assessment.
- Monitoring plans to be included.
- Renewal of consent to market required after 7 year period.
- Product based consents continue to be allowed – e.g. GMO pesticide could be evaluated under pesticides regulations.
- Streamlining authorisation procedures to reduce evaluation times.
- Reinforcement of EC Scientific Committees advisory role on applications.

The Commission proposal has no provision for a socio-economic 'risk' assessment, or references to sustainable development which environmental and consumer organisations, and some Member States, would like to see included in the revision. Austria, in its implementing legislation of the Deliberate Release Directive, does require GMO releases to comply with principles of sustainability. However, Austria does not appear to have tested applications under this part of the regulations yet. The Finnish Gene Technology Act also calls for the '…development of gene technology in a way that is ethically acceptable'.

In February 1999 the EU Parliament, while acknowledging there could be potential benefits of GMOs, agreed over 100 amendments to the Commission proposal covering issues such as:

- a ban on releasing GMOs containing genes that are resistant to antibiotics in use for medical or veterinary treatment;
- measures to prevent gene transfer;
- unauthorised releases;
- mandatory monitoring of all releases;
- clear labelling and identification;
- compulsory liability insurance by those releasing the GMO;
- use of the precautionary principle;
- prior informed consent for exports to non EU countries;
- time periods for market approval.

How, what and when to monitor GMOs will be crucial issues and there will need to be some definition of how monitoring should be approached in the final Directive. Box 3.9.12 identifies some of the key ingredients of monitoring plans.

The disputes between Member States have concerned the scope of the Directive, what constitutes an adverse effect and (although the Deliberate Release Directive *in theory* only concerns itself with safety) the socio-economic factors some countries bring to bear implicitly or explicitly in their judgements (Levidow *et al.*, 1996). For example, under Austrian law, products should be assessed for 'social unsustainability' and some regulators have acknowledged to researchers that they do consider the presumed benefits. These issues are summarised in section 4 below.

3.2. Regulatory developments in non-EU countries

Other European countries have either followed the approach of the EU and brought in special regulations for GMOs or adapted existing laws, although not all countries have regulations in place, especially in central and eastern Europe. Where there are regulations, many of these, such as in Poland, the Czech Republic and Hungary have been specifically designed to conform to the relevant EU Directives. However, although Poland has framework GMO laws there are no implementing regulations.

Other countries such as Switzerland have adapted existing regulations to conform to EU Directives, underlining the importance of the approach taken by the EU in shaping the risk-assessment process across Europe.

Those European countries without any clearly defined GMO regulations (although most are in stages of development) are: Georgia; Russian Federation; Latvia; Moldavia; Romania; Slovenia; Ukraine; Croatia; Albania; Estonia.

The country with the most different approach in principle is Norway. The Norwegian 1993 Gene Technology Act at Section 1 'Purpose of the Act' demands that '... the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment'.

The inclusion of an explicit reference to ethics, social justification and sustainable development allows a different framework of

risk evaluation to take place than that which is possible under the EU approach. In requiring these issues to be addressed in public, the Norwegian legislation recognises the inability of scientific risk-assessment knowledge to provide the sole means of 'closure' in such decisions. 'Justification' or social need is difficult to determine, but there may be lessons from the field of radiation, where justification has long been a part of international and national regulations.

3.3. International dimensions of GMO releases and regulations

There are also international dimensions to the regulation and use of GMOs. The most important include the World Trade Organisation's risk-assessment rules and the Biosafety Protocol as part of the international Convention on Biological Diversity.

3.3.1. World trade rules

There is tension between the demands for environmental protection and free trade. The US advocates the primacy of free trade, whereas the European Union considers that appeals under multilateral environmental agreements should have the same status as appeals to World Trade Organisation (WTO) rules on unjustified barriers to trade. Biotechnology and biodiversity policies are framed by the *Agreement on the Application of Sanitary and Phytosanitary measures* under WTO ruling and the negotiations on a *Biosafety Protocol* under the Convention on Biological Diversity (CBD). The trade versus environment issue is reflected in the disputes on the development of both regulatory frameworks.

Most of the WTO trade negotiations are aimed at not making a distinction between so called *non-product-related process and production methods* (PPMs). The current EU Deliberate Release Directive, however, is a process-based regulation and could therefore be challenged regarding some aspects under WTO ruling. The trade-environment dilemma is also present in the basic agreement on Agenda 21 at the UNCED conference in 1992. The precautionary principle was accepted at that conference as a basic principle for environmental policy but it is was also accepted that there should be 'no unfair or unjustified barriers for trade' imposed by national governments. Since the implementation of the precautionary principle leaves open a grey area of how trade barriers could be justified by scientific risk assessments alone, trade versus environment will remain a source of dispute between trade partners.

Box 3.9.12. Some key requirements of monitoring GMOs following market authorisations

Several levels of monitoring interconnecting with other nature conservation monitoring plans:

- baseline studies of areas without GMOs for comparison;
- following changes in agricultural practices and their impacts;
- specific studies related to GMO itself e.g. manipulated gene flow.

Minimum standards with room for additions:

- specified studies of transgene flow and relevant ecological parameters such as insect abundance and diversity for insect-resistant crops;
- specified basic information on agricultural practices the GMO is used in;
- flexibility to allow for additional monitoring should new knowledge require it, or for reduced monitoring if not needed.

Intelligence gathering:

- collection of data on how and where the GMO is being used and its end fate;
- tracking public attitudes to GMOs;
- political and regulatory developments;
- transgene and resistance;
- monitoring compliance with license conditions (e.g. crop isolation measures);
- systems that maximize the chances of discovering 'surprises'.

Labelling of GM products has formed one of the first areas of disagreement between trading partners in the biotechnology domain. Mandatory labelling schemes, such as the recent European Council Regulation 1139/98 concerning the compulsory labelling of products based on genetically modified soya or maize, would fall under the WTO Technical Barriers to Trade (TBT) Code, since it is a practice which forces producers to create separate production arrangements for the markets which require labelling. However, this mandatory labelling practice imposes the same requirements upon foreign and Community producers, which is the most basic requirement of WTO obligations.

Other countries such as Japan are preparing similar regulations as the EU. Labelling requirements may be justified under Article 2.2 of the WTO's Technical Barriers to Trade agreement which mentions a non-limited list of possible legitimate objectives for technical barriers to trade: 'inter alia national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment'.

'Consumer concerns', or 'a right of free consumer choice', or basic ethical values may be added to this list. The justification for labelling in the Europe with respect to GMOs is also related to the issue of safety and precautionary measures. Labelling facilitates tracing products in the production chain. The revision of Directive 90/220 (see section 3.1 above) foresees post-marketing monitoring of products which would be difficult to implement without labelled products. In addition, the Biosafety Protocol (see section 3.3.2 below) is likely to include requirements with respect to the labelling of, or the documentation to accompany, GMOs.

Countries which want to institute measures which restrict trade can justify these under the WTO when they are, among other things, necessary to protect human, animal or plant life or health, or relate to the natural conservation of exhaustible natural resources. These measures must not constitute 'a means of arbitrary or unjustifiable discrimination among countries where the same conditions apply, or as a disguised restriction on international trade'. The Environment field (including biodiversity) could, therefore, be a major exception to normal rules of free international trade. Parties can base their environmental case on either Multilateral Environmental Agreements or on real efforts to negotiate such agreements with parties before implementing environmental protection measures. They must also provide scientific evidence on the potentially adverse effects, including justification of any use of the precautionary principle. Disputes among WTO Members can be resolved by Article 5.7 of the Sanitary and Phytosanitary (SPS) Measures.

3.3.2. The Biosafety Protocol

Under the Convention on Biological Diversity, a Biosafety Protocol is being negotiated. The Protocol should provide a minimal legal framework for transboundary movements of living modified organisms (LMOs) for which there are currently no international rules.

The EU position has emphasised informed consent on the part of importers, to be facilitated by an Advance Informed Agreement Procedure for the transboundary movement of LMOs.

The US has called for a 'superiority clause' to be part of the Protocol which would make the biosafety protocol subordinate to the rules of WTO, in the event that the Protocol give rise to trade conflicts. The EU opposes this and wants to see Multilateral Environmental Agreements as complementary to the rulings of the WTO and to make them mutually supportive. Disputes over this, the scope of the protocol, the precautionary principle, and socio-economic impacts prevented an agreement at the Cartegna meeting in February 1999.

There are also International Technical Guidelines from the United National Environment Programme (UNEP) for Biosafety; they cover the assessment of the risks of GMOs for use by countries either in developing regims or when developing regulations. These were developed in advance of the Biosafety Protocol being negotiated and have helped restrict the scope of the Protocol which many nations had originally expected to include all uses, not only transboundary movement.

4. Defining risk assessments for GMOs

4.1. The Deliberate Release Directive in the European Union

The EU Deliberate Release Directive has been criticised because of its limited scope, excluding, for example, issues of agricultural practice and interactions, and also because assessments of GMOs allegedly give insufficient weight to their benefits.

4.1.1. The scope of the Directive

Differences over the scope of the Directive have been the most evident problem. These centre on whether the assessment should include secondary effects, not directly attributable to the GMO but related to the system of use. Some countries including Austria and Denmark have wanted to include the impacts on agriculture in their assessment of environmental harm. In the case of herbicide-tolerant crops, for example, this entails extending the assessment to include the impact of the herbicide and its changing use as a result of the introduction of the GMO.

Austrian research has questioned whether it is the deliberately engineered trait of a GM crop which has the greatest influence on its final environmental effect (Torgersen, 1996). Their research suggests that agricultural or horticultural practices have a greater influence on the environmental effects of the crop than do organism-specific parameters such as 'invasiveness' and 'gene transfer' which are more commonly associated with safety and which form the questions

included in the risk assessment under the Deliberate Release Directive. The implications are that environmental effects of the GMOs may be more contingent upon the local environmental and agricultural conditions than was previously thought – hence less deterministically predictable and likely to vary across the EU.

As well as differences in ecosystems and in agricultural systems there are also cultural and social differences between Member States in their approaches to food production and environmental protection. There may also be commitments to environmental protection made under other legislation, such as the Habitats Directive and the Biodiversity Convention, which are relevant to judgements about the acceptability of certain impacts but these wider consequences tend to be hidden in the specific discussions over one single GMO marketing authorisation as framed by the current regulatory system.

Other countries, such as the UK and the Netherlands, have adhered to a restricted scope for the risk assessment by considering only the direct effects associated with the GMO, leaving issues of pesticide use and agricultural practice to be addressed under pesticides regulations (see for example Advisory Committee on Releases to the Environment, 1997). Table 3.9.3 outlines the differences between countries in how they view the scope of the risk assessment under the Deliberate Release Directive and Box 3.9.13 shows that different interpretations of the scope can affect how a risk assessment is undertaken.

4.1.2. Defining an 'adverse' effect

Directive 90/220 leaves open what precisely can be considered as an 'adverse effect on human health and the environment' and what could be 'a sufficient demonstration of safety'. The combination of a case-by-case evaluation and the absence of fixed standards for evaluating these cases provide the background for ongoing deliberations at national level and in scientific advisory committees. And because knowledge is evolving, standards could be relaxed or strengthened over time depending on the accumulation of scientific evidence. For instance, the transgene transfer from GMOs to wild relatives may either be perceived as 'genetic pollution' or as a natural (and therefore acceptable) process depending on our knowledge of whether such a gene transfer poses a threat.

Member States also have differences in their 'yardsticks' against which they measure the direct environmental effects which can be attributed to the GMO itself. For example, comparisons may be made with reference to the effect on conventional agriculture (UK), safeguarding environmental, nature and health interests (Denmark/Sweden) or reduction of biodiversity (Denmark, Sweden, Italy, Austria) (Table 3.9.3). However, even if the same comparison was made to, say, conventional agriculture in all Member States the outcomes would still be different. 'Conventional' agriculture (meaning agriculture as it is currently practised) is very different in, say, Austria, Spain and the UK.

In addition a number of Biogeographic Zones have been defined in Europe and are the basis for the selection of Special Areas of Protection under the Habitats Directive. They contain significantly different ecosystems and species assemblages. The possible effects of GMOs on such ecosystems requires local consideration and knowledge. It cannot be performed meaningfully and with scientific validity on an EU-wide basis.

So instead of fixed and uniform standards, individual Member States use flexible standards to define the acceptability of releases such as 'Reduction of biodiversity' or 'comparison with the risks of conventional agricultural practices'.

Box 3.9.13. Assessing the effects of herbicide-tolerant crops – how the scope of the assessment may influence the outcome

Examples of effects considered under an assessment approach with restricted scope:

- Gene flow to wild species;
- Potential for becoming a persistent weed;
- Potential to invade and disrupt ecosystems;
- Toxicity;
- Individual crops.

Examples of effects considered under an assessment approach with a broad scope:

- Assessment of total benefits, costs and uncertainties in weed control systems.
- Altered pattern of herbicide use and effects on biodiversity.
- Cumulative impacts on gene flow, invasiveness etc of multiple releases.
- Practical implications of the emergence of herbicide tolerance in weeds.
- Cumulative impacts from use on large, adjoining areas from multiple releases.

One of the most contentious areas has been the use of antibiotic-resistance marker genes. This has been seen in the Novartis insect and herbicide-resistant maize which carries a gene coding for resistance to the clinically important antibiotic ampicillin. Austria and Luxembourg have introduced bans on its use under Article 16 of the Deliberate Release Directive because of the presence of this gene and other concerns (see Box 3.9.2). Other Member States have also had concerns about the ampicillin resistance gene, including the UK whose scientific advisory committee advised against allowing the marketing of the maize on these grounds. However, the two EU Scientific Committees which evaluated this point concluded that the ampicillin antibiotic gene does not raise a safety issue.

4.2. Knowledge limitations, uncertainties … and their resolution?

Although it is a part of any precautionary approach, the 'step-by-step, case-by-case' approach to safety has limitations. Cumulative impacts are neglected and small-scale trials may be an inadequate predictor of performance in the wider environment (GeneWatch, 1998). In addition, since the majority of field trials also consider agronomic traits such as yield it has been argued that they produce little relevant data for environmental risk assessment (Rissler & Mellon, 1993). Thus, remaining uncertainty is a pervasive problem, leaving explicit or implicit value judgements to be made. Even with commercially authorised GM crops, as a large-scale experiment is being conducted on the environment it would seem sensible, at the very least, to monitor the effects.

Despite all the controversies, no political actor, organisation or Member State has questioned the necessity of a precautionary approach (Von Schomberg, 1998). Although the lack of standards has caused disputes between Member States, perhaps this reflection and deliberation should be seen in a positive context as an inevitable part of balancing risk and innovation. GMO regulation is controversial but it can help facilitate the resolution of generic issues that surround the development of new technologies (Box 3.9.14).

Table 3.9.3. **Differences in interpretation of the Deliberate Release Directive***

	Germany	United Kingdom	The Netherlands	Denmark/ Sweden	Belgium	Italy	Austria	France
Scope	Safety	Safety	Safety/ biodiversity	Safety/ biodiversity/ agronomic effects	Safety/ biodiversity	Safety/ biodiversity/ agronomic effects	Safety/ biodiversity/ agronomic effects	Safety
Evaluation of Adverse Effects	Safety concerns in relation to the purpose of the release	No additional risk in comparison to conventional agricultural practice	Persistant effects on the composition of natural vegetation	Safeguarding environmental, nature and health interests Sustainable development	No aggravation of existing environmental problems through releases	May change on a case-by-case basis	Compliance with social institutions and conventions	Knowledge of the genetic construct of the organism

* Since this comparison was made some Member States have begun to expand the scope of their environmental assessment to include secondary effects on biodiversity and agricultural practice.

Source: Von Schomberg, 1998

Box 3.9.14. GMO regulation can facilitate:

1. An ongoing scientific and policy deliberation on managing uncertainties in a public policy context. This includes taking decisions not only on available data but also on plausible notions of what could be the case.
2. An ongoing public policy and scientific discussion on transformable/flexible standards within the regulatory framework but also in the societal context of this regulatory framework.
3. The awareness of the need for monitoring and continuous interest in the experience with releases and market products.
4. The awareness of the need for a long-term and holistic perspective, which is implemented by a precautionary and flexible practice.
5. EU-wide comparative discussion of different Member States' resolutions of trade-offs between scientific uncertainties and public values.
6. Debate about the trade-offs between single-market uniformity of risk assessment commitments and Member State variations in interpretation.
7. Resolution of the ' free trade' and environment/ health conflicts.
8. The development of acceptable approaches to the generic safety, health and environment issues that surround the development of new technologies, such as:

- justification , or 'need',
- risks to safety, health and environment,
- managing uncertainty and applying the precautionary principle,
- implementation and enforcement of measures,
- monitoring of impacts,
- information to the public via labels and emissions/release inventories,
- liability,
- informed consent for export/imports, and
- trade and risk trade- offs.

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