

EU-LEVEL REPORT

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‘Safety Regulation of Transgenic Crops: Completing the Internal Market?’

A study of the implementation of EC Directive 90/220

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INTRODUCTION

This EU-wide study investigated the safety regulation of genetically modified (transgenic) crops over the period October 1997 to late 1998 when the main data gathering was completed. This period coincided with an important new phase for gm technology in Europe, with commercial gm crops being grown for the first time (Bt maize in Spain and France) and gm ingredients beginning to enter the food chain from commodities imported from the United States (Bt maize and soyabean were first imported at the end of 1996 and the beginning of 1997).

Over this time, regulators and politicians of EU member states, who had gradually been working out ways round their initial disagreements over the implementation of Directive 90/220 (governing the release of genetically modified organisms, gmos), were suddenly faced with an unprecedented level of media interest and public anxiety. As a result of this anxiety, many major food retailers, and subsequently food processors, decided to guarantee their customers supplies of non-gm products as a way of maintaining consumer trust. These were factors that lay beyond the regulators' control but that inevitably affected their decision making.

Another significant factor beyond the regulators' control was the change to socialist governments in several key member states (notably, the UK, France and Germany). These governments tended to be more responsive than their predecessors to calls for additional precautionary measures to safeguard public health and the environment.

This study focused on safety regulation, and especially on the decision-making processes associated with Directive 90/220. For that reason, significant issues such as the role of the media, campaigners, public attitudes and consumer trust are only discussed insofar as they affected the decision-making processes.

This report provides an overview of the study. More detail on the ten contributory national studies (Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Spain and the United Kingdom), and on the legal aspects and a policy workshop, is provided in separate reports. Details of a previous related project, covering the period 1994-1995, can be found in a special issue of *Science and Public Policy*, Volume 23 Number 3, 1996.

Aims of the study

The study investigated the role of safety regulation in governing the commercial release of transgenic crops. Its aim was to inform policy debates on the most appropriate form of safety regulation, given the European Commission's aim of harmonising gm regulatory criteria across the European Union so as to complete the internal market. The study took as its objectives the four main objectives of DGXII's biotechnology programme on the ethical, legal and socio-economic aspects (ELSA), namely:

- (i) to clarify how ethical, social and legal issues are taken into account in regulatory decisions on gm crops, so that the procedure may be improved;
- (ii) to promote an informed dialogue among the key players in public debates on how to regulate gm crops;

- (iii) to suggest how risk-assessment research could better inform regulatory decisions; and
- (iv) to suggest how regulatory expertise could be appropriately broadened to encompass public and scientific concerns.

The main focus of the study was the safety regulation of gm crops, but the regulation of imported gm food and feed was also investigated as possibly setting precedents for European products in future.

Methodological approach

The key research issues and a common framework for the research were agreed at a two-day meeting of the research partners held towards the beginning of the study. A second two-day meeting was held mid-way through the study to discuss the main findings and the draft national reports. National reports were based on interviews and documentary evidence. The EU-level legal report drew on the national reports as well as on legal documentation.

In March 1999, towards the end of the project, the research coordinators organised a policy workshop with key stakeholders and research partners. The workshop was structured as a scenario-planning exercise. Participants discussed the practical implications of possible statutory changes to gm regulation in relation to three scenarios: the revision of Directive 90/220, the abolition of the directive, or the imposition of a moratorium. The main aims of this workshop were to contribute to dissemination of the research findings, and to obtain feedback to inform this final version of the EU-level report.

This EU-level report draws on the ten national reports and the legal report, as well as on interviews with more than 30 individuals involved in the regulatory procedure at the EU level, documentary evidence from the institutions listed in Appendix I, and feedback from the policy workshop.

The research framework

At their first meeting, in October 1997, research partners agreed that four issues were likely to be key to this new phase of gm regulation, namely: commercialisation, precaution and, to a lesser extent, predictability and acceptability. Acceptability in this case denoted the preconditions for a product to be permitted for sale and cultivation at all, rather than consumer willingness to buy it (as studied in market research).

These four issues were linked with the six main aspects of the study outlined in the research proposal (regulatory boundaries, normative judgements, risk-assessment research, labelling practices, a European market, and links to pesticide regulation) to provide a conceptual framework for the study, as shown in Figure 1. The relative position of each concept is intended to indicate how closely linked the research team considered the concepts to be, at the outset of the study.

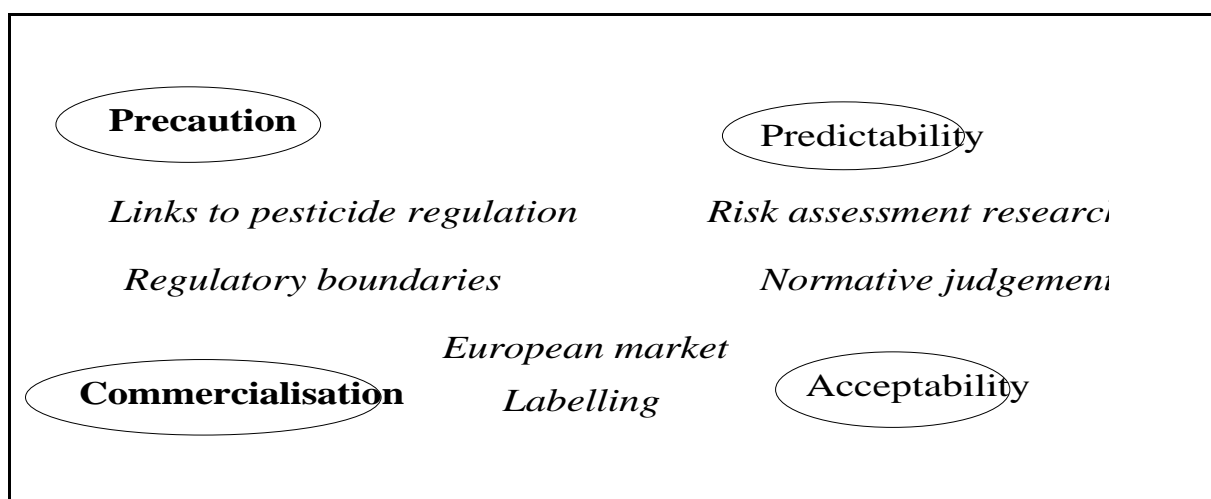


Figure 1 A conceptual framework for the research

The EU-level and national reports are all structured around the six aspects just mentioned (five in the case of sub-contractors), to aid comparisons.

Each national study was informed by the following set of questions:

- In what ways does commercialisation affect the precautionary approach to gm crops?
- How does each country respond to the commercialisation process?
- How does regulation adapt and respond to commercialisation?
- In what ways does commercialisation open up (or close) issues of predictability and acceptability?
- How do various actors articulate the relationship between predictability and acceptability?
- How are the various organisations and actors anticipating, accommodating or marginalising public concerns?

To illustrate the various regulatory issues, and to encompass gm imports intended for food and feed as well as gm crops intended to be grown in Europe, the research partners agreed to use the following three types of gm product for case studies (for precise identification, the originating company and the Directive 90/220 notification numbers are included):

- Glyphosate-tolerant soybean (Monsanto, C/GB/94/M3/1).
- Bt maize (Ciba/Novartis 176, C/F/94/11-3; Monsanto MON10, C/F/95/12-02; Novartis/Northrup King B-11, C/GB/96/M4/1; AgrEvo T25, C/F/95/12/07; Pioneer MON9, C/F/95/12-01/B).
- Glufosinate-tolerant oilseed rape (PGS, C/GB/94/M1/1, C/F/95/05-01, C/BE/96/01; AgrEvo, C/GB/95/M5/1, C/DE/96/5).

The key research findings at the EU-level are discussed in the Overview that follows. A more detailed discussion is provided in Sections 1 to 6 of this report.

OVERVIEW

New constituencies and pressures

In the mid-1990s it seemed that regulatory approval for commercial release would conclude or limit the responsibility of policymakers for each product. Each gm crop could follow a straightforward progression – from precautionary measures, to more credible claims for predictability, to public acceptability, and thus to commercialisation as normal products – that is, a clockwise progression through the four key concepts shown in Figure 1.

Since then, the dynamics have become more complex, even going into reverse in some respects. The commercial stage has catalysed a chain of pressures from consumers, to retailers, the food industry, farmers, biotechnology companies and thus back again to regulators. Consumer protest and boycotts have led major retailers to exclude gm ingredients from their own-brand labels. This commercial blockage has in turn led government and industry to devise further precautions for cultivating gm crops. Industry has become more willing to accept additional regulatory measures in the hope that these will gain public acceptability for commercial production.

Increased controversy over gm products has placed new demands on safety regulation. Since the BSE crisis, gm crops have become a focus for more general concerns about intensive agriculture. The result has been greater scrutiny of production methods ‘from plough to plate’. Consumer organisations are now taking up the environmental issues of gm crops previously raised only by environmental groups. In several countries, organizations of small-scale and/or organic farmers have protested against gm products as a threat to their livelihoods, even though other farmers want access to gm crops as a tool for economic competitiveness.

As more constituencies enter the public debate, new networks have challenged the previous basis of safety approvals. There have been widespread demands for more comprehensive labelling, for broader risk-assessment criteria, even for a moratorium on commercial cultivation. Some governments have promoted more precautionary measures of various kinds; for example, they have re-evaluated products whose approval they originally advocated, have blocked commercial use, or have devised market-stage precautions. These measures provide opportunities for some public input to the risk-assessment judgements of regulators and companies.

As the EU’s executive body, the European Commission has come under greater political pressure to delay or restrict commercialization of gm crops. The pressures come from more member states than before, from various Directorates-General, from the European Parliament, and from NGOs who express a more widespread public unease. As EU institutions and member states are pushed to share responsibility with the European Commission for regulatory decisions, they press for greater precaution (before and after market approval), for EU-level expert evaluation, for delays in product approval, and even for accepting national restrictions on commercial use after EU approval.

Consequently, it has been difficult to create an EU internal market, that is, to create the basis for approved products to circulate freely for normal use among member states. Despite Directive 90/220, designed to harmonize safety criteria for gm crops, there are EU-level regulatory delays, and even national bans on products which have already gained

approval. And despite new legislation designed to harmonize labelling rules for ‘gm’ food, there is continuing conflict over the criteria, as well as a partial blockage to the marketing of gm products in many member states, though mainly because of commercial barriers rather than regulatory ones.

There are different views about whether, or why, these obstacles are a problem. According to some proponents of approval: ‘The delays impede scientific-technological progress: gm crops will be essential for enhancing European economic competitiveness, and for reducing environmental harm from agriculture, so regulatory delays deprive us of the benefits.’ According to some critics of approval: ‘Claims for product safety and benefits cannot be accepted without more empirical evidence, especially in a European agricultural context; therefore the delays are helpful for improving scientific risk assessment prior to commercial use.’

Various explanations have been expressed about the fundamental source of the obstacles. Contrary definitions of the problems are indicated by the comments shown in Table 1, which are paraphrased from views expressed in the public debate and during the policy workshop held in March 1999 for this study.

Table 1 **Contrasting explanations of the fundamental causes of the delays in gm commercialisation, according to proponents and opponents of gm approval**

Proponents	Opponents
The public have been swayed by irrational fears of a new technology, compounded by the BSE crisis.	Public distrust of safety claims has a valid basis in the unpredictable effects of gm technology and its products.
The public doesn’t trust the scientific results of safety tests.	Scientific results often increase uncertainty about predicting harmful effects.
Risk assessment has been politicized; governments are basing delays and bans upon politics rather than science.	Safety claims come from experts who are biased in favour of gm technology and downplay uncertainties about risk.
National governments are avoiding responsibility for decisions, thus leaving the European Commission alone to bear the burden.	Directive 90/220 assigns excessive, undemocratic decision-making power to the European Commission.
Directive 90/220 leaves the risk-assessment criteria too vague, e.g. the definition of ‘adverse effects’.	Even when regulators define ‘adverse effects’ in a broad way, they compare gm crops to chemical-intensive agriculture.
EU member states are failing to implement the legislation as intended.	Directive 90/220 provides inadequate scope for subsidiarity – e.g., for subjecting gm crops to more stringent criteria via national procedures.

Gm crops are being subjected to both process-based and product-based regulation, thus imposing extra requirements after approval under Directive 90/220.

The 90/220 procedure leaves regulatory gaps which need to be filled by extra procedures, e.g. Plant Variety Registration.

Products are being caught in a chicken-and-egg impasse between Directive 90/220 and the Novel Food Regulation.

It is unrealistic to prevent food and feed uses after commercial cultivation begins, so such uses must obtain approval beforehand.

These different diagnoses of the problems lead to different prescriptions for solving them, thus polarizing debate and exacerbating the situation. Nevertheless, regulatory delays provide an opportunity for reflection and policy learning, e.g. for reconsidering the various problem-definitions.

Risk-assessment issues

Regulatory delays and blockages of gm crops involve several risk-assessment issues which date from the mid-1990s. Most have been debated previously in public fora, as well as in meetings of the national Competent Authorities (CAs) for Directive 90/220. Recently these issues have become more compelling, for various reasons. Backed by new social constituencies, critics have highlighted weaknesses in the official safety assessment. New scientific information has been cited to undermine claims about the predictability of potential effects, used to inform previous regulatory decisions.

Moreover, gm crops have been increasingly evaluated for how their associated agricultural methods may affect biodiversity and sustainable agriculture. More and more CAs have decided that the 90/220 procedure encompasses the herbicide implications of herbicide-tolerant crops. For example, in Austria gm crops are widely regarded as a threat to organic agriculture, which the government heavily subsidizes. The Italian Parliament foresees gm crops threatening traditional cultivars and high-quality products, perhaps through economic competition as much as through environmental effects. Amid growing protest in France, INRA abandoned its innovation research on herbicide-tolerant oilseed rape; some leading scientists there have criticized gm crops as a threat to sustainable agriculture, or have even joined calls for a moratorium.

All these concerns have been translated into regulatory disputes, as well as policy shifts which broaden the risk-assessment criteria under Directive 90/220. The disputes include the following related issues:

- the boundary or overlap between GMO regulation and other relevant laws (pesticide directive 91/414, the Plant Variety Directive 70/457, and the Novel Food Regulation 97/458);
- the burden and type of scientific evidence relevant for the predictability of effects;
- the role of new scientific knowledge in decreasing or increasing uncertainty about potential effects; and
- the types of ‘adverse effects’ which should be evaluated and prevented.

The definition of ‘adverse effects’ involves a normative judgement about the acceptability of potential effects. Some CAs take existing agricultural practices as a normative baseline: the impact of a gm crop is judged against the impact of a conventional one. Others adopt a more stringent baseline; they want evidence that a gm crop will cause relatively less harm than a conventional crop, and will not jeopardize any crop-protection methods that might contribute to sustainable agriculture. Some officials acknowledge the value-laden character of such definitions:

“All three types of judgement – scientific, legal, and political – are involved in any judgement on defining “adverse effects”. It involves considerations broader than science, e.g. by interpreting the law, and taking on board public concerns (interview, DGXI, 20.01.98)”.

The public debate has opened up several questions. Which present practices should serve as the normative baseline? Why should the baseline remain static, rather than become more stringent so as, for example, to support environmental policy objectives? And what is the appropriate expertise for answering these political questions?

The examples in Box 1 illustrate how the four overall issues listed above have arisen in disputes over specific products. They indicate how new scientific information (increasing rather than decreasing uncertainty), increased public pressure, and changes in government contributed to changes in national policies on risk assessment. Arguments previously put forward by a minority of CAs, and over-ruled at EU-level, gained wider support.

Box 1 Examples of regulatory disputes

Herbicide-tolerant oilseed rape: gene flow

For glufosinate-tolerant oilseed rape, which has considerable pollen flow and many weedy relatives in Europe, some CAs wanted the risk assessment to evaluate the potential loss of glufosinate as a future weed-control option. In the UK and France, the authorities originally classified such an effect as ‘an agricultural problem’. They argued that the inadvertent spread of glufosinate-tolerance is acceptable on several grounds, e.g. because other weed-control methods would still be available if necessary (EC, 1996b). This view prevailed in regulatory decisions at EU level.

Since these arguments arose in the mid-1990s, research results have increased uncertainty about the predictability of such effects. Studies have demonstrated greater pollen flow and a broader capacity for hybridization than previously thought, e.g. in Denmark, France and the UK (e.g. Mikkelsen. et al., 1996; Chevre et al., 1997; Reboud et al., 1998; Coghlan, 1999).

Eventually the policy changed in France, for reasons that had arisen there in earlier regulatory discussions. Although the advisory committee regarded glufosinate-tolerant weeds as an ‘agricultural problem’ and therefore irrelevant to Directive 90/220, it regarded this problem seriously enough to oppose any National List trials which might inadvertently result in multi-tolerant oilseed rape hybrids. The French CA, which was the rapporteur for the glufosinate-tolerant oilseed rape, initially advocated approval, but eventually changed its view in response to public protest. Rather than sign the final authorization as required to confirm EU-wide approval, France declared a two-year moratorium in November 1998. Citing its own field studies on hybridization with weedy relatives, the government argued that further research was needed before commercial use could be permitted.

Herbicide-tolerant crops: herbicide effects

There has been a long-standing boundary dispute over the remit of Directive 90/220 for herbicide-tolerant crops, which are generally designed to withstand broad-spectrum herbicides. In the mid-1990s several member states demanded that the risk assessment should encompass the overall environmental implications of cultivating the crop (including use of the corresponding herbicide), as well as the inadvertent spread of the herbicide-tolerance genes, which could undermine the efficacy of the herbicide (Levidow et al., 1996). This demand originally came from Denmark, which had a policy aim of reducing herbicide usage, partly in order to protect ground water for drinking purposes. A similar demand came from Austria, which regarded any increase in herbicide usage as unacceptable, relative to its baseline of organic agriculture.

In response, the advocates of herbicide-tolerant crops argued that these ‘secondary effects’ would be caused *not* by the crop, but rather by the herbicide, which is regulated under the pesticide Directive 91/414. In practice, however, this issue involves both a regulatory gap and an overlap. Directive 91/414 offers each member state some discretion to permit or restrict specific uses of herbicides within its national territory. Yet it offers no clear means to prevent the loss of preferable options, nor to evaluate the overall effects of herbicide usage. Moreover, as active ingredients are given EU-wide approval and thus added to Annex I of Directive 91/414, member states may have less scope to restrict use of pesticides based on those ingredients.

Given the inherent limitations and political uncertainty of Directive 91/414, some member states seek to establish environmental criteria for herbicide impacts within Directive 90/220. At least two Competent Authorities changed their stance in response to public protest. In 1998 the UK Environment Ministry re-interpreted Directive 90/220 to encompass the effects of agricultural practices. This move complemented the Ministry's previous initiatives aimed at encouraging farmers to reduce herbicide usage in ways which would benefit wildlife habitats and biodiversity. France likewise re-interpreted the Directive so as to encompass the herbicide effects.

Bt maize: insect resistance and non-target harm

For Bt crops, US regulatory debates have emphasized the prospect that the Bt toxin could intensify selection pressure for resistant insects. Accommodating public protest, eventually the US Environmental Protection Agency (EPA) took responsibility for Insect Resistance Management. When the first Bt maize was proposed for market approval in the EU in 1995, several CAs criticized the risk assessment for failing to evaluate this risk. In response, France adopted the company's argument: that such a scenario would not be an 'adverse effect', on grounds that other insect-control methods would still be available (EC, 1997a). Since then, US research has strengthened claims for the plausibility of insect resistance. More CAs have taken up this issue, even in member states where the European corn borer is no problem.

A different risk issue, taken up by some member states, is that the Bt toxin could harm beneficial insects. Research results have increased uncertainty about predicting such effects. Evidence of potential harm came from a Swiss-funded tri-trophic study, i.e. encompassing the three levels of predator, prey and crop. This experiment found that lacewing larvae had a lower survival rate after eating Bt-fed cornborers; similar results were found by testing the predator on different prey (Hilbeck et al 1998).

Debate ensued over the relevance of the 'artificial' experiments to real-life agricultural conditions, e.g. where predators might have a wider range of available prey. Properly designed, however, such experiments can test some cause-effect uncertainties more sensitively than large-scale field monitoring, which found no reduction in beneficial insect pests in Bt maize fields (e.g. Monsanto, 1995: 46). Evidence also came from feeding butterfly larvae on gm pollen (Losey et al 1999). Afterwards the European Commission delayed approval of a Bt maize from Pioneer Hi-Bred.

Controversy continues over the scientific basis for predicting non-target harm, as well as over the normative baseline for its acceptability. Advocates of market approval have argued that Bt maize would cause less harm than present chemical insecticide treatments. Such an argument assumes that conventional maize is sprayed with chemical insecticides, but such sprays are little used, partly because they cannot reach the corn borer once it is inside the stalk.

Antibiotic-resistance marker genes

Antibiotic-resistance marker (ARM) genes have been routinely inserted to help identify successfully modified cells in the laboratory; afterwards they have no further function in the gm crop. Critics argue that ARMs could inadvertently transfer to gut pathogens in livestock or humans, thus undermining the clinical efficacy of the antibiotic. Advocates of approval

argue that such an effect is implausible, or that gm crops could hardly add to the greater problem of pervasive antibiotic-resistance genes in the environment, or that it would be acceptable to lose the clinical efficacy of the corresponding antibiotic if it is not widely used.

This issue has led to regulatory blockages of products containing an intact ARM. The first Bt maize gained EU-wide approval but the approval was subsequently annulled by the French constitutional court, on grounds that the national regulatory procedure had failed to evaluate the risks of the ARM. For the Avebe potato and Monsanto's cotton, more data were requested by national CAs, as well as by the EU-level scientific committee. Among CAs and their advisors, there is a growing consensus that ARMs should not be used, but such genes cannot be removed from crops which were constructed years ago and then underwent several years of field testing.

Market-stage precautions

Since the mid-1990s, additional precautions have been proposed for gm crops, both before and after market approval. More recently, such proposals have been implemented for some products, especially in response to widespread demands for a moratorium. Market-stage precautions are officially intended to test and avoid potential harm in an agricultural context, thus testing claims about safety and benefits. However, they may also fulfill other functions, such as:

- gaining time for further discussion about regulatory criteria;
- providing public accountability for test methods, e.g. through extra advisory committees; and
- enhancing the public acceptability of commercialisation through regulatory procedures.

In these ways, market-stage precautions can help to manage regulatory conflicts, both within and among EU member states. The introduction of market-stage precautions means that commercialisation becomes a series of negotiated steps, rather than a distinct stage.

For each gm crop, market-stage precautions involve four related elements: cultivation protocols, large-scale environmental monitoring, smaller-scale research, and ecological cause-effect models of potential harm (Levidow et al., 1999). Each element involves further debate on its scientific basis. In particular:

- Cultivation protocols have been devised to prevent undesirable effects, some of which were not deemed 'adverse' by the EU consent for market approval. They stimulate further debate about how to evaluate the adequacy of the protocol design.
- Environmental monitoring too generates further debate, e.g. as regards what effects are the most important to detect and therefore what methods to use. In some member states, the CA has established or planned new committees that allow NGOs to scrutinize the experimental design and environmental effects.
- Small-scale controlled experiments, important for testing some cause-effect uncertainties, have generated methodological debate over the optimal design and the interpretation of results. Prominent examples test harm to non-target insects.

- Underlie market-stage precautions, as well as risk-assessment judgements, cause-effect ecological models. For example, resistance management for Bt resistance in corn borer has been based on a model that assumes the resistance gene is not dominant. This model has recently been questioned.

Requirements for market-stage precautions have now been officially accepted as part of the Directive 90/220 procedure, and the practical definition of ‘adverse effects’ is being broadened. At their December 1998 meeting the Council of Ministers decided that risk assessments henceforth would implement the redrafted Annexes II and VII of the Directive; these require prior evaluation and market-stage monitoring of ‘indirect effects’, a term which could encompass the herbicide implications. To evaluate such effects, CAs would need to set a normal baseline of acceptability, given that present agricultural practices already cause significant harm to wildlife. The debate about what counts as an adverse effect may be transferred, rather than resolved, to a debate about what counts as acceptable agricultural practice.

All these issues are illustrated by the examples in Box 2, which describe the market-stage precautions developed for Bt maize in France and glufosinate-tolerant oilseed rape in the UK.

Box 2 Examples of market stage precautions

Bt maize

Market-stage precautions have become mandatory for the first gm crop, Bt maize, through initiatives from companies and regulators. After the Ciba/Novartis Bt maize marketing notification met criticism from some CAs, the company sent DGXI an undertaking to monitor commercial use for insect resistance. Monsanto too submitted such an undertaking, as part of its original notification, followed by a more detailed plan. DGXI interprets these written commitments as statutory obligations under the Directive.

As already mentioned, for Bt maize on the US market, biotechnology companies had already devised Insect Resistance Management (IRM) plans. They recommended that farmers maintain refugia of non-Bt maize, where susceptible insects could survive and reproduce, in order to dilute any resistance genes in the next generation. Companies are also funding ecological research on the European pest, to learn more about how it feeds and breeds, in order to adapt their IRM plans from the USA to European conditions.

When the Monsanto maize notification came under challenge from some national CAs in late 1998, France and some DGs asked DGXI to solicit advice from the DGXXIV-based Scientific Committee for Plants (SCP). The committee evaluated the IRM plan as ‘adequate to delay resistance’. It also judged that insect resistance would anyway be an acceptable effect (SCP, 1998).

For market-stage monitoring to be meaningful, it must compare the effects of the Bt crop with a normal baseline, i.e. pre-existing levels of Bt resistance among insect pests. Under pressure from CAs, DGXI convened an expert group for advice on how to establish the baseline susceptibility of insects to Bt. The methods have been evaluated for the two main pests of maize (DGXI Bt IRM, 1998; SCP, 1999).

At a national level, France and Spain used National List registration as a convenient

instrument for requiring market-stage precautions for Bt maize (France, 1998; Spain, 1998). National List registration was originally intended to validate product quality and to protect plant health (EC, 1970). The precautions included a requirement to monitor the crop for harm to non-target insects, for which a normal baseline is unclear, especially given the variety of crop-protection practices. The French Environment Ministry established a *biovigilance* committee, including NGO critics of gm crops, to advise on these precautions.

Glufosinate-tolerant oilseed rape

Industry and regulators have been acting as if market-stage precautions were mandatory for the second major gm crop, glufosinate-tolerant oilseed rape. Although the Scientific Committee for Plants regarded gene flow and inadvertent hybridization as not an adverse effect under the Directive, the committee recommended that separation distances be used to prevent such an effect; it asked to evaluate any plans for a cultivation protocol and monitoring (SCP, 1998). AgrEvo has undertaken to assist efforts to monitor gene flow, at least from herbicide-tolerant oilseed rape in Germany; the German CA regards its commercial use as an opportunity to gain scientific information potentially relevant to future products.

Since 1997 the UK agricultural supply industry has developed a cultivation protocol, initially in order to ensure segregation is maintained along the agro-food chain, and later to limit the spread of herbicide tolerance genes. As requested by environmentalist critics, the UK CA is funding farm-scale trials to monitor the biodiversity effects of using broad-spectrum herbicides on gm crops, but there is no clear baseline for evaluating such effects.

Expertise as a policy issue

In general, technological risk controversies have led to greater public scrutiny of expert advice and its claims to neutrality. After the BSE crisis emerged, the EU's relevant expert committee was suspected of having unduly accepted UK safety assurances. The public response undermined the credibility of expert advice and perhaps food sales. In response, the European Commission restructured all its scientific committees.

In mid-1997 DGXXIV took over responsibility for committees which were formerly based in other DGs. In this way, the Commission sought to separate 'risk assessment' (product evaluation) from 'risk management' (legislative framework and product approvals). DGXXIV invited prospective members to nominate themselves and to declare any relevant material interests. In these ways, the reorganization sought to render the committees independent – of the legislative DGs, of the member states, and of material interests.

Unexpectedly, in November 1997 the DGXXIV-based Scientific Committee on Plants was asked to comment on product dossiers which had been stalled under the Directive 90/220 procedure. Officially, the SCP was asked to resolve risk issues which had been raised by some member states. Unofficially, some SCP members saw themselves as protecting scientific risk assessment from political bias, by contrast to national regulatory procedures which had been influenced by anti-biotechnology pressure groups (according to interviews with committee members during 1998).

In its advice on marketing notifications, the SCP has consistently adopted a definition of 'adverse effects' similar to that of the product advocates. It has regarded some undesirable effects (herbicide-tolerant weeds, insect resistance, and non-target harm) as acceptable.

Such judgements are represented as purely scientific, even though they involve a policy interpretation of legal and environmental issues.

At the same time, the SCP has recommended market-stage precautions for those undesirable effects. It has also asked to scrutinize the precise plans for precautionary measures. Thus its expertise blurs the official distinction between ‘scientific’ risk assessment and political risk-management. Although the new committees may be independent of vested interests, their advice is not (and could not be) completely independent of policy views.

National CAs have generally not drawn such a distinction in the first place. Some member states have sought to reconstitute their official expertise in ways which can better accommodate public concerns. For its advisory committee, the UK CA is seeking experts in agro-ecology, and it has said that in future it will appoint no one who has past or present financial links with industry. The French CA is likewise broadening its advisory committee.

Statutory changes: potential and limits

Since 1998 there has been an unofficial moratorium on approval of new gm crops and even on the cultivation of some gm crops which already gained approval. This *de facto* moratorium was openly acknowledged in June 1999, when the Council of Ministers announced that no more gm crops would be approved until a revision of Directive 90/220 is adopted. Consequently, risk-assessment research has acquired even greater importance for testing claims about the effects of gm crops.

The proposed revision of Directive 90/220 has many sources and aims. Some proposed changes aim to broaden the risk-assessment procedure by accommodating diverse concerns of member states, while clarifying their shared responsibility for EU-wide regulatory decisions, whether favourable or otherwise. Implicitly, these changes seek to ensure that any approval decision has a stronger consensual basis, so that member states will respect the decision rather than raise objections or impose further controls on the product; in other words, they would have less grounds to exercise subsidiarity after its approval. The political outcome will depend upon many contingencies, beyond the precise wording of a revised Directive.

Of the various changes proposed, some apparently have broad support – across the European Commission, Parliament and member states (CEC, 1998; Bowe, 1998). Some of these changes would formalize present practices. The practical implications of the proposed revisions to the Directive are considered in Box 3.

The proposed statutory changes could help to accommodate public and scientific concerns within regulatory procedures. Some of the proposed changes could help to open up and strengthen the precautionary criteria for gm crops, thus enhancing the legitimacy of any approval decision.

Box 3 Practical implications of proposed revisions to Directive 90/220

Indirect effects. The risk assessment would encompass all adverse effects, ‘whether direct or indirect’. Some member states interpret ‘indirect’ to mean the ‘secondary effects’ of herbicide usage; others may interpret it to mean simply the effects of ecological interactions, e.g. along the food chain. Thus the present disputes over ‘adverse effects’

could be replaced by further disputes over how to define ‘indirect’ ones. The phrase ‘indirect effects’ was eventually clarified to mean the effects of any changes in use or management (ENDS, 1999).

Monitoring/limited consents. Each marketing consent would be granted for a limited period, with a monitoring requirement; the notifier would have to submit a detailed plan to ‘identify any relevant direct, indirect, immediate or delayed effects...’...This change would overcome long-standing arguments that the Directive provides no basis to require market-stage monitoring. The time limit would also impose a greater burden of evidence upon consent holders to demonstrate that commercial use does not cause adverse effects, especially before regulators decide whether to renew the consent. Such a decision raises the stakes for how ‘adverse effects’ are defined in the first place, so this issue may remain contentious.

Scientific advice. EU scientific committees would be consulted and their advice made public (as is present practice). Such consultation could help to supplement national expert judgements with EU-level ones, offering greater transparency and interaction among specialists. However, such committees are being expected to resolve policy disagreements – e.g. about how to define and test ‘adverse effects’, how to set a normative baseline, and how to judge the adequacy and relevance of scientific data for decision-making. Expert advice cannot remain independent of such policy judgements.

Ethics assessment. In addition to scientific committees, an ethics committee might also be consulted. Member states too may raise ethical issues. Little has been said about what would count as an ethics issue for soliciting such advice. Risk assessment already involves ethical issues about how to define and manage the relevant uncertainties; these judgements could be further examined and illuminated by an ethics committee.

Seed-food links: segregation and labelling pressures

An internal market depends upon agreed criteria for identifying and labelling ‘gm’ products. This issue is largely resolved for gm seeds but remains contentious for food derived from gm crops. Indeed, gm ingredients have become a problem for the acceptability of all processed food.

Directive 90/220 has been amended to provide informative labelling, thus overcoming some objections to marketing applications. Decision 97/35 required labelling of all gm seeds as ‘gm’. Afterwards this requirement was retrospectively accepted by all companies which had already requested a consent for marketing gm seeds.

Officially, the new labelling requirements were justified in precautionary terms: an information register with molecular data is necessary ‘to assist the evaluation of similar or more complex products’, as well as to generate data from market-stage monitoring (EC, 1997d). Since then, member states have discussed how to establish and use such a register, e.g. so that any environmental effects can be traced back to their source.

As an implicit reason for Decision 97/35, seeds information is necessary for labelling products along the food chain, i.e. from farmers to grain merchants to food processors. For seeds of uncertain sources, the rules allow a ‘may contain’ label – which is adequate to guide food processors in labelling the food as ‘gm’. Seeds labelling is also important for

segregation, which can unpredictably become a legal requirement if a marketing consent is subsequently revoked; this happened to the Ciba/Novartis maize in France in late 1998. Going beyond any legal requirement, government-industry arrangements are seeking to ensure traceability of gm crops, so that any gm food can be reliably labelled as such.

For food products which may contain gm ingredients, consistent, credible labelling has been difficult to achieve. The principle of mandatory labelling has been widely accepted, but for diverse motives which have become difficult to accommodate in the food market. Officially, labelling provides the information essential for a free consumer choice among products whose safety is assured.

Unofficially, the pressure for labelling comes from less manageable sources – public distrust of safety judgements, public resentment at dependence upon official experts, and an interest in blocking some products on environmental grounds. Many consumer groups have taken up environmental issues, targeted the gm food market, and demanded an informed right to consumer choice – implicitly as a means to ‘vote’ against particular agricultural production methods, e.g. gm herbicide tolerance. Some NGOs campaign against all gm-based foods.

For such reasons, controversy continues over how to characterize the product, i.e. how to distinguish between ‘gm/non-gm’ food. Regulators have been trying to clarify the detectability criteria for mandatory labelling (EC, 1998b). NGOs are demanding process-based labelling in order to denote any food derived from a gm crop.

Accommodating consumer protest, major European retailers (and some major food processors) have undertaken to exclude gm ingredients from their own-brand products. Documentary control is being developed in some member states, e.g. Denmark, thus going beyond any EU statutory basis. These commercial blockages pose new policy challenges: how to set a credible threshold of gm ‘contamination’ for defining ‘non-gm’ food, thus indicating the producer’s intent to avoid gm sources; and, whether government can validate the documentary control of ‘non-gm’ sources. The outcome has high stakes because currently imported grains may set a precedent for gm food derived from crops to be cultivated in Europe.

Conclusion: difficulties as opportunities

In this conclusion, we view regulatory difficulties as opportunities to redefine policy problems, rather than as obstacles or deviations to be corrected. Differences among member states can be viewed as sources of ideas and a resource to be drawn on. For EU institutions, the policy challenge is to facilitate and learn from national efforts to accommodate public concerns, rather than suppress or marginalize them. In some member states, new practices suggest ways of opening up the policy process that help overcome artificial dichotomies, as shown by the examples in Box 4.

Box 4 New practices that help overcome artificial dichotomies

Precaution or commercialization?

As initially conceived, risk regulation assigned the precautionary principle to a preliminary stage before placing gm crops on the market. In practice, further precautionary measures have been introduced that test claims for the predictability of effects during the commercial

stage. These measures both accommodate and stimulate debate over environmental criteria for the acceptability of future products, as well as the product at hand. Commercialization is being treated as a series of transitional steps, rather than as a final step which concludes precaution.

Harmonization or flexible standards?

As initially conceived, regulatory harmonization aimed to achieve a mutual recognition of risk assessments, perhaps even uniform criteria across the EU. However, national procedures are translating broader cause-effect uncertainties into technical criteria, e.g. by redefining the 'adverse effects' to be assessed. Such flexible standards can be understood as an integral part of the harmonization process, whereby the regulatory criteria always remain subject to further change, potentially shifting EU-wide standards.

Internal market or subsidiarity?

As initially conceived, the internal market would be 'completed' by removing trade barriers; EU-wide safety approvals would allow gm products to be circulated and cultivated as normal commodities. In practice, however, some national procedures are developing their own means to hold commercial users accountable for undesirable effects, defined according to diverse national accounts of precaution, biodiversity and sustainable agriculture. This *de facto* subsidiarity pushes the EU system to redefine its precautionary criteria, potentially allowing an internal market, though on a somewhat different basis than before.

'Science-based regulation' or politics?

According to some accounts, regulatory delays and restrictions have political motives, rather than a scientific basis. However, the public debate about risk-assessment criteria involves social, political and ethical issues, e.g. in setting normative baselines and assigning the burden of evidence for risk/safety. Some regulators have requested more data concerning broader cause-effect uncertainties. New scientific knowledge has been cited as increasing uncertainty about potential effects of gm crops. Scientific risk assessment cannot be done independently of policy judgements or, indeed, of political agendas.

Expert or lay judgements?

As initially conceived, safety judgements would be made by official experts, e.g. by regulatory officials taking advice from scientific committees. However, member states have defined the relevant expertise in quite different ways; more recently, the official expertise has been further broadened, e.g. by involving agro-ecologists and even NGOs who criticize biotechnology. The expert/lay distinction can break down as value-laden judgements are opened up by public debate and acknowledged by the regulatory procedure.

As suggested at the beginning, any solutions depend upon how policy problems are defined. For Directive 90/220 the official problem was how to 'complete the internal market' by the harmonization of regulatory criteria. Specialist experts were expected to achieve a mutual recognition of risk assessments, or even uniform criteria across the EU. That 'technocratic' model led to an impasse, with the result that some regulators have been redefining the policy problem. They have sought to understand the diverse public concerns, to

accommodate them through risk-assessment criteria, to broaden the definition of ‘adverse effects’, and to introduce further precautions.

In various ways, the technocratic model of European harmonization is being challenged and superseded. National regulators (and advisors) are flexibly redefining the ‘adverse effects’ to be assessed, translating broader cause-effect uncertainties into technical criteria, and discussing these measures at the EU level. Such flexible standards can be understood as an integral part of the harmonization process, rather than as a failure to achieve a universal norm. Likewise, diverse national practices can be understood as valuable resources for an alternative harmonization model – rather than as deviations to be endured or suppressed. Examples of what this might mean in practice are listed in Box 5.

Box 5 An alternative model for harmonization

Risk-assessment procedures for gm crops

- Regard harmonization as a process rather than a definitive end-state.
- Allow and expect flexibility in regulatory criteria.
- Develop ‘science-based regulation’ as a stronger burden of evidence to demonstrate that a product will not cause adverse effects.
- Open up policy debate on the normative baseline of comparison with gm crops.

Agricultural context/content of risk assessment

- Expect that gm crops will continue to serve as a test case for intensive agriculture.
- Acknowledge that risk/safety assessments rest upon implicit models of sustainable development, which may justifiably vary across member states.
- Define ‘indirect effects’ to encompass the effects of agricultural practices.

Risk-assessment research

- Design risk-assessment research to test assumptions about the predictability of effects, for a broad range of cause-effect uncertainties (e.g. through tri-trophic studies of beneficial insects).
- Design market-stage precautions so as to enhance public accountability of risk assessment and its underlying assumptions about relevant uncertainties.

Regulatory expertise

- Acknowledge that expert advice depends upon policy views.
- Develop expertise which acknowledges value-laden judgements, e.g. as regards scientific unknowns, normative judgements and risk-management assumptions within risk assessment.

These measures should be understood primarily as ways of encouraging a social process of policy learning rather than as prescriptions for policy change. This process can enhance mutual understanding among relevant constituencies, build a basis for shared responsibility in decision-making, and strengthen the democratic legitimacy of decisions. The legitimacy of gm crops will depend upon such a democratization process.

SIX ASPECTS

1 REGULATORY BOUNDARIES

Regulatory boundaries remain contentious and fluid. As transgenic crops approach the commercial stage, precaution is extended by linking regulatory criteria across administrative boundaries. The 90/220 procedure has come under pressure to incorporate environmental criteria also relevant to pesticide regulation (see Section 1.3). The National List procedure has considered uncertainties which were downplayed by the crop approval under 90/220, and has even imposed market-stage precautions (see Section 3.3). Extra data and/or monitoring are requested in order to test the predictability of undesirable effects and thus to characterize the product more clearly. Unlike those contentious boundaries, the Novel Foods Regulation has accommodated the food safety issues for products which have undergone its procedure.

By extending environmental precaution, such measures can delay product use and/or enhance its acceptability. Industry has become more dependent upon a more stringent assessment and market-stage control of products, as prerequisites for commercial use to proceed. By the end of 1998, however, commercial cultivation had begun for only one product – Bt maize, mainly in Spain. Safety regulation has the potential to link a market for seeds and for farm produce, but regulatory gaps leave product approvals vulnerable to environmentalist criticism, which partly translates into demands for process-based labelling; a related difficulty has been how to standardize labelling criteria (see Section 4).

1.1 National/EU dynamics

Since the mid-1990s, international disharmonies have intensified. In some member states, public protests (and even some national Ministries) have been exerting pressure upon the 90/220 procedure to broaden the range of ‘adverse effects’, e.g. regarding insect resistance, herbicide resistance, herbicide effects, etc. Such uncertainties have been cited as grounds for delaying or monitoring commercial use.

Each marketing dossier has received an objection from at least one member state, often from several, and not simply on grounds of inadequate labelling. Many objections involve disputes over regulatory boundaries. These have been voiced by additional member states, since the early objections from Scandinavian countries and Austria. By 1998 it was unclear whether the Article 21 committee had a qualified majority to approve products still under consideration.

Facing these conflicts among national CAs, DGXI has had difficulty in playing its coordination role. In the Ciba maize case in 1996, DGXI awaited favourable advice from EU-level scientific committees before proceeding to gain Commission approval for the product – without support from the CAs. In late 1997, under precautionary pressure from some DGs and member states, DGXI extended that consultative precedent. The Commission referred more dossiers to the DG XXIV-based scientific committees, sometimes even before the national disharmonies had been manifest.

1.2 Crop/food effects

As intended, the Novel Foods Regulation has successfully replaced Directive 90/220 for market approval of food derived from transgenic crops. The NFR requires approval of any novel food which had not been used for human consumption to a significant degree in the EU by May 1997 (EC, 1997b). Its enactment avoided further arguments regarding whether product approvals under 90/220 should be delayed until the EU had an agreed safety procedure for gm food.

According to a consensual interpretation, even if a gm product has gained approval for food uses under 90/220, 'it may not be placed on the market as a food or food ingredient until it is authorised under the Novel Foods Regulation'. The NFR also provided a 'single door, single key' procedure, so that the same dossier can be submitted for the uses relevant to each law (DGIII, 1997a). Some products have undergone both procedures in parallel (see Section 5). Regarding 'the environmental effects linked to the food use' of a gm product, DGIII (1997a) has advised that such effects may be assessed either under the NFR or 90/220; it is unclear what environmental effects could occur without cultivation.

By May 1997 the EU had no significant use of gm food other than the Monsanto soybean and Ciba/Novartis maize, which had already gained the relevant approval under 90/220 (EC, 1996b, 1997b). Some member states have argued that these products should undergo a retrospective risk assessment through the NFR procedure, especially to evaluate claims for 'substantial equivalence'. In that regard, there are different views about how the Novel Food Regulation (NFR) should relate to Directive 90/220 for food safety.

Regulatory boundaries vary among EU member states. Some combine the food safety assessment with the environmental risk assessment within the same administrative and advisory procedure. Others allocate these assessments to different procedures. In any case, there is no clear correlation between these administrative arrangements and their risk-assessment approaches.

1.3 Crop/pesticide effects

Regulatory boundaries have become more contentious for herbicide-tolerant crops (HTCs). Regarding the weed-control implications, regulators continue to dispute whether these would be 'adverse effects' or merely 'agricultural-economic problems'. Regarding the herbicide effects on biodiversity, regulators continue to dispute whether these would be caused by the crop, not just by the herbicide. More member states have raised these issues within 90/220, by default of any clear criteria under pesticide regulation; some have unilaterally broadened their own national regulatory boundaries (see Sections 5.4 and 6). Since the Scandinavian countries demanded that 90/220 encompass the effects of agricultural practices, e.g. all herbicide implications, similar pressure has come from UK and France (e.g. *FoEE Biotech Mailout*, 15.12.98: 4).

Regarding secondary metabolites and residues in food, their safety has become an issue for herbicide-tolerant crops – initially those exported from the USA, and prospectively those to be cultivated in Europe (see section 6.2). Some applicants have submitted relevant data within their 90/220 dossier, though no member state has objected to an application on grounds that such data was missing. There are national differences in the breadth of the

food safety evaluation; these relate to national differences over regulatory boundaries between crop/food/pesticide regulation.

2 NORMATIVE JUDGEMENTS

Since the mid-1990s, more and more Competent Authorities have criticized risk assessments for regarding some undesirable effects as acceptable, rather than fully evaluating them. In making such criticisms, they counterpose a broader definition of the ‘adverse effects’ which must be prevented. This in turn demands a stronger burden of evidence for their predictability, and/or market-stage monitoring to test such claims. At least implicitly, at issue here is the normative baseline (or standard) for the acceptability of potential effects. In general, product critics seek to protect future options for sustainable agriculture.

Given the contentious interpretations of ‘adverse effects’ under 90/220, the issue has been depoliticized via legalistic arguments. As national CAs disputed the boundaries between GMO and pesticide directives, DGXI asked the Service Juridique to clarify the remit and interplay of the two directives; the official advice reinforced a narrow account of ‘adverse effects’ and of the authority to require market-stage monitoring. At the same time, some officials acknowledge the value-laden character of such accounts: ‘All three types of judgment – scientific, legal, and political – are involved in any judgement on defining “adverse effects”. It involves considerations broader than science, e.g. by interpreting the law, and taking on board public concerns’ (interview, DGXI, 20.01.98). By contrast, argues a member of an EU-level scientific committee, the definition of adverse effects is a ‘purely scientific’ matter (interview, SCP member, 17.06.98).

2.1 Predictive/normative links

Under 90/220 the product approvals have accepted present agricultural practices as a baseline for evaluating environmental effects of transgenic crops. These products had no plausible effect which would worsen the present situation. Therefore it was deemed acceptable if glufosinate became ineffective for controlling weeds oilseed rape; likewise if Bt became ineffective for controlling insect pests. By contrast, critics (e.g. Scandinavian countries) requested evidence that a transgenic crop would provide an environmental improvement over the present situation and that its effects would not preclude any potential options for sustainable agriculture.

Since the mid-1990s more member states have taken up such environmental concerns. Implicitly or explicitly, these involve ‘sustainable agriculture’ as a normative reference point. From that standpoint, member states have requested data relevant to environmental uncertainties which the marketing applications had not evaluated adequately (or at all).

Another reference point has been biodiversity, in two senses. For the spread of transgenes, regulators have evaluated the potential effects on wild populations; but they have not requested additional evidence, nor disagreed at EU level. For the effects of spraying broad-spectrum herbicides, regulators have done both. To the extent that herbicide effects are considered as ‘adverse effects’ under 90/220, they involve normative judgements regarding which agricultural practices shall serve as the reference point.

For all contentious effects, it is unclear what data could clarify the uncertainties prior to large-scale commercial use (see section 3.2 below). Consequently, demands for more evidence pose a difficulty for the ‘step-by-step procedure’.

2.2 ‘Risk assessment’

For transgenic crops, regulatory practice has acknowledged uncertainties about the acceptability and predictability of potential effects. However, regulators have tended to justify their practice – even their precautionary measures – within the stereotypical language of conventional ‘risk assessment’. Since 1994 DGXI has been attempting to devise a standard risk-assessment method for use by notifiers and regulators in all member states. It convened a Risk Assessment Group to elaborate ‘a framework approach’, initially based upon UK guidelines (DGXI, 1996; cf. DoE/ACRE, 1993: 61-65). In a series of redrafts, DGXI has sought to accommodate objections from CAs, in order to reach consensus on a final document. At the same time, it recognizes that national practices vary in ways which cannot be standardized across the EU.

In making these efforts, DGXI has had several aims:

- to clarify the range of potential effects which must be evaluated in risk assessments (as regards causal chains and acceptability);
- to establish a standard format for risk-assessment documents, so that the various elements are readily comparable (across countries, notifiers and products); and
- to include the final guidelines as an Annex of the revised Directive 90/220.

According to the early risk-assessment guidelines, ‘Hazards are those features of a GMO which have the potential to cause adverse effects, either directly or indirectly, as well as in the context of its intended use (DGXI, 1996).’ In itself, such language could not resolve long-standing disagreements about whether ‘secondary effects’ of herbicide usage would be *caused by* the crop and therefore should be included within 90/220.

As regards the acceptability of effects, the early risk-assessment guidelines defined ‘severe’ environmental consequences as ‘a significant change in the numbers of one or more species of other organisms’, or ‘serious negative effects on the functioning of the ecosystem’ (DGXI, 1996; cf. DoE/ACRE, 1993: 63). Moreover, an early redraft of 90/220 set an implicit normative baseline: the risk assessment would ask, ‘how do any identified risks compare with the risks that would be posed by the use of the corresponding non-modified organism’ (DGXI, 1997). Such a comparison implies that effects of the non-modified organism are acceptable, so that objectors must demonstrate that the gm plant would have worse effects – e.g. worse than conventional crops in current agriculture.

The DGXI (1996) guidelines were ambiguous about scientific uncertainty. On the one hand, GMO releases should be designed to ensure that ‘an acceptable level of risk is reached’, as if the risk could be objectively quantified. On the other hand, control measures may be needed ‘to take account of uncertainties’; indeed, a ‘high degree of uncertainty... may arise from the lack of relevant data’. Moreover, ‘many of the judgements will have to be qualitative’ (according to the latest version, Revision 5, paragraph 27; cf. DoE/ACRE, 1993: 61). According to one CA, those guidelines tend to flatten precaution into conventional risk-benefit analysis: ‘GMO regulation is restoring a traditional type of risk

regulation. This contrasts with the 1990 horizontal, precautionary Directive, which jarred all those officials responsible for sectoral [product] legislation' (interview, Belgian CA, 17.09.97).

The early risk-assessment guidelines were revised several times, eventually becoming Annex II, 'Principles for the Environmental Risk Assessment', of the revised Directive 90/220. This Annex clarifies that 'adverse effects' may occur through 'changes in management, including, where applicable, in agricultural practices.' The assessment must encompass 'environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP [higher plant] where these are different from those used for non-GMHPs'. Thus it incorporated broader causal chains, as did the overall revised Directive.

2.3 'Familiarity'

The term 'familiarity' gained prominence in risk-assessment discussions in the mid-1990s, but it has nearly disappeared. Ostensibly the term 'familiarity' concerns only the predictability of effects, e.g. a judgement that the behaviour of a transgenic crop will be as predictable as a conventional crop. According to draft guidelines, 'Risk assessment can be based on knowledge and experience with the organisms concerned, or with similar organisms and similar traits of the organisms, or with their environment and their applications, i.e. familiarity' (DGXI, 1996). However, the term familiarity has been dropped from DGXI documents and even from the European discussions.

Implicitly, the term 'familiarity' has been used for linking judgements about predictability and acceptability. Thus the known effects of current agriculture are regarded as a normative baseline for evaluating transgenic crops. For example, the UK evaluates any 'additional risk' from the transgenic crop, as compared to the unmodified one (interview, DETR, 27.03.98).

[For 'substantial equivalence' in the Novel Food Regulation, see Section 4.3.]

2.4 Specific cases

Herbicide-tolerant crops, e.g. oilseed rape

In approving the PGS glufosinate-resistant oilseed rape, the European Commission stated a normative judgement: 'that any spread or transfer of the herbicide-tolerance gene could be controlled by using existing management strategies' (EC, 1996a, 1997c). This is similar to the argument made by the UK and France, as rapporteurs for the earliest marketing applications. An EU-level official has elaborated: 'Relevant effects include the prospect that the gene flow could preclude the use of a herbicide which is presently used on a crop', but it would be acceptable to lose future options for weed control (interview, DGXI, 20.01.98).

This argument was supported by an EU-level scientific committee, which also made a predictability argument. The Scientific Committee on Plants acknowledged that gene transfer to wild *Brassica* relatives 'is a new issue in Europe' but doubted that these would infest crops; rather, any herbicide-tolerant weeds would be the oilseed rape itself, 'which

could be controlled in subsequent crops by conventional agricultural methods' (SCP, 1998b).

By contrast, different norms have been promoted by other countries – and even by regulators in France and UK, which changed their stance:

- Denmark has reiterated its earlier demand that the risk assessment encompass the implications for overall herbicide usage and future weed-control options, especially given that oilseed rape can hybridize with weedy relatives. In raising this objection, Denmark has demanded that DGXI resume its 1995 discussions on the long-term effects of herbicide-tolerant crops (for which responsibility was shifted to DGVI and then to the SCP).
- Sweden has warned that broad-spectrum herbicides would damage wildlife habitats, simply by eliminating all vegetation, and thus demands that the 90/220 procedure evaluates such effects for every crop tolerant to broad-spectrum herbicides. That concern has also been voiced by the UK's government-funded conservation agencies (apparently unaware of each other).
- France and Italy have raised the issue of multiply-resistant weeds which may result from the commercial use of various herbicide-tolerant crops (especially oilseed rape) – an argument originally raised by Scandinavian countries in 1994. At the same time, France still acted as a favourable rapporteur for glufosinate-tolerant OSR, but later reversed its stance by opposing approval in November 1997.
- UK regulators have not formally changed their stance towards market approval. However, in late 1998 the CA announced that its risk assessment would encompass 'indirect effects' of agricultural practices, e.g. herbicide effects on biodiversity, and that these would be monitored in commercial use. The CA also declined to permit the spread of glyphosate-tolerance genes from oilseed rape, in order to preserve this weed-control option, especially for the scenario of glufosinate-tolerant weeds.

Bt maize: insect resistance

In approving Ciba's Bt maize, the European Commission stated a normative judgement: that the generation of insect resistance 'cannot be considered an adverse environmental effect, as existing agricultural means of controlling such resistant species of insects will still be available' (EC, 1997a). This argument is similar to the stance taken by an EU-level scientific committee (SCP, 1996, 1998a), as well as by France as rapporteur for the earliest marketing applications (EC, 1997a, 1998a). An EU-level official has elaborated upon that judgement:

"The European corn borer cannot be controlled by Bt sprays because it lives inside the plant. If the spread of Bt-resistance precludes the use of Bt to control a pest that cannot be controlled by Bt anyway, then is this an adverse effect? A rational answer would be: that Bt-resistance is an adverse effect only if it compromises an existing or possible use of the insecticidal agent (interview, DGXI, 20.01.98)".

By contrast, more member states have been regarding Bt resistance as an adverse effect. Some countries have demanded additional scientific data prior to market approval and/or a requirement for market-stage precautions. In particular:

- Scandinavian countries have insisted that insect resistance would constitute an ‘adverse effect’, though they don’t necessarily regard such an effect as plausible for the Bt products now being evaluated. According to Denmark, the Bt gene in maize raises no environmental or health concerns, but dossiers must specify the resistance-management measures. Sweden has inquired whether a reduction of the target-organism population would affect insects which feed on them or would affect plants which they pollinate, and so requested additional data. (Note the analogous concern above, regarding broad-spectrum herbicides).
- Belgium did not claim that Bt maize could cause any adverse effects within its country, mainly because the cornborer is not a significant pest there. Nevertheless its CA demanded market-stage precautions to manage insect resistance.
- France eventually signed the Part C authorization for the Ciba/Novartis maize approval in November 1997, after much delay. By then the company had discussed its resistance-management plans with the CA and National List authorities (CTPS). As rapporteur for Monsanto’s Bt maize, France had given a favourable opinion, yet it reportedly abstained in the CAs’ vote in March 1998.

Bt maize: insect resistance

In the first marketing application for Bt maize, there was little argument about whether the product would harm non-target insects; the dossier presented reassuring evidence from field surveys (Ciba-Geigy, 1994). In approving the product, advocates assumed either that harm would not occur, or that any harm would occur solely within maize fields and therefore would be acceptable. Austria criticized the laboratory tests for using bacterial Bt rather than plant Bt, which may have a different composition; its CA asked that market approval be conditional upon monitoring the efficacy of the Bt gene and upon improving the toxicological data.

Non-target harm became a prominent issue after Swiss scientists published evidence for the potential of the Bt toxin to harm a predator of insect pests (Hilbeck et al., 1998; see section 3.2.1). If this occurred in the field, then farmers would lose a means to control Bt-resistant pests, so this uncertainty has relevance to resistance-management strategies.

In response to the new evidence, the EU-level scientific committee modified its earlier predictive judgement. Initially it stated that ‘no risk is identified to non-target herbivores’, when assessing Monsanto’s maize (SCP, 1998a). After seeing the Swiss study, the committee assessed Pioneer’s maize: it stated that any harm to non-target arthropod insects would be less than the present harm from chemical insecticides (SCP, 1998b). Thus the committee accepted the present effects of chemical-intensive agriculture as a normative baseline for the potential effects of transgenic crops. Debate ensued over which agricultural practices should provide the normative baseline.

Antibiotic-resistance marker (ARM) genes

There is an emerging regulatory consensus that ARMs should not be used in gm products for animal or human consumption. There are various reasons, e.g. because such a product design is ‘sloppy genetics’, or because the minimal risk is unacceptable, and because the product benefits can be achieved by other means.

The UK's food safety committee has sought to discourage the use of ARMs since the mid-1990s, especially regarding the Ciba/Novartis maize. Since then, more and more member states have done so. For example, the Spanish CA refuses to act as EU-wide rapporteur for any product which contains an ARM.

This issue has not proved controversial among member states in the NFR procedure. Most companies have submitted their dossiers to the UK Competent Authority, whose advisory committee is known to take a stringent approach to ARMs. So far, gm food products are fully processed, containing no intact DNA.

However, such conflict has arisen in the 90/220 procedure in 1998. An application for gm potatoes, containing an amikacin-resistance gene, requested authorization to market semi-processed starch as animal feed; the rapporteur was the Netherlands. More data was requested by several CAs and by the EU-level SCP.

3 RISK ASSESSMENT RESEARCH/MONITORING

Regarding transgenic crops, more scientists have been publicly questioning the predictability of undesirable effects. Pest-resistant crops attract greater scientific debate than those closer to the commercial stage, e.g. herbicide-tolerant and Bt crops. For the latter, some scientists emphasize plausible scenarios which were officially deemed acceptable (e.g. herbicide-tolerant weeds, Bt resistance, etc.). The prospect of commercialization has stimulated further precautionary research – beyond the official account of 'adverse effects', and beyond the 90/220 procedure. Large-scale monitoring has become important for the acceptability of commercial use, but this link involves difficult issues about the financial, legal and scientific basis.

Regarding food safety, expert committees publicly express little scientific disagreement on risk assessment, except regarding antibiotic-resistance marker genes. Yet the predictability of health effects remains contentious in public debate – e.g. as regards general scientific ignorance, detection methods for allergens, and secondary metabolites from pesticide sprays.

3.1 Funding sources and priorities

For transgenic crops, the DGXII Pre-Normative Research programme funds research mainly projects on pest-resistant crops. One project uses woody plants as a model system to study viral recombination, heterologous encapsidation and their potential effects. Another two projects have been funded on virus-resistant crops within Framework IV. According to some participants, an essential task is to ascertain the normal baseline of such naturally occurring phenomena, in order to detect any greater risks from gm virus-resistant crops (Tepfer and Balazs, 1997). Another essential task is basic ecological research to ascertain the role of viral infections in controlling wild populations, as a basis for assessing whether virus-resistance genes could inadvertently confer a selective advantage.

Another DGXII-funded project studies potential harm to beneficial insects from insecticidal crops, e.g. lectins in potato and Bt in oilseed rape (Pham-Delègue, 1996). In a lab study, exposure to protease inhibitors shortened the lifespan of ladybirds, which are natural

predators of aphids (Birch, 1997). A tri-trophic study of aphids and its parasitoids found no harm to the beneficial insects. In another tri-trophic study funded by the Swiss government, there was evidence that Bt maize could harm lacewings, predators of insect pests (Hilbeck et al., 1998). More funding is needed to develop standard protocols for tri-trophic studies and for field monitoring of beneficial insects.

More generally, EU-level funding has weak links to national risk-assessment research and to transgenic crops nearer the commercial stage. There are many possible reasons: After gm oilseed rape and maize obtained EU-wide market approval in 1996, perhaps scientists saw no clear basis to propose further research. The DGXII guidelines require each proposal to include related research in several member states. Most DGXII-funded projects study gm microbes, yet hardly any GMO releases are microbes in the EU.

To fund a broader range of risk-assessment research, NIAB-Cambridge has been coordinating a grant proposal from an EU-wide network. Their ambitious proposal includes prominent, experienced researchers throughout the EU, with a more complex 'division of labour' than permitted under the DGXII guidelines. They seek funding from the European Science Foundation, whose procedures require a long consultation among its national affiliates.

For risk research on transgenic plants near commercialization, funding has come mainly from some national governments (e.g. UK, FR, DK; see also section 3.2.2). For herbicide-tolerant oilseed rape, many national studies have gone beyond the early DGXII-funded ones. They have tested hybridization between the crop and back-crosses with weedy relatives, to simulate persistence of the transgene near agricultural fields. Studies found a significant hybridization capacity with prevalent weeds in Denmark and France (e.g. Mikkelsen et al., 1996; Chevre et al., 1997).

3.2 Large-scale and/or market-stage monitoring

There have been increasing pressures to conduct large-scale environmental monitoring in publicly accountable ways. Some companies have undertaken to fund market-stage monitoring, prior to obtaining market approval. DGXI regards the written undertakings as a condition of the consent, so the monitoring has a quasi-voluntary status. Given the great expense of large-scale monitoring, related issues are who should pay and what methods would yield meaningful information.

Bt maize

For Bt crops, the relevant companies are committed to fund laboratory and field research on selection pressure for resistant insects. Not coincidentally, Italy withdrew its national ban after Novartis explained its plans to conduct systematic monitoring there. DGXI accepted some responsibility to evaluate the plans by Novartis and Monsanto in November 1997, after the Article 21 committee refused to support the DGXI demand that AU and LU withdraw their national bans on the Novartis maize. In these ways, some public accountability is gained for market-stage monitoring, which then serves as a political compromise to allow commercialization.

In late 1997 DGXI convened a working group of experts on Bt Insect Resistance Management. The group evaluated the monitoring plans which entomologists had prepared

for biotechnology companies. They had devised standard laboratory tests for Bt susceptibility, so that baseline levels could be measured and then compared over time and across environments (DG XI EGBtIRM, 1998a, 1998b). In this way, any increase in Bt resistance could be detected at an early stage, even before apparent in the fields. The design was adopted by DGXI (1998) and forwarded to the SCP at its request (see section 5.2.1).

Some CAs have raised concerns about Bt crops causing harm to non-target insects. In research funded by the companies, several insect species had already undergone laboratory tests using microbial Bt and showed no evidence of harm (e.g. Ciba, 1994; Monsanto, 1995). Critics proposed that the applicant redo the tests with more insect species, and using Bt derived from the transgenic plant. However, enormous quantities would be needed in order to extract a high dose, according to Monsanto (interview, 24.11.98). Field tests showed no harm to ladybirds – the only other species which could be found there.

Uncertainties about non-target harm have attracted little research. One exception is a Swiss-funded tri-trophic lab study, which showed that lacewing larvae had a lower survival after eating Bt-fed cornborers (Hilbeck et al., 1998). By contrast the applicant's laboratory tests had shown no harm from microbial Bt to this species, which is 'a beneficial predator insect commonly found in maize' (Monsanto, 1995: 46). Lacewing feed on aphids, which may in turn ingest Bt in maize fields, though these dynamics are difficult to test.

Researchers have no standard method for testing non-target harm from Bt crops: 'For chemical plant-protection products, the EU standard test must include two leaf-eating insects plus two ground insects. The biotechnology industry is suffering from inadequate guidelines about what data is needed to satisfy the assessors of Bt crop' (interview, DGXXIV, 04.03.98). Industry has funded no tri-trophic studies.

Herbicide-tolerant oilseed rape

For herbicide-tolerant oilseed rape, the UK and France have funded large-scale trials on the frequency and viability of hybrids. These respond to concern about inadvertent 'stacking' of herbicide-tolerance genes from oilseed rape varieties tolerant to different herbicides. When such crops were cultivated in close proximity, simulating the rotation of crops, some progeny had multiple tolerance (Reboud et al., 1998).

Moreover, the UK's MAFF funds research which simulates commercial use, in order to study effects of broad-spectrum herbicides on nearby vegetation in field margins (Sweet et al., 1997). This research responds to the public debate over potential effects on wildlife and biodiversity. Initially these trials aimed to validate the assumptions in the original risk assessment, regarding gene flow and hybridization with weedy relatives; by the 1998 the aim had expanded, to inform voluntary monitoring of commercial use. The UK Environment Minister announced that the first commercial use of herbicide-tolerant oilseed rape would be monitored for ecological effects, especially the herbicide effects on biodiversity (DETR, 1998). In consultation with the German Competent Authority, AgrEvo undertook to monitor commercial use for out-crossing and volunteer management, through 'an intensive product stewardship with farmers' (pers.comm., 30.11.98).

3.3 National List registration

Plant Variety Registration is a system for granting proprietary rights over new seed varieties. First a variety must be accepted for registration on a National List. Then it can be considered for certification, which authorizes seed multiplication for mass marketing. It can also be considered for listing on the European Common Catalogue.

National Listing is the ultimate gateway to a market for food crops. Any new variety must undergo National List trials for at least two years in order to satisfy the criteria – DUS (distinct, uniform, stable) and VCU (value for cultivation and use); such ‘value’ means a clear improvement in agronomic characteristics. Before a variety can be marketed, it must obtain registration on the National List in a member state, and then becomes a candidate for the EU Common Catalogue.

The standard criteria of DUS-VCU have been re-interpreted for transgenic crops. For example, if a transgenic crop differs mainly by its resistance to a pest or herbicide, then this trait may qualify a variety as ‘distinct’ or ‘valuable’. Such transgenes have a metabolic cost which may impose a yield penalty, so agronomists must carefully select strains whose hybrids will maintain yields equivalent with a non-transgenic counterpart.

The Catalogue system was devised mainly to guarantee product quality, along with safety in a narrow sense. According to the original Directive, a registration may be denied if it is shown that the variety could harm other varieties or species from a plant health standpoint, e.g. by spreading diseases. Likewise, a registration may be revoked if such effects are shown afterwards (EEC, 1970, Articles 15.3 and 19). These criteria have little bearing upon the risk issues considered in the 90/220 procedure.

Nevertheless commercialization of some transgenic crops has been delayed or has been subjected to extra restrictions because the National List procedure has been linked to safety issues, by stretching or supplementing the official criteria for registering new varieties. Such products have obtained prior approval under Directive 90/220 despite uncertainties about undesirable effects and disagreements about whether they are ‘adverse effects’ which must be prevented. Consequently, the National List system has come under pressure to fill gaps or uncertainties which are left by the 90/220 procedure. In some cases, National Listing is being linked with risk-assessment research (see section 3.3.2).

PGS oilseed rape

The PGS spring herbicide-tolerant oilseed rape has faced long regulatory delays. The first PGS application (C/GB/94/M1/1) requested 90/220 market approval only for purposes of seed multiplication. The second (C/F/95/05-01) requested approval for all uses, but the Part C authorization has been blocked by France. The variety has undergone National List trials by NIAB in the UK since 1995.

There are several reasons for delay in gaining UK approval. There was doubt over whether the PGS varieties fulfill the DUS-VCU criteria, e.g. whether the male-sterile inbred line is 100% pure, and whether hybrid vigour offers consistently higher yields. In MAFF’s view, the PGS hybrid could not be approved for the National List anyway until the product gains EU safety authorization under 90/220 (see below and 5.4). Meanwhile environmentalists have opposed its approval, though this may not explain the delay. More recently, a UK court ruled that all recent National List trials were invalid because NIAB had failed to follow the standard regulations, though the ruling ostensibly had no bearing on safety issues (Meikle, 1998); the regulations were quickly amended to validate the earlier trials.

In France, when the CTPS was asked to conduct National List Trials in early 1997, the CGB raised environmental issues which had not been resolved by the 90/220 procedure. The CTPS proposed to test the crop in close proximity to non-gm oilseed rape, but this method could inadvertently spread herbicide-tolerance genes, according to the CGB. No trials have gone ahead there. By November 1997 similar concerns led the government to withhold approval from herbicide-tolerant oilseed rape, by refusing to sign the Part C authorization, even though France had been the national rapporteur advocating 90/220 approval for the product (C/F/95/05-01). After its Citizens' Conference in June 1998, the government confirmed that it would not grant approval to such products.

Ciba/Novartis Bt maize (C/F/94/11-3)

The original Ciba/Novartis Bt maize was further crossed with various non-modified lines, resulting in several new varieties designed for cultivation in specific regions, especially in Mediterranean countries. Their approval has been subjected to unprecedented conditions. (This section calls it 'the Ciba maize', as distinct from the later Novartis maize which had only the Bt transgene.)

After much debate and delay, in November 1997 the French government announced that it would permit cultivation. Three varieties were registered on the CTPS National List in February 1998. Unusually, however, the approval was granted only for an initial period of 3 years; and it required the company to monitor various environmental effects, e.g. insecticidal efficacy, unintended harm to insects, insect resistance to Bt, effects on other organisms, spread of the ampicillin-resistance gene, etc. (France, 1998). Spain (1998) imposed similar requirements on Ciba maize varieties there, as well as a general monitoring requirement for all transgenic crops in the future. In this way, the National List authorities carried a burden of precautionary issues beyond the 90/220 procedure and shared responsibility for them.

The insect resistance management (IRM) issue has an implicit link to the DUS-VCU criteria in the National List approval. Several traits (including yield) qualified the Ciba maize varieties as 'distinct', while the Bt gene gave the varieties 'value for cultivation and use' (*valeur agronomique et technologique*). However, there is some doubt about the efficacy of the Bt gene, whose expression levels 'were markedly lower in late-season, senescing plants' (Ciba, 1994: B-16). The Bt gene may not successfully protect the plant in southern France, where second-generation larvae attack maize towards the end of the crop cycle (according to the maize producers' association, AGPM, quoted in *Agrow*, 17.02.98: 11).

In theory, the high-dose Bt would kill all insects which are heterozygous for Bt resistance, while any rare homozygously-resistant insects would mate with homozygously-susceptible insects in the refugia. If some heterozygous insects survive, however, then insect populations have ideal conditions for developing insect resistance. There is some doubt about the IRM strategy and thus about satisfying the DUS-VCU criteria in the long-term.

Other hybrids of the Ciba maize may be undergoing National List trials in other countries. According to the company, it has not applied for registration in Germany; prior to registration, however, the Bundessortenamt allows 'pre-marketing' of 10 tonnes to wholesalers (*Nature Biotechnology* 16: 498, June 1998). The product will not be sold

anyway in some northern European countries where the corn borer is not a significant pest problem.

3.4 ‘Familiarity’

The term ‘familiarity’ was devised as a flexible criterion for judging whether a GMO is similar to another product whose behaviour is already well known and predictable. The term has become a linguistic reference point for identifying which uncertainties warrant further research.

Divergent interpretations

Risk-assessment researchers diverge over how to interpret ‘familiarity’ (Levidow et al., 1996: 146-47). Some scientists cite known characteristics of conventional plants – e.g. naturally occurring resistance to antibiotics, herbicides, viruses, etc. – as ‘familiar to the plant breeder’ (Dale and Scheffler, 1996). Other scientists emphasize that only the phenotypic trait is ‘familiar’. They question whether we know enough about the genetic basis and ecological role of such traits, as a basis for comparison with transgenic crops. For example, transgenic traits may impose a lower metabolic cost than naturally occurring ones, and so would more readily confer a selective advantage.

For diverse interpretations of familiarity, an example is provided by virus-resistant transgenic crops. If the transgene spreads to related plants, then this may confer a selective advantage, in turn disrupting weed-control measures and/or undermining natural biodiversity. To clarify such scenarios, research has investigated the presence of virus-resistance genes in wild populations, and how these may differ in transgenic crops (e.g. Cooper and Raybould, 1997). Other research investigates how plant viruses may exert selection pressure, e.g. via seed production and survival. The empirical results have been cited to propose further research before market approval is granted – or, alternatively, to declare that a virus-resistant plant is adequately predictable.

Thus the ‘familiarity’ criterion becomes a focus of further argument over the burden of evidence. Some scientists regard naturally occurring traits in plants as an adequate baseline for predicting the effects of ‘similar’ transgenes, and thus regard the gm plant as basically ‘familiar’. Others propose more research on their dissimilarity at the genetic and ecological levels. Implicitly, they disagree over what *unfamiliar* features of transgenic crops warrant the effort to obtain additional knowledge, and thus what more experience could enhance their environmental predictability. Such questions underlie disagreements over criteria for adequate evidence.

The term ‘familiarity’ has a prominent place in the DGXI (1996) risk-assessment guidelines, yet its place in actual debate is unclear. The DoE originally promoted the term at EU level, yet it appears in no risk-assessment document in the UK. At a January 1998 conference on transgenic plants in Bern, the term was promoted mainly by the US Dept of Agriculture.

‘Substantial equivalence’

As an implicit type of familiarity criterion, the NFR codified ‘substantial equivalence’ to guide the risk assessment (as distinct from ‘equivalence’ as the labelling criterion). This

provides a basis for evaluating any compositional differences between a gm food and a counterpart which has been widely consumed. At its January 1998 meeting, the DG XXIV-based Scientific Committee on Food expressed concern that the term is ‘increasingly interpreted in different ways’ within Europe. (For the UK interpretation, see section 4.3, which combines the risk-assessment and labelling aspects.)

Some critics challenge ‘substantial equivalence’ itself, on grounds that the concept is misleading for a new technology whose effects are unpredictable. Critics also raise specific weaknesses of laboratory testing. For the Monsanto soybean imported from the USA, for example, Greenpeace criticized the safety assessment for downplaying effects on test animals and for testing only the unsprayed crop. Perhaps in response to such criticisms, the Scientific Committee on Plants requested data on secondary metabolites and residues in order to evaluate 90/220 dossiers for herbicide-tolerant crops in December 1997. Such data was already supplied to the German CA under its pesticide legislation.

3.5 Ecological models

According to the early scientific rationale for GMO legislation, it was necessary to anticipate and prevent any ‘ecological imbalances’. In practice, risk assessment and related research have hardly drawn upon such a conceptual framework. Many ecologist-researchers regard the wider environment as relatively stable, due to its biodiversity, by contrast to agricultural systems. There is increasing interest in agro-ecology, towards understanding interactions between agriculture and its proximate environment.

4 LABELLING PRACTICES

For products which may contain gm ingredients, public acceptability depends upon clear, consistent, credible labelling – which has been difficult to achieve for gm food. Labelling was intended simply to identify products for free-market competition, yet divergent rules have been competing against each other. In dispute is how to characterize ‘the product’ – e.g. how to distinguish between ‘gm/non-gm’ food.

As the food industry recognizes, ‘The EU has potentially 15 different (national) markets. If there are no rules, then there is no obligation to label in the same way in all member states’ (interview, CIAA, 19.01.98). Closer to individual consumers, the retail industry realized that inadequate labelling would deny the consumer’s right to be informed: ‘If consumers react against this, then the image of the authorities, producers and retailers could be damaged, apart from the financial losses’ (interview, EuroCommerce, 24.11.97).

The principle of mandatory labelling has been widely accepted, but for diverse motives which have become difficult to accommodate in the food market. Officially, labelling provides the information essential for a free consumer choice among products whose safety is assured. Unofficially, the impetus for labelling arises from more awkward sources – public distrust of safety judgements, public resentment at dependence upon official experts, and from efforts at influencing innovation according to environmental criteria (Grove-White et al., 1997; Todt & Lujan, 1997). As comprehensive labelling has been demanded, an *unfree* market has come under challenge. Industry becomes more dependent upon state regulation to structure a ‘free choice’ which can make biotechnology products acceptable.

The disputes arise from two fundamental dilemmas:

- (i) There is an inherent conflict between two aims – to maximize the range of gm products for which labelling is required, yet to base rules upon compositional differences which are reliably detectable and therefore enforceable. Technical reliability has been uncertain or disputed, especially for gm DNA. Available tests for gm protein in maize give false negatives, while the available tests for gm protein in soya give positive results even for miniscule contaminants.
- (ii) There is also a related conflict between two policy aims – to keep labelling requirements separate from safety issues, yet to give consumers a comprehensive right to choose between gm/non-gm food. Both those aims respond to public distrust of official safety judgements. The distrust has several sources, e.g. the BSE precedent, ethical opposition to gm technology, perceived risks, scepticism at scientific over-confidence, concerns about environmental effects which were ignored by the 90/220 procedure, etc.

Public distrust has raised the stakes for how the labelling rules are formulated. Some pressure groups (e.g. Greenpeace and Green MEPs) explicitly link labelling to risk, while others (e.g. EuroCommerce) remain ambiguous, and still others (e.g. BEUC) seek to separate labelling from risk. EU-level legislators have sought to delink the rules from risk perceptions, e.g. by putting the detectability criteria into general labelling law rather than in biosafety laws.

Nevertheless the stigma of genetic modification has been difficult to overcome. For example, the industry discusses tolerance limits of gm ‘contamination’ for labelling food as ‘non-gm’. Some retailers plan how to guarantee ‘pure’ or ‘clean’ food. The implicit link with risk raises the political stakes for the labelling criteria, aggravates the EU-wide disagreements, and renders a food market unstable, both within and among member states.

Subsections are classified according to whichever DG is the *chef de file* for the relevant regulations. Subsection 3.1 combines food risk-assessment and labelling issues under the Novel Food Regulation.

4.1 DGIII: food labelling disputes

This subsection traces the development of labelling rules for gm soya and maize. At first the public demand for mandatory labelling was rejected, e.g. by DGIII and EuropaBio, on grounds that such rules would unfairly stigmatize all products of genetic modification. After consumer protests mounted, the EC authorities adopted mandatory labelling as an essential means to stabilize a Europe-wide food market (EC, 1997b, 1997e). It has been difficult to implement the labelling rules. Such rules have been adopted in three stages, each attempting to clarify what was left ambiguous in the previous version. Yet Europe remained far from harmonized practices in late 1998, especially for bulk commodity products imported in mixtures from the USA.

Regulation 1813/97

The Monsanto soybean and Novartis maize gained safety approval under Directive 90/220, without any labelling requirement. To fill this gap, Regulation 1813/97 was adopted as an amendment to a 1979 labelling directive. The Regulation required that such food must be

labelled if it is detectably 'not equivalent' to non-gm food, but did not specify the technical criteria for detectability (EC, 1997e). It had to be implemented by November 1997, but the deadline had no practical effect.

There were disagreements over how to interpret the rules or how to specify them further. 'People are awaiting labelling requirements which will put order into the market', noted an official (interview, DGIII, 25.11.97). Indeed, a European market for soya-based food was in disorder; as product identity was in dispute, it could not be resolved simply by a labelling rule.

As another problem with the Regulation, it permitted the label to say 'may contain gm'. That option avoids any need to segregate or test supplies. However, this wording implied that food companies don't know their own grain sources, thus undermining their credibility. There arose a broad consensus that the label must say 'contains gm', in case of uncertain or mixed sources.

However, that potential alternative led to further disputes over consumer choice. If most processed food were labelled 'gm', then consumers would have little access to non-gm food. The 'contains gm' label would become meaningless, as the food industry acknowledged (interview, CIAA, 19.01.98).

For the 'non-gm' category, both consumer groups and industry have advocated 'identity preservation'. This criterion accepts that non-gm sources contain a small percentage of contamination, rather than be literally 'gm-free'. According to Fediol, a 'tolerance threshold' is essential to avoid labelling all food as 'gm', and thus to provide consumer choice. Already some retailers were offering 'gm-free' food, though the European industry has no standard method to certify such a claim. Some NGOs proposed that a 'purity standard' be devised by industry and/or government.

Given the disputes over the appropriate laboratory testing, there have been proposals that labelling be based instead on certificates which preserve product identity, from the start of the food chain. Such a system has been advocated by consumer organizations, e.g. BEUC and the Konsumentenbond. Such a system would build upon the routine practice of the food industry, which anyway obtains documents about the source of its raw materials: 'The specifications for bulk supplies will include a test for gm protein' (interview, CIAA, 19.01.98). Likewise, a 'certificate of non-gm origin' would anyway be a prerequisite for laboratory testing to be worthwhile.

As a statutory basis for labelling, however, a certification scheme would contradict DGIII's 'science-based' criteria for evaluating a gm foodstuff as 'non/equivalent' to an existing one. And it would require a drastic change of the present legislation.

Some sectors of the agro-food industry disagreed over whether any segregation is feasible. Trans-Atlantic grain merchants originally insisted that segregation would be impossible or very expensive; according to GAFTA, 'product identity is lost' after the grain harvest. By late 1997 that claim was refuted in practice, as some European companies established a niche market for 'non-gm' imports.

Interim voluntary guidelines, national practices

During the confusion over how to implement Regulation 1183/97, there were no harmonized EU-level rules for labelling gm food. To fill the gap, the European food industry (CIAA) devised its own voluntary guidelines, which adopted a gm protein criterion for labelling food as 'gm'. According to the CIAA, the detectability criteria would be applied at the stage of bulk supplies at EU ports, and would be applied to all grain from countries where the gm crop is cultivated (interview, CIAA, 19.01.98).

On that basis, the voluntary guidelines would result in labelling more products than would be required by a statutory criterion of gm protein in processed food, where the protein may no longer be detectable. On the other hand, the CIAA guidelines fell short of demands for broader criteria, e.g. for gm DNA and even rapeseed oil. Representing the European retail sector, EuroCommerce advocated mandatory labelling for all gm-based products, partly in order to avoid 'discrimination' against those which have detectably different substances. However, the gm protein criterion was preferred by the UK and Belgian members of EuroCommerce.

The November 1997 CIAA guidelines were set to be implemented in February 1998. However, they did not guide practice throughout Europe, partly because of disagreements between the retail sector and food industry in some countries. Even where gm food was labelled as such, e.g. in the UK and NL, this meant labelling any products derived from US soya, which is presumed to 'contain gm' soya. Some retailers sought certified 'non-gm' soya but could not obtain sufficient quantities to fulfil the consumer demand.

The CIAA interim guidelines had the following results in early 1998 (according to a EuroCommerce officer, interview, 06.03.98, with extra information added in brackets):

- In the Netherlands the industry used the voluntary system which it pioneered and adopted in 1997; approx. 30-40 products there are labelled as 'gm' (see Schenkelaars, 1997).
- In the UK, the system was working well because the gm protein criterion was agreed by the food industry and retailers, who anyway had preferred that criterion. (Supermarket chains were starting to label their 'own-brand' soya-based products as either 'gm' or 'non-gm'. The Iceland chain guaranteed that all its soya-based products are non-gm. The baking industry undertook to use 'Identity-Preserved' soya.)
- In Germany, industry alone adopted the gm protein criterion but had no support from commerce [retailers], which wanted broader criteria, partly because a gm protein criterion alone could be misleading to consumers. So no labelling system was implemented there.
- In France, commerce wanted to label gm food on a rDNA criterion, but industry was holding out for a gm protein criterion. No system was implemented there.
- In Sweden, (the food) industry and commerce agreed the rules, but no products were labelled 'gm'. Probably there were unlabelled gm products.
- In Switzerland, some food was labelled 'gm'. For example, 'Tost' bread was labelled as containing 'gm soya' by Nestle.
- (In Austria, major retailers banned gm materials and devised a stringent system for applying a 'gm-free' label.)

Regulation 1139/98, non-gm trade

To clarify the previous ambiguity, DGIII drafted a regulation which would require that gm soya and maize be labelled if gm protein *or* DNA is present. This criterion aimed to maximize the range of products which would require a 'gm' label. To some extent, government stances coincided with that of the respective retail sector. The DGIII proposal gained support only from Sweden, Denmark, Germany and Austria; other member states objected, e.g. by citing the high cost of DNA tests. The Council of Ministers approved a revision of that proposal, Regulation 1139/98, which required a 'contains gm' label if gm protein *or* DNA is present; this became legally binding in September (EC, 1998b).

Apparently European retailers intended to apply a 'genetically modified' label to any soya or maize ingredients obtained from a country where genetically modified crops are cultivated – initially the USA and Canada, and then Argentina too. Exceptions are processed products that contain no DNA or protein, e.g. rapeseed oil and lecithin. Yet consumer groups still demanded labelling of all gm-derived food, regardless of detectability, and some supermarket chains have accommodated these demands. In late 1998 the European Commission announced an intention to include additives such as lecithin within new labelling rules; difficulties remain in finding a reliable means to enforce such rules.

In some countries, e.g. Germany and Denmark, 'gm' labels are rarely found on food. Although some retailers may be violating Regulation 1139/98, most are avoiding gm ingredients: either they find non-gm supplies or they substitute other ingredients for soya or maize. No company wants to be the first to sell gm products.

In the UK, a non-gm food market was developed by one supermarket chain, which found alternative supplies from abroad and then made them available to competitors. This breakthrough has led to a dual market for gm and non-gm food products, the latter usually not labelled at all. By early 1999 most UK supermarkets had excluded gm ingredients from their own-brand products.

Most 'non-gm' products contain some detectable contamination from gm sources and so require a 'gm' label under the present criteria (EC, 1998b). As a related problem, the German and Austrian governments are seeking to validate technical standards for negative labelling of products as 'gm-free'. For both reasons, there have been EU-level proposals to specify a percentage threshold, below which no 'gm' labelling would be required. This level was initially set at 1% of gm contamination.

For implementing the detectability criterion, another issue is the way in which food is tested. The technical method and food-processing stage can affect the test results. For example, when processed gm maize undergoes testing for gm protein, the results can yield a false negative, though gm DNA is detectable at any stage. By contrast, processed *non-gm* soya tests positive for gm protein, perhaps because the test is highly sensitive to a small contamination. Given those technical difficulties, the food industry wants to avoid dependence upon unreliable, changeable methods of detection. Indeed, competing methods have been promoted by various laboratories, exploiting the entrepreneurial opportunity.

Towards a solution, the EC's Joint Research Centre in Ispra has devised standard methods. These are designed not simply to detect the presence/absence of gm material, but rather to detect whether its presence exceeds a specified percentage (Lipp, 1998). Thus the JRC

experiments could inform and reinforce proposals to set a threshold within Regulation 1139/98.

4.2 DGXI: DRD 90/220 and Decision 97/35

In parallel with the food labelling criteria, there were disputes over whether to require labelling of specific gm crops under the Deliberate Release Directive 90/220. Such disputes contributed to delays in their approval. With Decision 97/35, Directive 90/220 was amended to require labelling of all transgenic seeds as 'gm'. Officially, the new labelling requirements were justified in precautionary terms: an information register with molecular data is necessary 'to assist the evaluation of similar or more complex products', as well as the generation of data from market-stage monitoring (EC, 1997d). According to DGXI, 'These measures are relevant mainly to the progeny of the GMO, e.g. hybrids with other varieties. A label would help to trace the lineage back to the transgenic crop which gained approval' (interview, DGXI, 20.01.98). It is unclear how the information register will be used to develop precautionary measures. As an implicit reason for Decision 97/35, such information would be available for labelling products along the food chain, i.e. from farmers to grain merchants to food processors to retailers.

Decision 97/35 was not retroactive for any product applications which had already been submitted under 90/220. So DGXI asked all those applicants to undertake to label their products accordingly – which they did in writing. According to DGXI, such commitments carry legal force. Consequently, CAs dropped their previous objections to such products on grounds of inadequate labelling, though some had raised other objections. For the four products approved in early 1998, the labelling commitment was mentioned in the preamble/recital of the consents, though not as a formal requirement (e.g. EC, 1998a).

For these decisions to achieve reliable 'gm' labelling along the food chain, it is essential that 'seed packets' carry such a label. Such a requirement was included in a draft revision of the plant variety registration (CEC, 1997) and was approved by the Agriculture Council of Ministers in December 1998.

4.3 DGIII: Novel Food Regulation 258/97

Several gm products have been approved under the Novel Food Regulation (NFR), specifically under the 'substantial equivalence' criterion of Articles 3(4) & 5. After one member state grants approval under this simplified procedure, EU-wide marketing is permitted, in parallel with any objections (EC, 1997b). According to Article 5, an annual summary of the notifications shall be published in the 'C' series of the *Official Journal*, but this has not yet been done for 1997.

Rapeseed oil from herbicide-tolerant oilseed rape (of PGS, AgrEvo and Monsanto) was submitted to the UK under its voluntary procedure which pre-dated the NFR. MAFF accepted the applicants' claim that the oil products had substantial equivalence with existing products from non-gm sources. All three were notified to DGIII shortly after the NFR came into effect in May 1997. The oil is literally 'equivalent', devoid of any protein or DNA, so it requires no labelling.

Again under its voluntary procedure, in February 1997 the UK granted approval to three Bt maize products (Monsanto, Northrup King, and Pioneer) for use in processed food. On

advice from the ACNFP, MAFF accepted the applicants' claim that the processed maize had 'substantial equivalence' with non-gm maize (ACNFP, 1997: 6-7). The processed food was also assessed as 'equivalent' to its non-gm counterparts, on grounds that no gm DNA or protein is detectable after processing. MAFF's Food Advisory Committee (FAC) asked companies to label the maize on a voluntary basis 'in response to public interest', though none undertook to do so.

After the NFR came into force in May 1997, the companies notified the UK approvals to DGIII under the substantial equivalence criterion of Article 5 between late 1997 and early 1998, thus gaining authorization for EU-wide commercialization. Apparently there were no objections from any member state, though only *processed* grain was permitted by the approval. Meanwhile, some of the same products were being assessed for both food and feed safety approval under 90/220.

4.4 DGXI/DGVI: animal feed

Unlike novel or gm food, safety approval and labelling of gm feed remains within Directive 90/220. DGVI is redrafting a Feed Materials Directive which would incorporate gm feed and would require labelling. Segregation has been advocated by the DGVI Commissioner.

5 A EUROPEAN MARKET?

So far, few transgenic products have been marketed in the EU. They are mainly bulk commodity crops for processing into food or animal feed (see section 4.1). For the Monsanto soybean in particular, inadequate labelling rules may jeopardize an EU-wide market for all soya-derived products.

For transgenic crops, the commercial stage has been used as an opportunity to extend precaution beyond market approval. Monitoring plans have enabled companies to obtain authorization to cultivate Bt maize in particular. For market approval of most products, however, the decision-making procedure has become delayed by EU-level conflicts. DGXI has referred several stalled products to an 'independent' advisory committee, which has recommended market-stage precautions to prevent undesirable effects, though without regarding these as 'adverse effects' under 90/220. This procedure may strengthen the authority of the Commission to approve products, as well as facilitate an EU-wide market for these products.

5.1 EU versus national authority?

EU-level dynamics are more complex than a contest between 'EU versus national authority', for several reasons. Each member state seeks to use the EU-level procedure to accommodate and/or to manage domestic pressures, in diverse ways. Internal divisions arise at EU level, e.g. among DGs, and in MEPs criticizing product approvals.

Some national CAs have resented a loss of authority. As an extreme case, the European Commission approved the Ciba/Novartis maize in December 1996, despite the CAs' opposition: 'The Commission was initially defined by Directive 90/220 as a coordinating secretariat of the member states for the good management of procedures, yet has established

itself as a supra-national competent authority', according to an officer of the Belgian CA (interview, 17.09.97).

On the other hand, as gm products are stalled in the Article 21 cttee or banned by member states, some CAs have used the opportunity to strengthen EU-level precautionary measures (see section 5.2). Under EC law in general, the comitology procedure is officially designed to 'support' the Commission, though in practice this is a euphemism for limiting its authority – e.g. deciding whether or not a member state should be disciplined by the Commission (Winkler, 1999). In GMO regulation, member states have not only limited the Commission's authority to enforce the internal market, but have also pressed the Commission to take responsibility for extra precautionary measures, e.g. monitoring methods and advice from EU-level committees.

DG XXIV's role

Prior to 1997, the European scientific committees were being criticized for a failure of both political independence and precautionary risk-management. For example, prospective members were nominated by national governments; many members overlapped with those of the corresponding national committee. They often reiterated national policy rather than engage with wider perspectives on risk assessment. The committees were also perceived as accommodating the policy of their host DG, which in turn was perceived as having a vested interest in the outcome.

After the BSE scandal erupted at EU level, the European Commission restructured its scientific committees. In May 1997 DG XXIV took over responsibility for committees which were formerly based in other DGs. In this way, the Commission sought to separate 'risk assessment' (product evaluation) from 'risk management' (legislative framework and product approvals). DG XXIV invited prospective members to nominate themselves and to declare any interests relevant to the risk-assessment issues. In these ways, the reorganization sought to render the committees 'independent' – of the legislative DGs, of the member states, and of material interests.

However, it may be more difficult to achieve intellectual independence from the reductionist assumptions of laboratory science. As an official acknowledged, the SCP has a deficiency of ecological expertise, except for ecotoxicology. Indeed, 'The experts [members] say that the genetic modification technique is familiar to them, so that the evaluation need not take a long time' (interview, DGXXIV, 04.03.98).

Products approved

The rest of this section emphasizes marketing pathways and blockages under 90/220. Also essential for cultivation is National List registration, described in section 3.3. Products so far approved (with 90/220 dossier numbers):

- Monsanto glyphosate-tolerant soybean (C/GB/94/M3/1), which gained 90/220 approval before the NFR, is used mainly in soya-based processed products.
- PGS glufosinate-tolerant oilseed rape (C/GB/94/M1/1) gained 90/220 approval for seed multiplication only. From this and other oilseed rape (from AgrEvo and Monsanto), rapeseed oil was approved by MAFF and was then notified to DGIII under the NFR.
- Ciba-Geigy/Novartis Bt-maize 176 (C/F/94/11-3), which gained approval under 90/220 for all uses, has been cultivated in France in Spain but has not obtained National Listist elsewhere (see section 3.3).
- Other Bt maize products (from Monsanto MON10, Northrup King Bt-11, and Pioneer MON9) gained approval for food-processing purposes in the UK in February 1997, and were later notified to DGIII under the NFR; likewise Novartis and AgrEvo maize were notified in 1998. Most gained 90/220 approval for import (e.g. EC, 1998a), though the Pioneer maize failed to gain a qualified majority in December 1998.
- The above Bt maize products – and others – may be included in mixed shipments from the USA (see section 5.2.2).

National restrictions have been overtly imposed and maintained on the Ciba/Novartis Bt maize, initially by Austria and Luxembourg, and subsequently by the constitutional court in France. Austria has asked companies to respect a voluntary moratorium on other products, perhaps as a way to avoid a court test. France has delayed EU-wide approval of a PGS glufosinate-tolerant oilseed rape, for which the Commission decision had authorized all uses. See details below.

5.2 Bt maize

Bt maize has become a test case for linking several issues – trade barriers, the CAs' authority, precautionary measures, and political responsibility for them.

National bans on Ciba/Novartis Bt maize

After the Ciba/Novartis Bt maize gained EU-wide approval (EC, 1997a), it was banned in Austria and Luxembourg under 90/220 Article 16. Austria presented more scientific evidence of risk, e.g. the potential for Bt crops to generate selection pressure for resistant insects. DGXI then requested advice from the former scientific committees. It judged that there was no 'new evidence' to cast doubt on the favourable opinion which they had originally given; for example, e.g. it reiterated the earlier argument that insect resistance would not constitute an 'adverse effect' (SCAN, SCF, SCP, 1996). DGXI then asked the CAs' Article 21 committee to support the Commission demand that the national bans be withdrawn, while Austria and Luxembourg requested a delay.

In response, the CAs asserted their authority by not voting at all. A vote was twice deferred – first in November 1997, and then again in January 1998. In November several CAs (BE, DK, SW, IR, UK) announced that they would abstain or vote against the Commission proposal; DGXI backed down, for lack of a qualified majority. In January 1998, France supported further delay, even though it was the national rapporteur which had advocated approval of the product. Finally in March-April a written vote was conducted: at least four countries abstained (FR, BE, DK, IR), as well as three countries voting against (AT, LU, GR), thus depriving DGXI of a qualified majority (FoEE Mailout, 15.06.98).

The procedural delays and abstentions had two apparent motives, concerning political responsibility. Some CAs feared that an inconclusive vote would allow the decision to fall to the Commission alone (as had happened over the original approval in mid-1996). Also, Sweden and Denmark now used the impasse as pressure upon DGXI to take responsibility for insect-resistance monitoring plans. Although some CAs had asked DGXI to do so in 1995, it finally convened an expert working group in January 1998, whose timing was not coincidental (see section 3.2).

In September 1998, after the first season's plantings in France and Spain, another obstacle arose. The French constitutional court, the Conseil d'État, ruled that the original approval was invalid because its national authorities had not adequately evaluated the ampicillin-resistance gene, though this was later evaluated as safe by an EU-level scientific committee (SCAN, 1996; SCF, 1996). In December the Conseil d'État formally asked the ECJ-Strasbourg to clarify the national scope for a rapporteur to reconsider a marketing authorization. The EU-wide authorization had depended upon the signature of France, so its court ruling created more uncertainty for the entire approval system. After the September

decision, moreover, farmers segregated the harvests of gm conventional maize, in case the former must be excluded from the food chain.

Monitoring 'contamination'?

Safety regulation has come under trans-Atlantic trade pressures, especially from US shipments of bulk commodity crops. By imposing a time-pressure on EU approval, the shipments cast public suspicion on the risk-assessment procedure, even if the products themselves raise fewer safety concerns than previous ones had done. The shipments also intensify intra-European conflicts, as regards what type of control and inspection is legally required.

In late 1997 it was widely reported that maize shipments from the USA contained products not yet approved in the EU. US exporters faced uncertainty about the fate of their shipments. In November 1997 the European Commission received letters from seed companies and the US government protesting at the regulatory delays. Such shipments were destined for Spain and Portugal, both long-standing substantial importers of US maize. These countries temporarily had to find alternative sources until all the US products gained EU approval (e.g. EC, 1998a).

Processed corn-gluten is not subject to 90/220, but environmental activists claimed that the shipments were 'contaminated' with live kernals. The Dutch and German authorities, whose ports had admitted the shipments, claimed that heat treatment had killed any live kernals, though Greenpeace disputed this claim. The UK and NL argued that gm maize kernals no longer contain reproducible DNA after processing into corn gluten, and so is no longer regarded as a GMO. By March, Greenpeace protests led the Swiss authorities to impound the shipments and return them to the Netherlands, their EU port of entry.

Meanwhile, the European Commission faced a dilemma – either accept the exports and suffer an internal legitimacy crisis, or restrict them and provoke a EU-US trade conflict. Eventually the European Commission ordered that all US maize shipments be inspected for any products which lack EU approval. It has been asked to set 'purity' standards for 'gm contamination' of shipments.

Unblocking trade, sharing responsibility

Beyond the first Bt maize, from Ciba/Novartis, additional ones were delayed by national disagreements in the 90/220 procedure. Three of these were contained in US maize shipments. As a 'high priority', in December 1997 DGXI sent the Scientific Committee for Plants those three dossiers (Bt maize from Monsanto, Novartis and AgrEvo) along with one for an AgrEvo oilseed rape.

DGXI was reluctant to initiate this procedure but had little choice. France refused to vote on the products unless advice was obtained from the SCP – even though France was the national rapporteur for the Monsanto dossier. This referral was also requested by DGVI and DGXXIV, aware that the Commission overall would face any criticism for a decision to grant approval (DGXXIV, interview, 04.03.98).

At the laboratory stage, these new products had been designed to avoid the disputes surrounding the original Ciba/Novartis maize – and perhaps to replace that product in US exports. None contained an ampicillin-resistance gene, unless a significant part was verifiably missing, so that the gene could not be reproduced. None of these products contain a microbial-derived promoter, so that the gene could not be expressed in microbes. In these

ways, the applications avoided some features which had proven controversial and thus helped scientific advisors to recommend approval.

Cultivation was requested for only one of these products, Monsanto's Bt maize (C/F/95/12-02). As regards non-target harm, 'the SCP noted that we have little relevant data; ultimately the SCP saw no risk problem for beneficial insects but would have liked to have more data to substantiate this claim' (interview, DGXXIV, 04.03.98; see also Section 3.2.1). The SCP also evaluated the resistance-management plan as 'adequate to delay resistance', while remaining silent on whether or not insect resistance would be an 'adverse effect'.

The SCP (1998a) gave all the products a favourable opinion on 10 February. Then the Article 21 Committee voted to approve them on 18th March. France reportedly abstained on the Monsanto maize, even though France originally had been the rapporteur favouring market approval. The Environment Committee of the European Parliament issued a negative opinion on those products, on grounds of inadequate labelling, given that Regulation 1813/97 Article 3 had not been implemented.

Nevertheless the European Commission approved all four products; more precisely, this decision authorizes the rapporteur to issue a consent (EC, 1998a). France was the rapporteur for the two products approved for cultivation purposes. There remained political uncertainty about when France would sign the authorization, though it eventually signed Monsanto's.

5.3 Monsanto soybean

Products containing gm soybeans have an uncertain market – depending upon whether consumers trust their national labelling regime, accept safety claims for gm products, and/or buy 'non-gm' food instead. The Monsanto glyphosate-tolerant soybean (C/GB/94/M3/1) has become a test case for the type of labelling necessary in order to stabilize a food market wider than gm products alone (see Section 4.1). Given consumer protest and suspicion about gm soya, inadequate labelling has jeopardized a market for all soya-based products. Under such pressure, eventually the European food industry decided to use a 'gm' label for all soya-based ingredients from countries where gm soya is cultivated, unless the source can be certified as non-gm. However, reliable labelling has been implemented in only some countries.

These developments have opened up an opportunity for a niche market for 'Identity-Preserved' soya products, usually called non-gm, though generally without any negative labelling. Sometimes they are also called 'gm-free', though the latter term is misleading because some contamination is unavoidable. This could be understood as a 'grey market', in the sense that non-gm soya is widely exchanged and used in order to avoid the legal requirement for a 'gm' label. Although gm soya faces no formal trade barriers, it does face an informal boycott, amidst a growing market for non-gm soya.

5.4 Herbicide-tolerant oilseed rape

For herbicide-tolerant oilseed rape, full commercialization has been delayed or deterred by regulatory procedures. No such crop had obtained EU approval for cultivation by the end of 1998. Moreover, glufosinate may not be approved for use on OSR in some member states,

e.g. Denmark, thus deterring sales of any transgenic crop whose main advantage is glufosinate-tolerance (see Section 6.3). Thus an EU-wide market remains in doubt.

For the first PGS glufosinate-tolerant oilseed rape (C/GB/94/M1/1), the consent ‘only covers the notified use of the product for growing for obtaining seed, but does not extend to the use for human food or animal feed....’ (EC, 1996a). This restriction precluded seed certification in the National List. Later the same product was submitted for all commercial uses to France, which recommended EU approval (C/F/95/05-01). The proposal gained a qualified majority in December 1996 and was approved by the European Commission in June 1997 (EC, 1997c). Final EU approval depends upon the national rapporteur signing the Part C authorization – normally a routine matter.

However, in November 1997 France announced its refusal to sign, on grounds that herbicide-tolerant oilseed rape warrants further safety evaluation: ‘No authorization for commercial use of plant species other than maize (notably rapeseed and beets) will be given until scientific studies show there is no risk to the environment and until a public debate has been conducted.’ In a further statement in December 1997, the government declared that it would not approve any more products which contain an antibiotic-resistance gene; yet it asserted the safety of the most controversial product, the ampicillin-resistant Ciba maize. In July 1998 France announced a two-year moratorium on commercial cultivation of gm rapeseed.

In blocking the PGS oilseed rape, the French government responded to public protest. Environmental NGOs there had been advocating a moratorium on the commercial use of all transgenic crops; many French scientists signed a petition along these lines. French scientists published stronger evidence that oilseed rape produces viable hybrids with weedy relatives (Chevre et al., 1997). This evidence strengthened arguments that gene flow could create glufosinate-tolerant weeds, though France had regarded such an effect as *not* environmental harm when initially supporting EU-level approval under 90/220.

Another candidate lost for cultivation was an AgroEvo glufosinate-tolerant OSR (C/GB/95/M5/1). After the original dossier requested authorization for all uses, it met objections from member states. For example, the risk assessment was criticized for assuming that volunteers could not survive the winter; in response, Italy and Spain requested additional data to verify that assumption for their environments. By agreement with the applicant, the rapporteur (UK) later changed the proposal to request authorization only for food-processing purposes. Consequently, the DG XXIV-based SCP did not need to evaluate environmental uncertainties which had proven most controversial, especially the spread of herbicide-tolerance genes. The revised dossier obtained a favourable opinion from the SCP (1998a) and then a qualified majority in March (EC, 1998a).

Further opportunities arise with another marketing application from PGS (C/BE/96/01) and from AgrEvo (C/DE/96/5). The risk assessments basically repeat the argument which prevailed in 1994-95, when the CAs discussed the first PGS OSR (C/GB/94/M1/1): namely, that spread of the herbicide-tolerance gene would be acceptable because other herbicides would be available to control weeds. However, such an argument may be rejected by even more member states than before.

6 LINKS TO PESTICIDE REGULATION

Herbicide-tolerant crops (HTCs) pose a difficult case for precaution and for regulatory boundaries, for several reasons. Broad-spectrum herbicides could damage wildlife habitats. Herbicide-tolerance genes could be spread inadvertently from the original oilseed rape to other varieties or to weedy *Brassicas*, thus jeopardizing use of the herbicide. There is a predictive uncertainty about the modes of product use, the overall environmental effects, and the future scope of pesticide regulation for such effects. All these uncertainties have been cited to declare HTCs unacceptable, or to impose more stringent criteria for market approval, or to demand market-stage monitoring.

Also for the above reasons, HTCs present difficult boundary issues – especially between Directive 90/220 and the pesticide directive 91/414 (EEC, 1991). More member states have raised these issues within crop regulation, by default of clear criteria within pesticide regulation. This regulatory boundary was discussed by DGVI and DGXI, which then issued a 1995 document declaring that all such matters lie with DGVI under 91/414 (see Section 1.3).

Afterwards DGVI shifted the issue to its Scientific Committee on Pesticides (SCP), which went no further. The SCP was later reconstituted by DG XXIV as the Scientific Committee on Plants. Ever since DGXI (1995) declared that the herbicide implications lay with DGVI, the two DGs have not formally met to discuss the boundary issues. Both DGs presume that the pre-existing pesticide law is adequate to manage any problems from HTCs: ‘Herbicide-tolerant crops present no new situation relative to past approvals of pesticides. Partly for this reason, we did not feel the need to be involved in the regulation of GMOs, e.g. herbicide-tolerant crops under 90/220’ (interview, DGVI, 20.01.98).

Aided by its advisory committee, DGVI has limited its role to evaluating pesticidal substances. The Scientific Committee on Pesticides did not address the issue of herbicide-tolerant crops (interview, DGVI, 20.01.98). Its successor, the Scientific Committee on Plants, started to do so on a case-by-case basis after receiving specific dossiers under 90/220 from DGXI. Thus by default an expert committee has the implicit task of policy-making.

Under Directive 91/414 the EU has had a limited role in harmonizing safety judgements. At present, each member state decides on the conditions for any pesticide to be used. The Directive leaves much room for national discretion in justifying why a particular use is permitted or prohibited.

All pesticides approved before 1993 are undergoing a review. After a rapporteur presents recommendations to the Standing Committee on Plant Health (SCPH), the EU will decide whether to include each ‘active substance’ in Annex I. Glyphosate was assigned to Germany, whose Agriculture Ministry will report in 1999. Glufosinate was assigned to DGVI itself as rapporteur.

If an active substance does gain EU approval for inclusion in the Annex, then it could either be ‘unrestricted’ (for all uses) or ‘restricted’, specifying particular uses or conditions. Subject to any such restrictions, decisions on specific product uses will remain at national level. However: ‘If an unrestricted listing is made in Annex I, under Article 10 on mutual recognition it would be possible to seek a market use in those countries which do not accept

a registration. For this reason, worst-case scenarios have been used in the risk assessment and very stringent conditions on use have been proposed to prevent such uses being listed' (Tooby, 1997: 755). Conversely, perhaps anticipating that an active substance will gain unrestricted listing, GMO regulators have an incentive to establish criteria within Directive 90/220, rather than defer all the herbicide effects to 91/414.

6.1 Herbicide-resistance

The prospect of widespread resistance has become an issue for herbicides in general. Directive 91/414 mentioned herbicide-resistance management and was later amended to specify the duty: ‘Where there is evidence or information to suggest that in commercial use the development of resistance is likely, applicants have to provide a management strategy designed to minimize the likelihood of resistance or cross-resistance’ (EC, 1993). However, this duty applies only to pesticides which are listed in Annex I; broad-spectrum herbicides may well be sprayed on HTC before they are listed there.

Until then, implementation remains the responsibility of each member state, without any EU-level resistance-management strategy or obligation. Consequently, Directive 90/220 comes under pressure to fill the EU-level gap for HTCs (see Section 5.4). At the same time, national pesticide authorities come under pressure to do so.

6.2 Secondary metabolites and residue limits

Under the pesticide directive 91/414, the EU set a Maximum residue Limit of 20 mg kg⁻¹ glyphosate on soy-beans – an increase from the previous MRL of 0.1 mg kg⁻¹. The higher limit applies equally to gm and non-gm soya. It came into force in 1997.

For HTCs which are proposed as food sources, member states have disagreed about whether the 90/220 risk assessment must evaluate herbicide usage, secondary metabolites, residues, etc. Some member states have argued that it must do so, especially for herbicide-tolerant crops which are imported from third countries (e.g. the USA), because the herbicide sprays would be applied there rather than in the EU. ‘Some CAs argue that secondary metabolites should be considered under 90/220, though some of these CAs are now beginning to accept that such effects would be adequately considered under 91/414 – which is the position of the Commission’ (DGXI, interview, 20.01.98).

When the DG XXIV-based SCP evaluated dossiers for such crops in early 1998, it requested data on pesticide effects, as a prerequisite for giving a favourable opinion. The companies then supplied extra evidence via DGXI. The SCP noted that the proportion of metabolites was different for the HTCs than for the conventional plants, though the types were similar. By broadening the precautionary scope of the 90/220 procedure, the SCP may accommodate some criticisms of the original risk assessment.

Those products became a test case for regulatory gaps and boundaries.

“DGXXIV and the SCP felt that the committee evaluation must include imported maize which has been sprayed elsewhere. The health effects would not be considered under the Novel Food Regulation, nor under 91/414, because glufosinate is not yet approved for spraying on these crops in any EU member state. In Germany, some companies had already supplied pesticide data to the BGVV, the food safety agency of the Health Ministry, because the data was required in order to obtain food approval under the pesticide-residue regulations there. But companies hadn’t submitted this data to all member states (interview, DGXXIV, 04.03.98).”

Thus the broader assessment in one member state provided a potential model for an EU-wide evaluation.

6.3 Herbicide extension

If an HTC is marketed on the basis of its herbicide tolerance, then its sales depend upon extending approval of the relevant herbicide for spraying on the new crop. Such decisions rest with each member state, under the pesticide directive 91/414. 'If a member state grants such approval, then it must show that the new use satisfies the criteria of 91/414, though this could be done in divergent ways across the EU', according to a DGVI official (20.01.98). Some member states are unlikely to grant such approval, e.g. because they seek to discourage any herbicide usage, even if the new one is relatively less harmful. Denmark has already made this explicit; it imposes more stringent standards on residues, partly because groundwater is used as drinking water.

For HTCs, the relevant herbicides are glyphosate and glufosinate. All member states have approved them for some use or another, though not for the same uses in all member states. In 1997 AgrEvo requested approval for farmers to spray glufosinate on its glufosinate-tolerant oilseed rape. Monsanto has submitted a similar request for its glyphosate-tolerant oilseed rape in most northern European countries. Unlike the GMOs procedure under 90/220, pesticide regulation generally does not disclose such applications, nor disclose the test data after announcing a decision.

REFERENCES

- ACNFP (1997) *ACNFP Annual Report 1996*.
- ACNFP (1998) *ACNFP Annual Report 1997*.
- Avebe (1997) Apriori and Apropos: genetically modified potatoes, notification C/NL/96/10.
- BEP CAG (1997) Biotechnology and the European Public Concerted Action Group, 'Europe ambivalent on biotechnology', *Nature* 387: 845-47.
- BEUC (1997) Comments on the Commission Green Paper on the General Principles of Food Law in the EU, COM (97) 176 [+ numerous short documents]. Brussels: Bureau Européen des Unions des Consommateurs.
- Birch, N. et al. (1997) 'Interactions between plant resistance genes, pest aphid populations and beneficial aphid predators', in *SCRI Annual Report 1996-97*, pp.68-72, Dundee: Scottish Crop Research Institute.
- Bowe, D. (1998) Draft report on the proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the Deliberate Release to the Environment of Genetically Modified Organisms. Brussels: Committee on the Environment, Public Health and Consumer Protection, European Parliament, 5 November.
- BSPB et al. (1998) Guidelines for Growing Newly Developed Herbicide Tolerant Crops, June.
- Carr, S. and Levidow, L. (1997) 'How biotechnology regulation separates ethics from risk', *Outlook on Agriculture* 26(3): 145-50.
- CEC (1996) Report on the Review of Directive 90/220/EEC in the Context of the Commission's Communication on 'Biotechnology and the White Paper'.
- CEC (1997) Amended proposal for a Council Directive amending Directive 70/457 on the common catalogue of varieties of agricultural plants [EEC, 1970], pursuant to Article 189a(2).
- CEC (1998) Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC, on the Deliberate Release into the Environment of Genetically Modified Organisms, *Official Journal of the European Communities*, C 139, 4 May: 1-23.
- Chevre, A-M et al. (1997) 'Gene flow from transgenic crops', *Nature* 389: 924.
- CI (1996) *Genetic Engineering & Food Safety: The Consumer Interests*. Consumers International (fax +44-171-354 0607, email gpcu@consint.org.uk, consint@consint.org).
- CI (1997) *Genetically Modified Foods: Magic Solution or Hidden Menace?*, Briefing Paper no.8, November.
- Ciba-Geigy (1994) Application for placing on the market a genetically modified plant (maize protecting itself against corn borers), according to Part C of Directive 90/220/EC and Commission Decision 92/146, notification C/F/94/11-03, typescript; placed on DoE public register, March 1995.
- Cooper I and Raybould AF (1997) 'Transgenes for stress tolerance: consequences for weed evolution', *British Crop Protection Conference – Weeds*, pp.265-72. Farnham, Surrey: British Crop Protection Council.
- Dale, P.J. and Scheffler, J.A. (1996) 'Gene dispersal from transgenic crops', in E.R. Schmidt & T. Hankeln, eds, *Transgenic Organisms and Biosafety*, pp.85-93, Berlin: Springer-Verlag.
- DETR (1998) 'Government Announces Fuller Evaluations of Growing Genetically Modified Crops', 21 October press release.

- de Vriend, H. (1998) 'Labelling GMOs and Methods of Detection: the certificate of origin option', presented at 'Genie Genetique' conference, European Parliament, 5-6 March, typescript.
- DGIII (1997a) Interpretive Document on the Interplay between Regulation 258/97 on Novel Foods and Novel Food Ingredients and Directive 90/220 on the Deliberate Release into the Environment of Genetically Modified Organisms, document III/5127/97.
- DGIII (1997b) Draft Commission Regulation concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms..., document III/5268/97, April [to replace EC, 1997e; was finalized as EC, 1998b].
- DG XI (1995) Draft document on the Assessment of the Environmental Impact of Herbicide Use Linked to the Placing on the Market of Genetically Modified Herbicide-Tolerant Plants, Document XI/763/95, Revision 1 (undated)
- DG XI (1996) A Framework Approach to Environmental Risk Assessment for the Release of Genetically Modified Organisms, Doc XI/087/96, Revision 4 and Revision 5 [January 1997].
- DG XI (1997) Working document on the Revision of Directive 90/220, December.
- DG XI (1998) Draft Protocol for Monitoring of ECB Resistance to Bt Maize, XI/157/98, 30 March.
- DG XI EGBtIRM (1998a) Expert Group on Bt IRM, 'Working document on monitoring of ECB resistance to transgenic Bt-maize', January, typescript [for *Ostrinia nubilalis*, the main pest in France].
- DGXI EGBtIRM (1998b) Expert Group on Bt IRM, 'Draft protocol on monitoring of Mediterranean corn stalk borer resistance to transgenic Bt-maize', March [for *Sesamia nonagrioides*, aka pink stem borer, a pest prevalent in Greece, Spain and southern France].
- DoE/ACRE (1993) Guidance note no.1: *The Regulation & Control of the Deliberate Release of Genetically Modified Organisms*.
- EEC (1970) Directive du Conseil 70/457/CEE concernant le catalogue commun des variétés des espèces de plantes agricoles, *J.O. des Communautés européennes*, L225, 12 octobre: 1-6.
- EEC (1990) Council Directive 90/220 on the Deliberate Release to the Environment of Genetically Modified Organisms, *Official Journal of the European Communities*, L 117, 8 May: 15-27.
- EEC (1991) Council Directive 91/414 Concerning the Placing of Plant Protection Products on the Market, *Official Journal of the European Communities*, L 230, 19 August: 1-32.
- EC (1993) Directive 93/71 amending Directive 91/414, *Official Journal of the European Communities*, L 221, 31 August: 27.
- EC (1996a) Commission Decision 96/158/EC of 6 February 1996 concerning the placing on the market of a product consisting of a GMO, hybrid herbicide-tolerant swede-rape seeds, *Official Journal of the European Communities*, L 37, 15 February: 30-31. [PGS dossier C/GB/94/M1/1]
- EC (1996b) Commission Decision 96/281/EC of 3 April 1996 concerning the placing on the market of genetically modified soybeans..., *Official Journal of the European Communities*, L 107, 30 April: 10. [Monsanto dossier C/GB/94/M3/1]
- EC (1997a) Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified maize, *Official Journal of the European Communities*, L 31, 1 February: 69-70. [Ciba-Geigy/Novartis dossier C/F/94/11-3]

- EC (1997b) Regulation 97/258/EC of 27 January 1997 concerning novel foods and novel food ingredients, *Official Journal of the European Communities*, L 43, 14 February: 1-6.
- EC (1997c) Commission decision concerning the placing on the market of a genetically modified oilseed rape (*B.napus L.oleifera* Metzg. MS1, RF1), in conformity with Council Directive 90/220/EEC, *Official Journal of the European Communities*, 6 June, L 164: 38-39. [PGS dossier C/F/95/05-01A]
- EC (1997d) Commission Directive 97/35/EC of 18 June adapting to technical progress for the second time Council Directive 90/220/EEC, *Official Journal of the European Communities*, 27 June, L 169: 72-73.
- EC (1997e) Commission Regulation 1813/97/EC of 19 September 1997 concerning the compulsory indication on the labelling of certain foodstuffs produced from GMOs....[soya and maize], *Official Journal of the European Communities*, L 257, 20 September: 7-8.
- EC (1998a) Commission decision concerning the placing on the market of a genetically modified... [four products], in conformity with Council Directive 90/220/EEC, *Official Journal of the European Communities*, 5 May, L 131: 26-33.
- EC (1998b) Council Regulation 1139/98 concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified organisms..., *Official Journal of the European Communities*, 3 June, L 159: 4 [replaces EC, 1997e].
- ENDS (1999) 'Overhaul of EC regime for regulating GMOs', *ENDS Report* 294:50-52
- EuropaBio (1997) *European BioNews*, June (email mail@europa-bio@be).
- FoEE (1996-98) various *Mailouts*, Brussels: Friends of the Earth Europe Biotechnology Programme.
- France (1998) Arrêté du 5 fevrier portant modification du Catalogue officiel des espèces et variétés de plantes cultivées en France (semences de maïs), *Journal Officiel* 33: 2037, 8 February.
- Greenpeace (1997) *From BSE to GMOs: Science, Uncertainty and the Precautionary Principle* (<http://www.greenpeace.org.uk>).
- Grove-White, R. et al. (1997) *Uncertain World: Genetically Modified Organisms, Food and Public Attitudes in Britain*. Lancaster: CSEC.
- Hilbeck, A. et al. (1998) 'Effects of transgenic *Bt* corn-fed prey on mortality and development time of immature *Chrysoperla carnea*', *Environmental Entomology* 27(2): 480-87.
- Huggett, A.C. and Conzelmann, C. (1997) 'EU Regulation on novel foods: consequences for the food industry', *Trends in Food Science & Technology* 8: 133-39.
- INRA (1998) *Organismes Génétiquement Modifiés à l'INRA : environnement, agriculture et alimentation*. Institut National de la Recherche Agronomique.
- Jones, D. ed. (1994) *The Biosafety Results of Field Tests of Genetically Modified Organisms*, Proceedings of the 3rd International Symposium, Monterey.
- Levidow, L. and Carr, S. (1997) 'How biotechnology regulation sets a risk/ethics boundary', *Agriculture and Human Values* 14 (1): 27-41.
- Levidow, L., Carr, S., von Schomberg, R., Wiold, D. (1996) 'Regulating agricultural biotechnology in Europe: harmonization difficulties, opportunities, dilemmas', *Science & Public Policy* 23 (3): 135-57.
- Levidow, L., Carr, S., Wiold, D. (1999) 'Market-stage precautions: managing regulatory disharmonies for transgenic crops in Europe', proceedings, *5th International Symposium on The Biosafety Results of Field Tests of Genetically Modified Plants and Microorganisms*, Braunschweig (6-10 September 1998), forthcoming; also

- AgBiotechNet* 1:1-8, forthcoming, <http://agbio.cabweb.org/reviews/April1999/html/Levidow.htm>.
- Lipp, M. (1998) 'Detection of GMOs in food: current approaches', conference proceedings, 'Genetically Modified Foods: From Seeds to Supermarket', London, 2-3 December.
- Meikle, J. (1998) 'Obey the rules, ministers told', *The Guardian* 22 June.
- Mikkelsen, T.R. et al. (1996) 'The risk of crop transgene spread', *Nature* 380: 31.
- Monsanto (1995) Application for placing on the market a genetically modified plant (Insect-Protected maize line MON 810 and seeds of any progeny), according to Part C of Directive 90/220/EC, notification C/F/95/12-02, typescript; placed on DoE public register, June 1996.
- Novartis (1998) *Novartis B-11 Maize*.
- Pham-Delègue, M. (1996) 'Environmental Impact of Transgenic Plants on Beneficial Insects', proposal submitted for DGXII funding, 1996-99.
- Pham-Delègue, Minh-Ha and Jouanin, L. (1997) 'L'impact sur l'abeille domestique', *Sciences de la Vie*, Avril: 36-37, CNRS.
- Reboud, X., Gasquez, J., Darmency, H. (1998) 'A multisite-cooperative research programme on risk assessment of transgenic crops', conference on Risks and Prospects of Transgenic Plants, Bern, 29-31 January.
- SCAN (1996) 'Report of the Scientific Committee on Animal Nutrition on the safety for animals of certain genetically modified maize lines notified by Ciba-Geigy', DGVI, 13 December.
- SCF (1996) Scientific Committee on Food, 'Opinion on the potential for adverse health effects from the consumption of genetically modified maize', DGIII, 13 December.
- SCP (1996) 'Opinion of the Scientific Committee on Pesticides on the genetically modified maize lines notified by Ciba-Geigy', DGVI, 13 December [notification from Ciba-Geigy/Novartis, C/F/94/11-3].
- SCP (1998a) 'Opinion of the Scientific Committee on Plants Regarding...[four notifications]': Monsanto's MON10 Bt maize (notification C/F/95/12-02); Novartis' [formerly Northrup King] Bt-11 glufosinate-tolerant maize, C/GB/96/M4/1; AgroEvo's T25 Bt, glufosinate-tolerant maize, C/F/95/12/07; AgroEvo's glufosinate-tolerant oilseed rape (C/GB/95/M5/1), 10 February. Full texts available at <http://europa.eu.int/en/comm/dg24>.
- SCP (1998b) 'Opinion of the Scientific Committee on Plants Regarding...[two notifications]': PGS' MS8xRF3 glufosinate-tolerant hybrid oilseed rape (C/BE/96/01) and Pioneer's MON9 Bt, glyphosate-tolerant maize (notification C/F/95/12-01/B), 19 May.
- SCP (1998c) 'Opinion of the Scientific Committee on Plants regarding.... glufosinate-tolerant swede rape, transformation event GS 40/90 notified by the AgrEvo Company (notification C/DE/96/5)', 14 July.
- Schenkelaars, P. (1997) 'Dutch labelling rules on foodstuffs containing soy protein and/or soy flour', *FoEE Mailout*, 15 June.
- Scott, S.E. and Wilkinson, M.J. (1998) 'Transgene risk is low', *Nature* 393: 320.
- Spain (1998) Ministerio de Agricultura, 'Orden de 23 de marzo por la que se dispone la inscripción de variedades de maíz en el Registro de Variedades Comerciales' [registration of two varieties based on Ciba's Bt maize], 26 marzo, *Boletín Oficial del Estado* 73: 10193-95, 10289-90.
- Squire, G.R. et al. (1997) 'A model for the impact of herbicide tolerance on the performance of oilseed rape as a volunteer weed', *Annals of Applied Biology* 131: 315-38.

- Sweet J et al. (1997) 'The impact of releases of genetically modified herbicide-tolerant oilseed rape', *British Crop Protection Conference – Weeds*, pp.291-301. Farnham, Surrey: British Crop Protection Council.
- Tepfer, M. and Balazs, E. (1997) 'Concluding remarks and recommendations', in Tepfer and Balazs, eds, *Virus-resistant Transgenic Plants: Potential Ecological Impact*, pp.121024. Versailles: INRA, Heidelberg: Springer-Verlag.
- Todt, O. & Lujan, J. (1997) 'Labelling of novel foods and public debate', *Science & Public Policy* 24 (5): 319-26.
- Tooby, T. (1997) 'Directive 91/414/EEC: recent practical experience and a look to the future', *British Crop Protection Conference – Weeds*, pp.747-56. Farnham, Surrey: British Crop Protection Council.
- Urech, P.A. (1997) 'Crop protection between the needs of market and regulation', in *British Crop Protection Conference – Weeds*, pp.427-34. Farnham, Surrey: British Crop Protection Council.
- Vernet, E. (1998) 'France: INRA supports the arguments of environmentalists about GMOs' [excerpts INRA, 1998], *FoEE Mailout* 4(4): 2-3, 15 June. Brussels: Friends of the Earth Europe Biotechnology Programme.
- von Schomberg, R. (1998) 'An Appraisal of the Working in Practice of Directive 90/220 on the Deliberate Release of Genetically Modified Organisms: Final Study', STOA, PE 166.953, January.
- Winkler, R. (1998) 'Legal Aspects at the EC Level', report for 'Safety Regulation of Transgenic Crops: Completing the Internal Market?', coordinated by the Open University. Wynne, B. (1998) 'Does Europe Have to be Reductionist?', March, SPSG/ESRC conference

APPENDICES

Appendix I Institutional Actors

	EU	(trans-DGs)
	S-G: EGE	DGXXIV: SSC
Crop regulation	DGXI (90/220)	
Advisory committee	Article 21,CEN	
Risk-assessment research	DGXII	
Food regulation	DGIII (258/97)	
Advisory committee	StCtteeFood	SCF
Pesticide regulation	DGVI (91/414),SCPH	SCP, SCAN
National List certification	DGVI (70/457), NIAB, CTPS, BS	
Industry: biotechnology	EuropaBio ¹	
Industry: crops	GIBiP ¹ , PIP	
Industry: food	CIAA, Fediol, EuroCommerce, GAFTA	
Industry: pesticides	ECPA, CEFIC, EPPO	
NGOs: environmental	FoEE, GP, CPE	
NGOs: food	BEUC, EuroCoop, ECF	

¹. Also regulatory applicants, e.g. AgroEvo (including PGS), Nickerson Seeds/Limagrain.

Appendix II Abbreviations

ACNFP	Advisory Committee on Novel Foods and Processes
ACP	Advisory Committee on Pesticides
ACRE (UK)	Advisory Committee on Releases to the Environment
Article 21	Committee of CAs for 90/220
BAA	British Agrochemicals Association
BEUC	Bureau Européen des Unions de Consommateurs
BIA	Bio-Industry Association (emphasizes pharmaceuticals)

BRC	British Retail Consortium (UK affiliate of EuroCommerce)
BSPB	British Society of Plant Breeders
BS	Bundessortenamt, Hannover (Sorten Schutzgesetz)
CA	Competent Authority for DRD 90/220
CBI	Confederation of British Industry (has Biotech Working Party)
CEC	Commission of the European Communities
CEFIC	Conseil Européen des Federations de l'Industrie Chimique, Brussels
CEN	Comité Européen de Normalisation, Paris
CIAA	Confederation de l'Industries Agro-Alimentaires
Co-op	Co-operative Union (UK affiliate of EuroCoop)
CTPS	Comité Technique Permanent de Sélection
CPE	Confederation Paysanne Européen
DGIII	Directorate-General for Industry and Internal Market, CEC; handles NFR
DGVI	Directorate-General for Agriculture
DGXI	Directorate-General for Environment, Nuclear Safety and Civil Protection
DGXII	Directorate-General for Science, Technology and Research
DGXXIV	Directorate-General for Consumer Policy and Consumer Health
DETR	Dept of the Environment, Transport and Regions, London (formerly DoE)
ECF	European Confederation of Food Workers, part of IUF
ECPA	European Crop Protection Association
EGE	European Group on Ethics in Science and New Technologies
EPPO	European Plant Protection Organization
EuroCommerce	'Retail, Wholesalers and International Trade Representative to the EU'
EuroCoop	[consumer cooperatives]
EuropaBio	European Association of Bio-Industries

FAC	Food Advisory Committee (labelling issues)
FDF	Food and Drink Federation (UK affiliate of CIAA)
Fediol	Federation of Seed Crushers and Oil Processors
FoE	Friends of the Earth (UK)
FoEE	Friends of the Earth Europe, especially Bund, its German affiliate
GAFTA	Grain and Food Trade Association (trans-Atlantic, though based in London)
GIBiP	Green Industry Biotechnology Platform (transgenic crops)
GA	Green Alliance
GEN	Genetic Engineering Network (direct action groups)
GF	Genetics Forum
GP	Greenpeace
IGD	Institute of Grocery Distribution
IUF	International Union of Food & Agricultural Workers
JICPSR	John Innes Centre for Plant Science Research
JRC	Joint Research Centre, Ispra
MAFF	Ministry of Agriculture, Fisheries and Food; Pesticide Safety Division (PSD), Plant Varieties and Seeds (PVS)
NCC	National Farmers Union
NIAB	National Institute of Agricultural Botany
PIP	Plant Industrial Platform
RAAW	Rural Agricultural and Allied Workers, T&GWU
SAFE Alliance	Sustainable Agriculture, Food and Environment
SCAN	Scientific Committee on Animal Nutrition, formerly in DGVI
SCF	Scientific Committee on Food, formerly in DGIII)
StCtteeFood	Standing Committee for Foodstuffs [legislative advice], DGIII
SCP	Scientific Committee on Plants (formerly ‘on Pesticides’), formerly in DGVI

SCPH	Standing Cttee on Plant Health [legislative advice], DGVI
SCRI	Scottish Crop Research Institute
S-G	Secretariat-General, European Commission
SSC	Scientific Steering Committee [coordination of scientific advisory committees]
UKASTA	UK Agricultural Supply Trade Association