

## The research team's national and EU-level reports

- Austria: *Precautionary Blockage of Agricultural Biotechnology*  
(Helge Torgersen and Franz Seifert, Institute of Technology Assessment, Austrian Academy of Sciences)
- Belgium: *Precaution through Coordinated Administration*  
(Katrin Bilmeyer, Vita Vitalis, Antwerp)
- Denmark: *Potential Polarization or Consensus*  
(Jesper Toft, Roskilde University)
- France: *Broadening Precautionary Expertise*  
(Alexis Roy and Pierre-Benoit Joly, INRA/SERD, Grenoble)
- Germany: *'Elite Precaution' along with Continued Public Opposition*  
(Marion Dreyer and Bernhard Gill, Ludwig-Maximilians University, Munich)
- Ireland: *Contested Precaution as Policy Evolves*  
(Brian Motherway, Dublin)
- Italy: *Precaution for Environmental Diversity*  
(Fabio Terragni and Elena Recchia, CERISS, Milan)
- The Netherlands: *Reopening a Consensus on Agricultural Biotechnology Policy*  
(René von Schomberg, International Centre for Human and Public Affairs, Hengelo)
- Spain: *Commercialisation Drives Public Debate and Precaution*  
(Oliver Todt and José Luis Luján, University of Valencia and University of the Balearic Islands)
- UK: *Precautionary Commercialisation*  
(Les Levidow, Susan Carr and David Wield, The Open University)
- EU: *EU Level Report*  
(Les Levidow, Susan Carr and David Wield, The Open University)
- EU: *Legal Aspects at the EU Level*  
(Roland Winkler, Salzburg University)

This summary was compiled by Susan Carr.

# EU safety regulation of genetically-modified crops

The late 1990s were characterised by unprecedented media coverage and public concern in the EU about genetically-modified (GM) crops and the food derived from them. Researchers in ten EU member states\* were investigating GM regulation throughout that period, analysing the regulators' response and the policy implications. This report presents highlights from that research (see Box 1 for individual reports and authors). In summary:

- By the late 1990s, the European Commission had approved several GM crops for commercial release throughout the EU.
- Regulators had assessed these crops as safe, judging that any undesirable effects would be no worse than those of conventional products.
- The public protest against GM crops and food that erupted in 1997 challenged the basis of those approval decisions.
- In response, regulators delayed further commercial approvals and introduced additional precautionary measures.
- Concerns that had previously been raised by a minority of member states during the EU risk-assessment procedure became more mainstream. Precautions initiated by companies and individual member states became examples for others to follow, some being officially incorporated into the regulatory procedure or into its proposed revision.
- The findings suggest that minority views and independent initiatives should not be viewed simply as deviations from the path towards harmonised regulation, but as important signals and sources of ideas for gaining wider legitimacy for regulatory decisions.
- In effect, GM crops have become a testing ground for several wider issues:
  - How to interpret and apply the precautionary principle in practice
  - How to devise an EU-wide regulatory approach that accommodates national differences
  - How to set environmental standards for the sustainable development of European agriculture.



\* The research team included members from Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Spain and the UK. Co-ordinated by the Biotechnology Policy Group within the Centre for Technology Strategy at the Open University in the UK, the research was funded by DGXII under the Ethical, Legal and Socio-economic Aspects (ELSA) component of its biotechnology programme.

## Approval decisions challenged

The European Union's regulatory framework for GM crops, based on Directive 90/220 (see inside back cover), represented an innovative attempt to combine technological and commercial advance with precaution. The aim was to establish an internal market to allow GM crops to be grown in Europe and GM products to circulate freely, while requiring member states to take steps to avoid any possible adverse effects on human health and the environment.

### *From precaution to commercialisation*

Proponents of GM technology envisaged that as each GM product cleared successive regulatory hurdles the need for precaution would decline. Uncertainties about the impacts of GM crops would gradually be removed as knowledge and experience was gained in laboratory experiments and field trials. As the impacts became more predictable, GM crops would become more acceptable, so that by the time crops were approved for commercial use it would be possible to treat them as conventional products. In effect, the idea was that there would be a linear progression, from precaution to predictability to acceptability to commercialisation.

The first applications for the commercial release of genetically-modified versions of crops widely grown in Europe, maize and oilseed rape, met objections from several member states and criticisms from some environmental groups and scientists about the possible adverse effects. However, eventually the European Commission granted market approval, even though this involved over-ruling some objections. In 1998, the first commercial GM crops were grown in Europe (20,000 ha of insect-resistant maize in Spain and 2000 ha in France).

**The arrival in Europe of GM soyabean and maize from the United States attracted considerable media attention**

### *Public outcry*

The arrival in Europe of GM soyabean and maize from the United States at the end of 1996 and the beginning of 1997 attracted considerable media attention, fuelled by an upsurge in anti-GM campaigning. Following hot on the heels of a succession of food scares, this raised public awareness and concern, even in countries such as Spain and Italy where the issues surrounding GM crops had previously caused little discussion. A public outcry about GM food erupted. It called into question the idea that precautions would be unnecessary once crops had been approved as safe for commercialisation. Retailers and food processors throughout the European Union became drawn into the centre of the GM controversy. Consumer groups and organic farmers joined the increased demands from environmental groups for greater precaution, some of them calling for a moratorium on GM crops and food.

### *Policy changes*

The changed context contributed to a more cautious approach to GM regulation in some member states. In turn, this triggered or accelerated changes at the EU-level. This summary highlights two of the main changes relating to Directive 90/220 as GM products began to make the transition from field trials to the market. The first concerns a shift in views about risk assessment. The second involves the introduction of additional precautionary measures, most of which began as voluntary initiatives beyond the official regulatory system. The implications for future policy on GM regulation are considered in the conclusion.

## Shifting views about risk assessment

There was a marked shift in views about risk assessment between 1997 and 1999 among national competent authorities (CAs, the bodies nominated in each member state to take responsibility for GM safety regulation). In particular, public protest contributed to policy shifts in France and the UK, the two countries that had most frequently acted as EU-wide rapporteurs for, and recommended approval of, GM crops submitted for market release. Objections that had previously been expressed by a minority of CAs during the risk-assessment procedure of Directive 90/220 gained more support, in some cases leading to a change in policy at EU-level. Examples detailed below include demands for:

- seed labelling;
- rejection of crops with antibiotic-resistance marker genes;
- assessment of secondary effects; and
- inclusion of agricultural effects in the definition of adverse environmental impacts that must be assessed under Directive 90/220.



### Seed labelling

Denmark had always voted against any marketing application that lacked conditions for labelling seed as genetically modified. From 1996, more member states supported this position, partly in response to the public protest about GM food. Initially the Commission argued that labelling lay beyond the remit of Directive 90/220, since it could not be justified on grounds of risk – approved crops by definition had been assessed as safe. Eventually the Commission gave way, amending Directive 90/220 with Decision 97/35 to require seed labelling. Officially, this was justified mainly as a precaution to allow the progeny of hybrids with GM crops to be traced back to the GM parent. Unofficially, it would allow GM food to be traced back to the farm. Companies with GM products that had already been approved agreed to accept the labelling condition retrospectively.

### Antibiotic resistance

In the case of antibiotic-resistance marker genes, the UK's food safety committee had sought to discourage their use since the mid-1990s. Initially the prevailing view among CAs and their advisors was that the risks of a transfer of antibiotic resistance from GM crops to pathogens in livestock and humans was negligible, and that even if it occurred alternative antibiotics would be available for clinical treatment. By the late 1990s, there was a growing consensus that this type of marker gene should not be used, if only to respond to public concern. For example, the Spanish competent authority decided in 1997 that it would not act as EU-wide rapporteur for marketing applications that featured such markers.

In September 1998, the French Conseil d'Etat ruled that the French CA's risk assessment of an insect-resistant maize was incomplete because it had failed to assess the antibiotic-resistance marker gene in the maize (see Box 2). National CAs and the EU-level scientific committee have since increased their scrutiny of GM products containing antibiotic-resistance marker genes, for example, seeking further information on market-release applications for Avebe's potato and Monsanto's cotton.

**Scrutiny of GM products containing antibiotic-resistance marker genes increased**

## Box 2

### French national report

A national report has been produced for each of the member states represented in the research team. Aspects of the French report are highlighted here because some of the events with the most significance at EU-level over the two years of the research have occurred in France. In the mid-1990s, France acted as the EU rapporteur for more GM products than any other country, so its change in policy has special importance.

In February 1997, the French prime minister banned the cultivation of an insect-resistant maize that had been given EU-wide market approval the previous December on France's recommendation. His justification was that the risks of cross-pollination were still unknown, even though maize has no wild relatives in Europe with which it can cross-pollinate. In response, the chair of his advisory committee resigned.

In May 1997 a new government was elected and sought further advice on the risks associated with several GM crops. In November 1997, on the basis of that advice, it lifted the ban on maize but imposed a two-year moratorium on the cultivation of GM oilseed rape and sugar beet pending further research on the risks of cross-pollination.

In 1998, France became one of the first two EU member states to grow GM crops (maize) commercially. Because of uncertainties about the market for GM crops, farmers planted a much smaller area than anticipated by the company. NGOs appealed to the French Conseil d'Etat against the decision to allow commercial cultivation, on grounds that the original risk assessment was incomplete and had failed to consider the crop's antibiotic resistance marker gene. In September, the Conseil d'Etat accepted the appeal, stating that the precautionary principle had not been applied. In December, the Conseil d'Etat sought the advice of the European Court of Justice on the right of the French government to revoke an EU-wide approval decision. The verdict could have far-reaching implications for GM regulation in Europe, so this action has added to the uncertainties about commercialisation.

### Secondary effects

There has been a long-standing dispute among CAs about whether risk assessment should encompass the secondary effects of herbicide-tolerant crops, such as the environmental impact of the resulting changes in herbicide use. Denmark has always argued that it should, because it has a policy of reducing herbicide use, partly to prevent pollution of groundwater used for drinking purposes. Austria has always regarded any increase in herbicide use as unacceptable, because of its emphasis on organic agriculture. Until the late-1990s, the prevailing view at EU-level has been that indirect effects are caused not by the GM crop but by the herbicide, beyond the remit of Directive 90/220 and covered by the pesticide directive, 91/414. In 1998, at least two CAs changed their stance in response to public protest. The UK and France re-interpreted the Directive's remit to include the effects of agricultural practices in their risk assessment. The draft revised Directive 90/220 states that risk assessment should cover indirect effects, including any changes in agricultural practice. (See inside back cover for proposed amendments to Directive 90/220.)

## Agricultural problems versus environmental harm

Another source of disagreement concerns the distinction made by some CAs between agricultural problems and environmental harm. For example, the UK and France, supported by the European Commission, have argued that although the use of herbicide-tolerant oilseed rape may lead to herbicide-tolerant weeds, this is an agricultural problem that can be solved by using other herbicides to control them. Recent research has increased uncertainty about the scale of this problem. Citing this research, France has refused to sign the final consent required for market release of a GM oilseed rape that it had originally proposed for EU-wide approval, and unilaterally imposed a two-year moratorium to prevent its farmers from growing this crop.

## Baseline for comparison

A more fundamental source of disagreement concerns differences in the baseline that CAs and advisors are using in their judgements about the acceptability of impacts. Approvals so far have been based on the predominant view among CAs that the impacts of GM crops should be compared with the impacts of conventional (high input) agriculture. So, for example, an insect-resistant crop, even if it had an adverse impact on other insects, is judged unlikely to cause more harm than a conventional crop sprayed with chemical pesticide. Some CAs do not accept this baseline. Austria bases its judgements on the impacts of organic agriculture. Denmark considers that GM crops should offer an environmental improvement over conventional agriculture and should not prejudice future policy options on sustainable development. The Italian parliament, in its inquiry into biotechnology in 1997, recommended that Italian biodiversity and traditional food products should be protected from the impact of GM crops. Such views are likely to become more prominent as international agreements concerning sustainable development begin to permeate policy more widely.

## Market-stage precautions

Directive 90/220 did not require market stage precautions. Initially, it was assumed by proponents that regulatory oversight and precaution would no longer be needed once GM products had been approved as safe for commercial release. Partly in response to increased public concern, and to counter demands for a moratorium on commercial use from critics of GM crops and food, market stage precautions have been introduced. They include environmental monitoring, cultivation protocols and labelling schemes. The measures are intended to detect and avoid any probable effects whose acceptability remains in dispute within the regulatory procedure. Most began as voluntary initiatives on the part of the biotechnology and food industry, beyond the formal requirements of the directive.



**Market stage precautions have been introduced**

## Environmental monitoring

After the commercial release of an insect-resistant maize from Ciba/Novartis was approved in January 1997, Italy, Austria and Luxembourg imposed bans on its cultivation. Italy withdrew its ban once the company submitted a specific plan to monitor the crop for insect resistance. Monsanto similarly undertook to monitor its insect-resistant maize, as part of its original application. As written undertakings, these consequently became statutory obligations under the Directive.

In 1998, France and Spain made use of the National List registration procedure to impose monitoring of the maize for all the impacts debated during the Directive 90/220 procedure, including harm to insects other than the targeted pest.

For the second major GM crop, herbicide-tolerant oilseed rape, AgrEvo has volunteered to help monitor gene flow, at least in Germany. The UK government has funded such monitoring for several years. In addition, it is now funding farmer-managed trials to test the effects on wildlife of changes in agricultural practices resulting from GM crops. One example is changes in the use of broad spectrum herbicides.

If the proposed amendments to Directive 90/220 are accepted, monitoring to 'identify any relevant direct, indirect, immediate or delayed effects' will become a statutory requirement.

## Cultivation protocols and good practice guidelines

For insect-resistant maize, the company concerned submitted a cultivation protocol to delay the development of insect resistance. For herbicide-tolerant oilseed rape, industry is voluntarily developing a cultivation protocol to limit the spread of herbicide-tolerance. There remain policy issues about how to evaluate the adequacy of the protocol design and how to ensure the compliance of growers.

In the UK, agricultural suppliers and biotechnology companies have joined forces to devise good practice guidelines for seed and grain merchants and growers, with penalties for non-compliance. These guidelines have since been approved by the UK government.

In addition, there have been voluntary agreements between industry and government in the UK and Denmark to delay commercialisation until the results of large-scale field trials are known. France has banned the cultivation of herbicide-tolerant oilseed rape and sugar beet until further research on gene flow is completed.

## Food labelling by retailers

Food labelling is not covered by Directive 90/220. DGIII has responsibility for food labelling. At first it rejected the public demand for mandatory labelling of GM food on grounds that it would wrongly link such products with risk and would be impractical to implement. Eventually it agreed, but there were further delays while the labelling requirements were clarified. Meanwhile, to maintain consumer trust, the European food industry (Confederation de l'Industries Agro-Alimentaires, CIAA) and the European retail sector (EuroCommerce) devised their own labelling



guidelines. Some supermarkets guaranteed to keep their own-brand products GM-free and encouraged their suppliers to use non-GM ingredients. Many retailers decided to label all food derived from GM crops, rather than only those products with detectable GM DNA or protein as required by the EU.

The result of these voluntary initiatives has been that labelling practices and criteria have varied from country to country. The markets for non-GM and organic products have received a stimulus.

## Policy implications

As GM products approached the marketing stage in Europe, the uncertainties increased rather than decreased, causing renewed controversy. The idea of a linear progression, with precaution leading to increased predictability, which in turn would make GM crops more widely acceptable and allow them to be marketed just like conventional products, turned out to be inappropriate. Further precautions had to be introduced in response to heightened concern, affecting not only food products but also crops, field trials and the genetic modification process. With the benefit of hindsight, it is possible to see at least three factors that contributed to the barriers to commercialisation:

- 1 the outvoting of minority views among regulators and their advisors;
- 2 the narrow range of expertise considered relevant to risk assessment;
- 3 the restricted involvement of stakeholders.

These three factors are examined below to draw out their implications for future policy.

### Minority views

Most of the issues that later caused public controversy and led some governments to alter their policies at the market stage were evident early on as objections raised by a minority of competent authorities. Examples include questions of labelling, antibiotic resistance, indirect effects, and the impacts of changed agricultural practices. These objections were initially over-ruled or outvoted. The lesson for future policy is that minority views can provide valuable indications of matters that may subsequently be seen as important or that are widely shared by another audience. Even if they are regarded as beyond the remit of regulatory risk assessment, they should be assigned to another arena for further discussion and feedback rather than being over-ruled.

An example that is central to the current public controversy is the appropriate baseline for judging the acceptability of environmental impacts. This is likely to become a more pressing issue as regulations on pesticide use tighten and as international agreements on biodiversity and sustainable development become more relevant to agricultural policy. There is an urgent need to review the baseline for risk-assessment judgements in relation to possible future agricultural strategy.

**Further precautions had to be introduced in response to heightened concern**



### *Appropriate expertise*

A related factor concerns the limited range of expertise drawn on by some competent authorities. Involving a limited range of disciplines on advisory panels, for example molecular biologists and geneticists, makes consensus easier to achieve, since these experts share the same language and theoretical models. However, a narrow disciplinary base limits the range of uncertainties that are considered in risk assessment. Difficulties arise when decisions are subsequently challenged by experts from other disciplines who use other models, for example ecologists, or by competent authorities who draw on other expertise.

Even when ecologists are consulted, official advisors may take for granted their own baseline for judging what potential effects are acceptable or relevant. This compounds the difficulties when the experts' decision is presented to a wider, public, audience in each member state. Although this audience may respect the scientists' professional knowledge, it may not share their value judgements about the acceptability of potential effects. To address the controversy about GM crops, with its competing accounts of the relevant uncertainties, there is a need to ensure all competent authorities consult a similarly wide range of disciplinary and inter-disciplinary expertise.

The European Commission has sought to reduce the political aspects of risk-assessment decisions by establishing EU-level scientific committees, less susceptible to the domestic political pressures of individual member states. However, there is a need to acknowledge that such committees can never be completely neutral towards the agricultural context and the public debate. Decisions about genetically-modified crops, while they need to be science-based, are inevitably political.

**Decisions about genetically-modified crops, while they need to be science-based, are inevitably political**

### *Involvement of other stakeholders*

This leads into the third point, concerning the involvement of other stakeholders. Judgements about the acceptability of potential impacts need to involve a wider constituency than the competent authorities, their scientific advisors and the biotechnology companies. For example, such judgements should incorporate the views of stakeholders such as farmers, food processors and retailers, as well as consumers. Some member states have well-established procedures for incorporating the views of other stakeholders. In Denmark, parliament takes up queries raised by the electorate with the regulators.

Elsewhere, other mechanisms are being tested. The UK is establishing an Agriculture and Environment Biotechnology Commission to provide an input to policy from a wider range of stakeholders. In France, NGOs and seed companies are being given a bigger say by being included on a Biovigilance Committee to monitor market-stage precautions. While labelling provides end-users with some degree of choice, this is only after all the important decisions have been taken. Costly delays and the rejection of marketed products might be avoided if end-users were involved at a much earlier stage. This would not only help inform companies' strategic decisions about product development but would also lead to better informed users.

When individual member states and companies develop precautions beyond those required by the existing EU-regulations, they provide valuable experience for the EU-wide system to draw on. In this respect, they are a resource, like the minority viewpoints. A democratic Europe can reach legitimate decisions about biotechnology only by acknowledging and learning from the views of all member states and stakeholders rather than allowing a partial view to predominate.

## Policy workshop

In March 1999, the research team held a policy workshop in Brussels to provide feedback on the results and the preliminary conclusions. Participants included national regulators, biotechnology companies, officials from DGs XI and XII, food processors, and NGOs (see Box 3). The workshop discussions helped to inform the EU level report.

### Policy workshop

To stimulate discussion about the best way forward in a non-threatening way, participants were invited to consider one of three possible scenarios: a moratorium on production, abandoning the directive, or amending it.

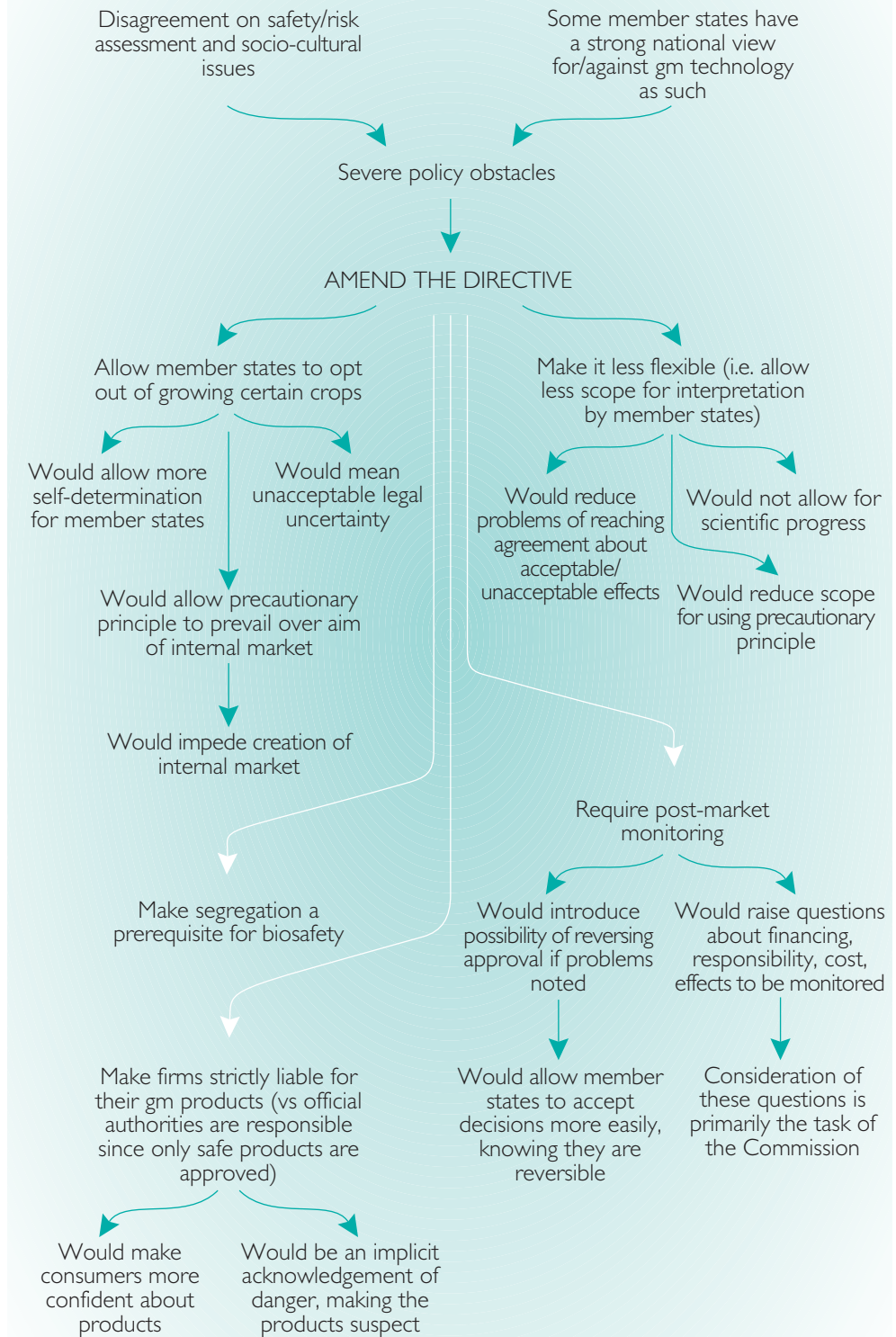
The discussion about amending the directive proved to be the most fruitful, since it allowed participants room for manoeuvre and to express a range of views. The likely consequences of a number of policy options were discussed, including allowing member states to opt out of growing certain crops, making companies strictly liable for their GM products, requiring post-market monitoring, and making the directive less flexible (see diagram overleaf).

The other two scenarios, being more extreme, tended to force people to adopt a particular stance for or against the scenario, reproducing polarised positions on the controversy and inhibiting the expression of alternative views. Even so, some valuable points emerged. For example, the initial view was that a moratorium was unlikely since the Commission had already ruled it could have no legal basis. After some discussion it was agreed that, despite this ruling, there were several ways in which a moratorium might come about and a number of forms it could take. Discussion of the impacts led several participants to conclude that in the long run a moratorium might increase public acceptance of GM products rather than halt the technology altogether. Discussion of abandoning the directive led participants to conclude that, despite the difficulties of reaching agreement, member states did share some common ground. If the directive was abandoned, and each member state imposed independent regulations and standards, they would be more susceptible to pressure from the World Trade Organisation. The costs of seeking market approval separately in each country would be prohibitive for smaller companies.

### Box 3



## Scenario 2: The Directive is Amended



## Further information

Details of this research will be published in a special issue of the *Journal of Risk Research* in 2000 and on the web page of the Biotechnology Policy Group at the Open University ([www-tec.open.ac.uk/cts/bpg.htm](http://www-tec.open.ac.uk/cts/bpg.htm)). The results of a previous related study (covering the period 1994 to 1995) were published in a special issue of *Science and Public Policy* Volume 23 Number 3, June 1996. For further information on the national and EU-level reports, and other related publications, please contact:

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## Directive 90/220

Directive 90/220 requires organisations that propose to market GM products commercially to apply for prior consent. The applicant (or 'notifier') must submit a risk assessment for each product to the designated regulatory authority (the 'competent authority'; CA) in the member state where the product is first to be marketed (see Figure 1). That CA then evaluates the risk assessment. If the evaluation is favourable, the CA passes a summary dossier to the European Commission recommending approval. The Commission forwards the dossier to all the other member states. Provided they raise no objections within 60 days, the Commission publishes the marketing consent in its Official Journal. That consent is valid throughout the European Union once the notifier has received confirmation in writing from the original competent authority.

If there are any objections, they are discussed by the CAs, if necessary in a meeting of the 'Article 21' committee. If there is still no clear decision (a qualified majority vote in favour), the proposal is considered by the EU Council. If the Council cannot reach a decision (by a qualified majority) within three months, the Commission adopts a proposal to approve the product.

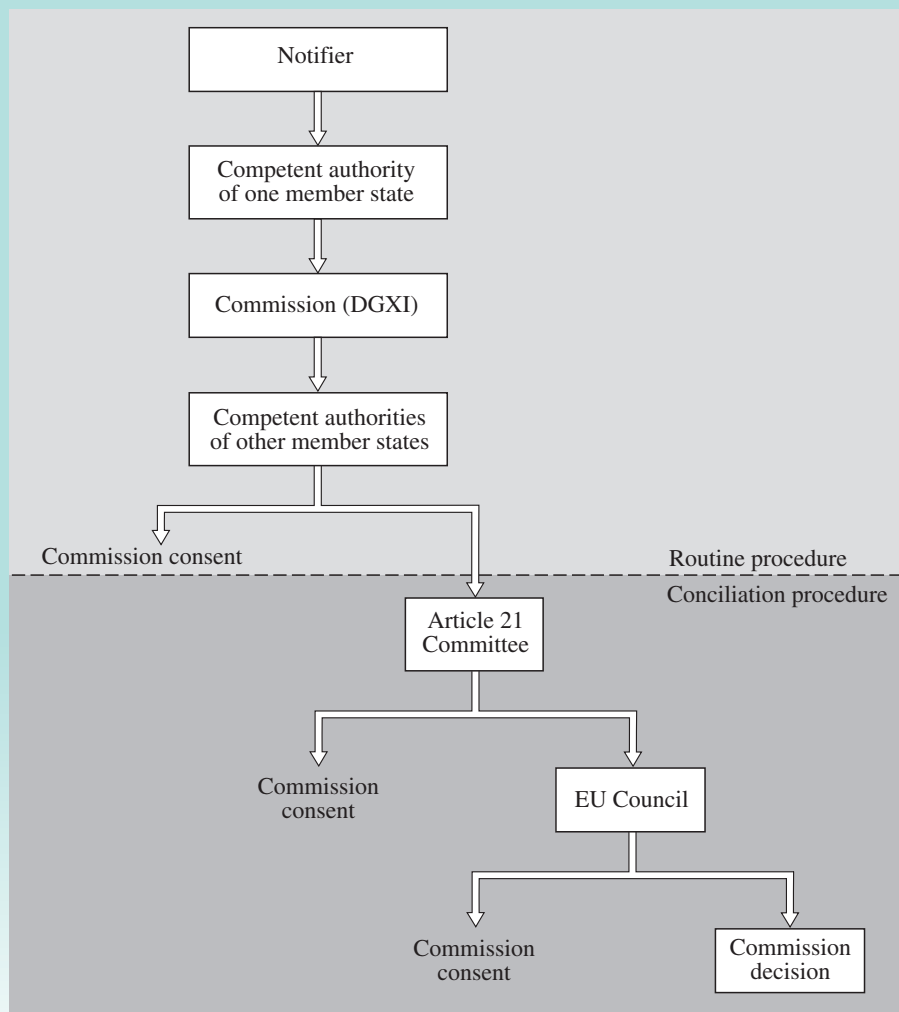


Figure 1

The Directive 90/220 procedure for market releases of GM products

In June 1999, the European Council adopted a 'common position' (reached agreement) on a number of amendments to Directive 90/220, including the following:

- some modifications to the procedure, with clearer deadlines for most stages;
- specific references to the precautionary principle to be inserted in the directive (previously a 'preventive' principle was mentioned);
- guidelines for risk assessment to be included in an annex (previously there were no guidelines stated in the directive);
- clarification that risk assessment must cover indirect and delayed effects, including those resulting from changes in use or management (previously the directive was open to interpretation on this matter);
- a requirement that the risk assessment must 'give particular consideration to' antibiotic-resistance marker genes, with a view to phasing out those with an adverse impact (not specified previously);
- a requirement for applicants to submit a monitoring plan, recording who will be responsible, to confirm assumptions in the risk assessment and to identify adverse effects that were not anticipated (already being adopted in practice);
- the Commission to be empowered to consult its ethics committee about applications, provided the decision-making procedure is not affected;
- consents to be conditional on labelling of all GM products;
- first-time marketing consents to be limited to ten years (previously indefinite); applications for renewal must include the results of monitoring in accordance with the consent conditions;
- member states to be duty-bound to ensure that GMOs are 'traceable' at all stages.

Once the amended directive is adopted, member states have 18 months to implement it. Implementation is unlikely before the end of 2001 at the earliest.