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Precautionary Expertise for GM Crops (PEG)

EU Workshop Report

**Quality of Life and Management of Living Resources
Key Action 111-13: socio-economic studies of life sciences
Project no QLRT-2001-00034**

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October 2003

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1 Introduction

This policy workshop was organised as part of the research project, 'Precautionary Expertise for GM Crops' (PEG), funded by the European Commission. The project includes research partners in seven member states (Austria, Denmark, France, Germany, the Netherlands, Spain and UK) and is co-ordinated by the Open University (UK).

For regulating GM crops and their food uses, the precautionary principle has been widely accepted in Europe, but its meaning can be contentious. Indeed, it can have diverse meanings. The PEG project is analysing how current European practices – regulatory measures, expert bodies and stakeholder roles – compare with different accounts of the precautionary principle. How do these accounts inform policies and practices regarding GM crops? And how do they facilitate (or impede) efforts to mediate conflicts?

From the findings of the research, we will suggest:

- how to clarify EU guidelines, so that they better reflect national regulatory measures, and so that decision-making procedures can be publicly accountable and scientifically defensible
- how expert bodies could better accommodate public-scientific controversy within their judgements
- how national practices could contribute to an EU-level precautionary expertise
- how to enhance policy learning about these issues among users of the research findings.

To achieve these aims, the project has involved stakeholders and policy-makers at an early stage of the research, in order to ensure that it is policy-relevant and incorporates emerging issues. EU-level advisory panel meetings were held in Brussels in March and September 2002, to consult on the research plan and preliminary results. Advisors were also consulted about how best to structure scenario-analysis exercises for the policy workshops.

These workshops were held by national partners in their countries in early 2003. Drawing upon those experiences, the project coordinator organised an EU-level workshop in July 2003. This report discusses the context, background, method, results and implications of that workshop.

2 EU context

For the EU and national workshops, an important reference point was the *de facto* unofficial moratorium. In the EU Environment Council, many member states had declined to consider further requests for commercial authorisation since 1999. According to declarations which they signed then, the EU must first adopt measures to ensure full traceability and labelling of GM crops across the agro-food chain, as well as more transparent risk-assessment procedures, based on precaution. Some member states were imposing restrictions on GM products which had already gained EU approval. Moreover, since the late 1990s most large food retail chains (and some processors) had largely blocked GM grain as an ingredient in their own-label products, though GM soya and maize were being widely used as animal feed. In response to these pressures, the European Commission included more stringent measures when revising the Deliberate Release Directive; it also prepared entirely new legislation on traceability and labelling of GM food and feed.

By 2003 there were signs that the moratorium would be lifted in the near future. The week before our EU workshop, draft regulations on traceability and labelling of GM food had their second reading at the European Parliament. If differences could be resolved between the Parliament and the common position (of the Commission and Council), then the regulations could come into force later in that year, thus satisfying the 1999 demands of

the Council. Given widespread demands for measures to ensure co-existence of GM and non-GM crops, this issue was being addressed by proposals from the Commission and member states.

Applications for commercial authorisation of additional GM crops were now going through the EU-wide decision procedure under the revised Deliberate Release Directive. Companies had updated their marketing applications to comply with its new requirements. By early 2003 these applications were circulating for comment among national Competent Authorities; summaries were available to the general public on a website of the European Commission. However, uncertainty continued about how member states would respond to these applications, amid continuing public concerns about GM products.

Meanwhile in May 2003 the USA led a challenge to the EU under the WTO's disputes procedure, complaining about the EC's moratorium which blocked approval of any additional GM products, as well as the EC's failure to reverse national bans on some biotech products already approved by the EC. This WTO challenge was nominally aimed at ending the *de facto* moratorium but could have the opposite effect, e.g. provoking European resentment which might cause further delays to commercial approval. (For more details on the EU context, see Appendices III and IV.)

3 National workshops as background

During early 2003, PEG research partners held national policy workshops to illuminate issues relevant to the regulation of GM crops, especially precaution. Most were run as scenario-analysis exercises: the organisers and/or the participants formulated a set of plausible futures, as a basis to discuss ideas about possible causes and consequences for each future. The aim was not to predict the future, but rather to identify underlying dynamics and issues which warrant attention. The exercises presumed some national scope for influencing GM policy and decision-making, in the context of EU and international developments. That basic format was adapted by each national partner in ways appropriate for attracting relevant individuals involved in the policy process around GM crops. (The national workshop reports are available on the website of the Biotechnology Policy Group, Open University, <http://www-tec.open.ac.uk/cts/peg/index.htm>)

3.1 Scenario-analysis exercises in general

Scenario analysis has a long history. Its development as an aid to strategic decision making is generally credited to the Royal Dutch/Shell Group, and in particular to Pierre Wack who directed Shell's planning department during the 1970s (van der Heijden, 1996; Wack, 1985). Scenario analysis is especially useful for structuring discussions about uncertainties, whose potential impact is otherwise often ignored because they are regarded as too vague to consider. Forecasting generally assumes that underlying trends will continue in a more or less linear way; by contrast, scenarios can help decision makers prepare for the surprises and discontinuities that inevitably occur. Compared with forecasting, scenario analysis is concerned less with predicting outcomes than with understanding the forces or drivers that lead to particular outcomes (Wack, 1985).

Scenario analysis can serve a number of purposes. It can help users to:

- bring unspoken assumptions into the open
- incorporate creativity into rational analysis
- anticipate and understand risks
- explore and distinguish between predictable forces and uncertainties
- organise apparently unrelated social, technological, economic, ecological and political information into a framework for decisions and judgements
- question conventional wisdom
- uncover new strategic options, and

- learn from each other's experience and perceptions, so as to
- reconsider and revise their assumptions about the world.

Since the last two purposes are the most significant, the process is as important as the specific outcomes.

Many accounts and guidelines of scenario analysis refer to examples within companies. In general these have a clear strategic vision; there are relatively clear boundaries between the driving forces which lie within and outside the company's control. Guidelines have to be adapted if they are to be used for exploring government policy options, where various stakeholders seek to influence the outcomes. In general terms, the scenario is like a theatre set and opening scene in a play. It serves as a stimulus for imagining how the plot might unfold as a result of the interactions of the various characters.

3.2 Scenarios on prospects for commercialisation

For their workshop structure, some research partners (UK, NL, ES) decided beforehand to use scenarios which focused on prospects for commercialising GM crops. Commercialisation was chosen in order to focus discussion on key policy decisions, rather than assume that precaution would be a central issue. Organisers formulated the following three scenarios:

- i. Moratorium continues (or Full stop to GM crops)
- ii. Limited commercialisation goes ahead
- iii. Full commercialisation goes ahead (or Full steam ahead)

Those brief, ambiguous wordings left considerable scope for participants to develop their own meanings, in the context of the *de facto* moratorium. The first scenario could mean no additional uses beyond the current ones, or no uses at all – i.e., more restrictive than the current situation. 'Full commercialisation' could mean all uses which already had EU approval or, alternatively, all uses which were being requested for additional GM products. 'Limited' could mean various limitations, resulting in commercial use somewhere between the other two scenarios. In general the timescale was presumed to be the next few years – a period when the EU regulatory system would be deciding whether, or how, to go beyond the *de facto* moratorium.

Each in its own way, the three workshops considered scientific uncertainties of GM crops and stakeholders' views about how these should be regulated. Discussions included efforts to clarify potential effects of such products before or during their commercialisation. Relevant effects included adventitious presence of transgenes, as well as environmental harm. In some cases, participants acknowledged disagreements in interpreting the results of risk research. However, they did not explicitly discuss 'uncertainty', much less 'precaution', unless prompted by the organisers.

Other research partners devised a different workshop structure, as described in Section 3.3 for Germany and Section 3.4 for France.

3.3 Scenarios on precaution

In Germany the workshop organisers consulted prospective participants and eventually decided to emphasise precaution in the workshop structure. Early on, they found that industry representatives were reluctant to attend a workshop, e.g. because they saw no way to go beyond the familiar polarised arguments with NGOs. But NGO representatives and administrators expressed interest in exploring the meanings of precaution, so the organisers successfully made special efforts to attract such individuals.

For planning the workshop, the organisers formulated two different scenarios – 'effective' versus 'comprehensive' precaution. However, when the workshop began, this terminology was criticised and was then changed by general consensus – to 'weak' versus 'strong'

precaution. Participants then analysed each of the three scenarios in terms of overall political direction, scientific and administrative procedure, and market rules.

There was relatively greater consensus on how to characterise weak precaution. This approach corresponded to the situation in the early 1990s in Germany, when government claimed to base regulatory policy on 'sound science', with national standard criteria. There was less clarity or agreement about the shape of strong precaution. Possible features included aspects already apparent in the *Agrarwende* – the recent policy of turning agriculture towards environmental and consumer concerns. Such features could include: a greater burden of evidence upon operators to demonstrate safety, regional diversity of norms, and statutory regulation of co-existence.

3.4 Scenarios on crop innovation

In France too, the organisers consulted prospective participants and eventually decided to emphasise crop innovation in the workshop structure. Early on, they realised that NGOs would be reluctant to focus on prospects for commercialising GM crops, partly because they sought a more diverse basis for crop innovation overall. So eventually the organisers formulated this central question: 'In a horizon of 15-20 years, describe the evolution of forms of governance for crop innovation. What would be your ideal and nightmarish evolutions?' As the organisers explained, the same scenario could be seen as either ideal or nightmare by different people. This focus successfully attracted many participants, though mainly from NGOs and research institutes, despite the organisers' efforts to attract participants also from government agencies and companies.

The French workshop discussions resulted in three sociograms – institutional structures for directing crop innovation – along the following lines:

- i. Liberal-monopolistic: companies and shareholders subordinating R&D to the profit motive, while an oligopoly monopolises and standardises innovation.
- ii. Centralised, top-down: a global body involving diverse actors who negotiate priorities for innovation, while delegating risk management to politicians.
- iii. Decentralised, bottom-up, self-managed: international networks of local collectives, facilitating co-production of R&D with research institutes and peasant-creators, etc.

For most participants, those scenarios were perceived as part of a continuum from nightmare (i) to ideal (iii).

4 EU workshop design

The EU workshop drew upon various aspects of the national workshops, in order to devise a structure most appropriate for the EU-level policy process. The title was based on several national workshops, especially the UK one: 'GM Futures? Exploring Options for GM Crops in the EU'. The invitation letter emphasised the main objective: to gain policy-relevant insights into options for future decision making on GM crops in the EU. A related objective was to explore the possible relevance of precaution for various regulatory issues.

4.1 Timing and participants

For our project timetable, we needed to hold the event around mid-2003. As indicated by our conversations with prospective participants in Brussels, they had many other meetings and other work in late June, leading up to the second reading of draft GM regulations in the European Parliament plenary session in early July. It was decided to hold the workshop on the Monday following that plenary session, when there would be fewer meetings, though some people might be unavailable for other reasons.

Invitations were sent to nearly a hundred people whose work relates to GM crop issues around Europe. These included a wide range of policy actors – including Commission officials in Brussels, Competent Authorities in EU member states, other relevant people based not far from Brussels, and an expert network in Eastern Europe. The invitation list was deliberately long because the organisers anticipated that many invitees would be unable to attend, for various reasons.

In the event, 15 individuals took part. Half were based in Brussels, and the others came from elsewhere in Europe. They included officials from the European Commission and the European Parliament; national Ministries of Health, Environment and Food Safety; regulatory officers from industry; and academia (see Appendix I). There were several Commission officials but few centrally involved in policy-making on GMOs; reportedly those people had been over-worked by the draft GM regulations and US-EU WTO dispute. No one attended from an NGO or farmer organisation, despite efforts to attract them.

The event was managed by two professional facilitators, to ensure that the overall plan was smoothly followed and that the discussion resulted in a clear record which could be photographed. Ten research partners of the PEG project acted as facilitators or note-takers in the small-group discussions. The discussions were held on the understanding that comments would not be attributed to a specific individual.

4.2 Method and structure

The organisers decided to focus the workshop on precaution, with the aim of generating ideas and debate on what that concept means. In their introductory talks, Les Levidow and Patrick Rudelsheim surveyed possible meanings of precaution for regulating GM crops in the EU (see Appendix III). The pre-circulated briefing document was entitled, 'EU Regulation of GM Crops: What Role for Precaution?' (see Appendix IV).

The organisers also decided to structure the workshop in a relatively open-ended way, rather than formulate specific scenarios in advance. One reason for this plan was a view that policy actors might be suffering from 'scenario-fatigue' and might therefore be reluctant to attend yet another workshop with this format. A more open-ended workshop structure would allow the participants themselves to formulate possible policy futures. In that spirit, discussion started with the following question: 'For GM crops and the implementation of the Precautionary Principle in the European Union, what are key elements of your ideal and nightmare futures?' This question drew upon the 'precaution' emphasis from the German workshop, as well as the ideal/nightmare contrast from the French workshop. The organisers intended that the key elements, as identified by participants, would then be combined into three different policy futures, as a basis for discussing their possible causes and consequences during the afternoon session of the workshop.

The workshop took place in the following stages:

- i. Small-group discussion. After the introductory talks, participants were divided into three groups to generate elements of their 'ideal' and 'nightmare' futures. The main points were recorded on post-it notes. Then each group discussed how some elements could be combined into overall futures or wider issues (see Section 5).
- ii. Choice of thematic groups. Before breaking for lunch, participants indicated which issue or future they most wanted to discuss further. Each person 'voted' by putting a sticker onto the post-it note phrase which most interested them. Three issues gained the most votes: multiple agricultures, regulations and legislation, and societal and consumer choice. These then formed the basis of the afternoon's activities. Participants selected which topic group to join. Many people wanted to discuss multiple agricultures, and few wanted to discuss societal and consumer choice, so some people volunteered to change groups.
- iii. Mapping causes and consequences. Each group then attempted to 'map' in a logical sequence the possible causes and consequences related to their topic (see Section 6). In many cases, participants thought that the same factor could be both

a cause and consequence, in different ways. After completing the map, individuals were invited to discuss the implications for their own roles.

- iv. Carousel presentation. A carousel approach was used to give each participant the opportunity to report back their group's discussion to the participants of other groups. This was done by forming new groups containing one member from each of the previous groups. These new groups took turns to visit each of the original groups' diagrams, with the member common to both the new and the original group summarising their original group's discussion of causes and consequences. Others had the opportunity to add comments or ask questions.

Finally, Jan Staman closed the event with reflections on the day (see Appendix III).

5 Post-it note session

As explained above, participants were initially divided into three groups to generate elements of 'ideal' and 'nightmare' futures for GM crops. The group discussions often reached consensus on how to classify various elements as either 'ideal' or 'nightmare'. Perhaps consensus was relatively easy to achieve because few participants were opposed to GM products.

Nightmare elements tended to be extremes – e.g. either blind trust or no trust in regulation, all GMOs or no GMOs, everyone polarised for or against GMOs, no choice for farmers or consumers, precaution ignored or mis-used. According to some participants, it would be a nightmare if the organic lobby could dictate where GM crops are grown, or if various restrictions hindered R&D on such products.

In one group, the facilitator led a process which grouped together some 'ideal' elements under the heading 'Go' and some 'nightmare' ones under the heading 'Stop'. This distinction implied that ideal elements would or should be linked to commercialisation of GM crops, while nightmare ones would be linked to blockages. Ideal elements included the following:

- Think about risks before authorisation of GMOs
- Precautionary Principle = identifying good questions
- GMOs regarded in a global view (benefits/risks, current and future situation)
- Paving the way for new GMOs
- GMOs actuated and pesticides use declines
- A better agriculture for sustainability
- Solutions for local problems.

In the same group, nightmare elements included the following:

- Endless research without any decisions taken
- Food producers reject all GMOs
- GMOs will not help to feed the Third World.
- Stop using GMOs
- All R&D activity moves to US
- Losing opportunities for progress.

In the second group there was consensus on 'co-existence', as in current EU policy, but participants questioned why it should include only three categories of agriculture - GM, conventional and organic. Participants thought an ideal future would need to accommodate more variety (see Section 6.1). Ideal futures also included the development of beneficial GM crops, e.g. drought-resistant or medicinal types.

This group had strong disagreement about whether other elements should be classified as nightmare or ideal. Such elements included the following:

- establishing global regulation of GM products or, alternatively, abandoning any regulation specific to GM technology.
- making decisions solely on a scientific basis or, alternatively, on more than science;
- precaution having a lax or strict interpretation; and
- eventually abandoning mandatory GM labelling.

On mandatory labelling, some participants regarded such rules as a 'quality' indicator essential for the free market to function.

6 Topic mapping exercise

The topic mapping exercise was structured around the three topics that received the most votes at the end of the morning. These were: multiple agricultures; regulations and legislation; and societal and consumer choice. With hindsight, it is apparent that the first provided a specific and novel scenario, while the other two coincided closely with current policy language and aims. The three main topics could be seen as related elements of the same future, rather than as three different futures.

The discussion below of the three topics corresponds to diagrams devised by the participants during the afternoon session. The diagrams depict chains of causes and consequences; they were produced by re-arranging the post-it notes from the morning session and by adding extra ones. Main concepts were put in the middle, and some important ones were written in all-capital letters. The diagrams used arrows to link causal chains. Afterwards these diagrams were reproduced in electronic form, in a way which attempts to convey the original intentions, while adding dashed lines to indicate implied causal chains (see Section 7 for the diagrams).

6.1 Multiple agricultures: 'remodelling institutional arrangements'

This group began by discussing fundamental problems of how to link economic and environmental aspects of European agriculture. According to some participants, the present agricultural system adds little value, so a competitive advantage remains difficult outside the EU or in Eastern Europe. Farmers face pressures to adopt sustainable, environment-friendly methods, which incur greater costs and so need a means to recoup these, e.g. through niche markets. Biotechnology has been widely opposed by critics as leading to a further industrialisation of agriculture, though R&D could result in new products seen as desirable, including novel types of GM products. So the establishment of measures to allow the co-existence of different production methods becomes essential to maintain differential markets which could reward quality products, through a long process that may need another decade.

Taking up the idea of multiple agricultures, the group explored the problems and opportunities associated with making a commitment to various types of agriculture running side-by-side in Europe. Initially the discussion assumed three categories of agriculture – organic, conventional and GM. It was agreed that all of these needed to be viable and that GM should not undermine the viability of the other two.

However, further discussion recognised that these categories may not be fixed. New categories may emerge and the definition of existing ones might change; for example, there could be differentiation among types of organic products. A range of scientific, political and cultural influences might bring about such changes. These could strain the policy-making process if it was too inflexible and unable to accommodate the emergence of new categories. So this discussion gave a central role to the idea of co-existence, which is

currently being elaborated in Europe. However, the participants wanted debate to go beyond the current model of three fixed agricultural categories.

As a way forward for Europe, the discussion formulated three central policy elements:

- i. a commitment to multiple agricultures,
- ii. remodelling institutional arrangements, and
- iii. incorporating the Precautionary Principle as a normal part of good governance.

These features would ensure the co-existence of crops and of regulatory regimes, on more than a voluntary basis, e.g. by preventing gene flow from GM to other crops. Through labelling, it would also provide consumer choice (though the US case at the WTO could challenge this). Beyond the policy arena, stakeholders could make choices about the Precautionary Principle for themselves, thus sharing responsibility with government. By contrast to that ideal scenario, a nightmare future would be chaos across multiple agricultural types – e.g., GM contaminating other types, or co-mingling of organic with high-value GM crops.

According to one comment in this group, people have strong moral feelings which run beyond any risk (in the biophysical sense) of current technological developments. So society must provide a clear forum to debate the value basis, alongside science. Otherwise NGOs will more easily organise protest.

6.2 Regulation and legislation: ‘publicly trusted legislation’

This group explored the causes and consequences of ideal regulation. They decided that the main issue was trust and acceptability, as the basis for regulation to work. So they decided to focus on the elements that would contribute to trusted regulation.

First they identified reasons for the moratorium (as an example of regulation not working) in order to elaborate on ways to move towards workable and acceptable regulation, and to consider what role various stakeholders would play in that process. Because GMOs were widely perceived as a symbol of globalisation in public debate, it was difficult to separate scientific risk issues from ideological or political ones; as a way forward, public discussion should include all such issues. Often ‘what consumers (or the public) want’ was invoked in wider debate, but with little basis for knowing their views.

An issue that had led to conflicting views in the morning discussion – ‘decisions not based on science but presented as being based on science’ – was identified as a cause of mistrust. This led to further discussion on what factors could legitimately be considered in decision making. According to one participant, for example, ‘science is science’ – i.e. the boundary is obvious. There was disagreement about whether regulatory decisions are generally based on science, about how to distinguish between scientific/non-scientific issues, and about whether or how extra-scientific criteria should be included. Some participants proposed that governments should make explicit how decisions are based on more than science, as a means to gain public trust. But they disagreed about how value judgements should (or do) enter the regulatory procedure.

This group also discussed the precautionary principle and its role in ideal regulation. Disagreements arose over what precautionary elements would look like. Some argued that precaution would radically change risk assessment (not just risk management). Others maintained a traditional understanding of risk assessment, e.g. as straightforwardly based on science. From that standpoint, precaution had relevance only to risk management, and its proper role was already settled by Commission policy documents.

Apart from accounts of science and precaution, other important elements were liability for damage and development of ‘good GMOs’.

All the above elements were seen as possible causes of the central goal, 'publicly trusted legislation'. Its content would influence public trust and acceptance. In those ways, trust was seen as both a basis and result of regulation. Ideally, risk research, regulation and management would work as a continuous interactive triangle (not simply a linear sequence).

Regarding the consequences, workable regulations ideally would lead to a proliferation of agri-bio R&D programmes. The group also discussed whether this ideal regulation could serve as a global model. The EU framework might be globally recognised as 'a model for the responsible and safe promotion of new technologies'. The global co-existence of different regulatory regimes could push the WTO to take a decision on the appropriate role for 'other legitimate factors' in regulatory decisions.

6.3 Societal and consumer choice: 'a trustworthy system'

This group discussion was the most difficult because it was located near the main door, where some extra participants arrived after the discussion had begun. Consequently, some made statements with little reference to the previous discussion.

The group made a distinction between consumer choice (implying a product) and societal choice (implying technological directions), and decided to consider the two topics separately. For a while they struggled with societal choice, but the topic seemed too general and open-ended. So eventually they concentrated on consumer choice. As a prerequisite, this would require transparency by government and industry, e.g. through clear labelling. Transparency was important because consumer preferences have reasons other than risks, e.g. dislike for a particular production method.

The group decided that the central policy aim or future was informed choice ('as informed as I want to be'), that is, giving the consumer enough information to allow informed choice. This central aim was re-interpreted as 'a trustworthy system', i.e. providing an informed choice.

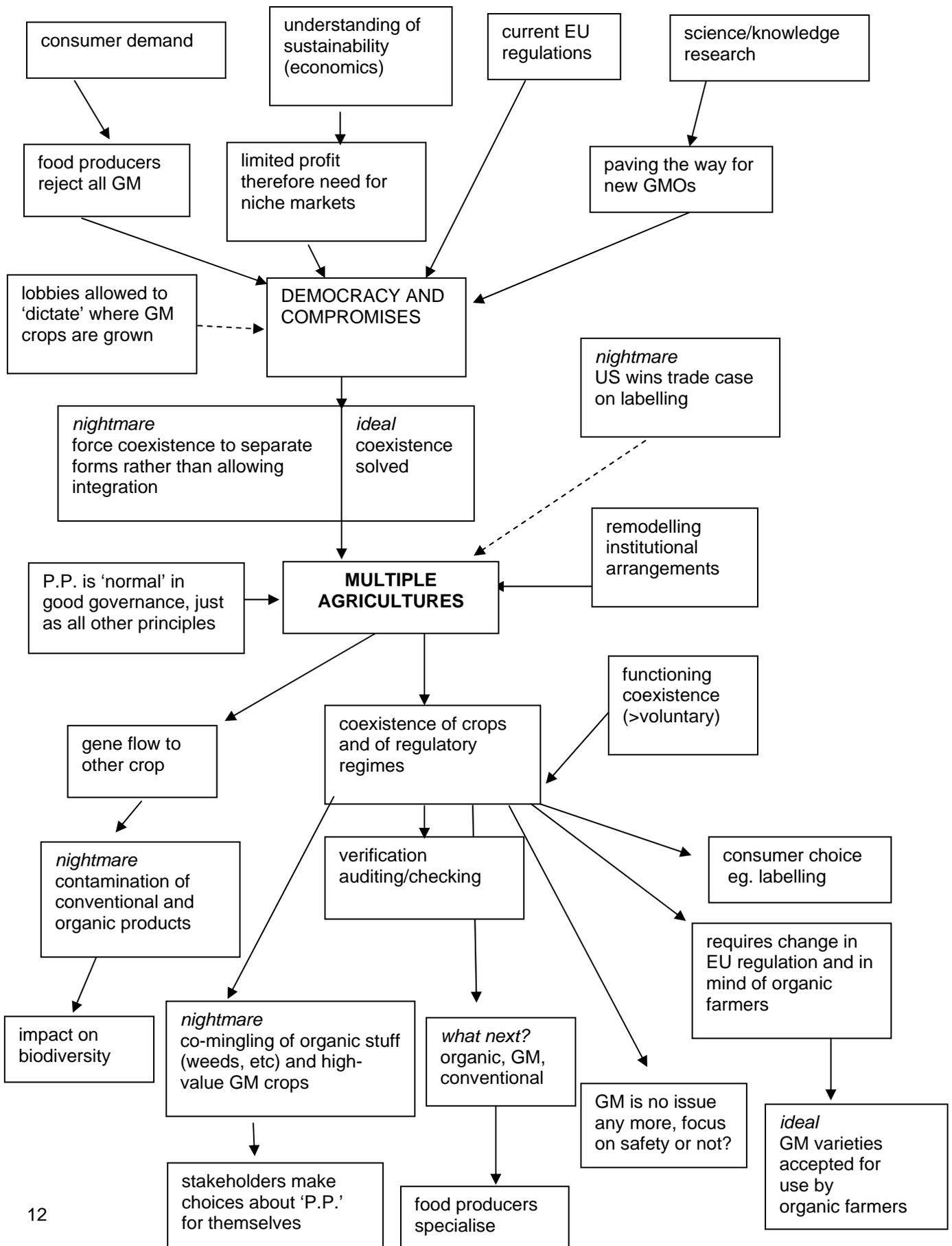
From that central goal, there were three possible chains of consequences:

- i. If the choice was left to consumers and a free market, then that arrangement might help preserve a diverse range of products.
- ii. Food producers might decide to reject GM products if they thought there would be no market for them, thus restricting choice.
- iii. Consumers might be content with being allowed informed choice and would become accustomed to GM products, thus eventually allowing abandonment of GM labelling.

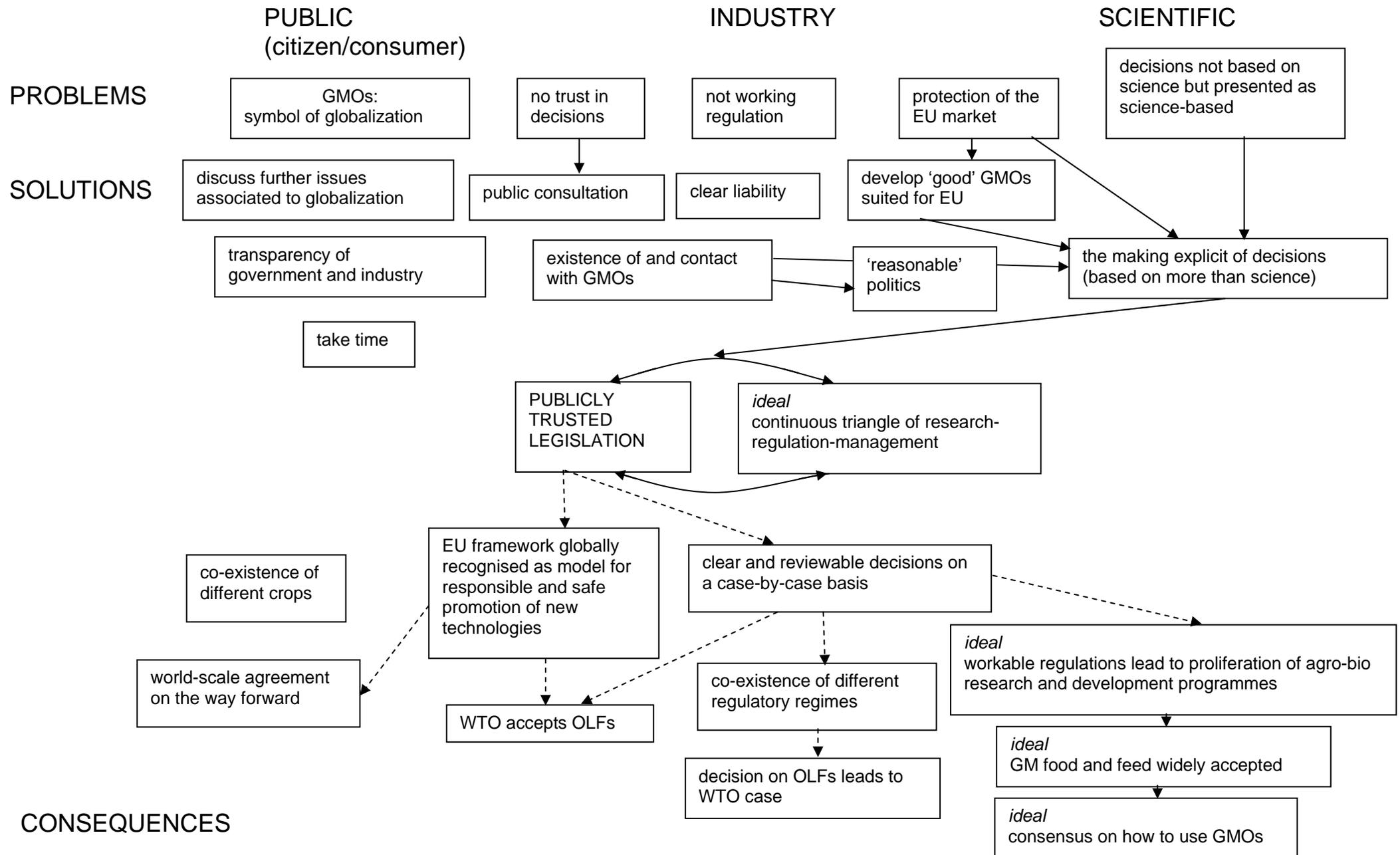
The discussion took up some of the difficulties in recognising and addressing public concerns. People may not act in the real world on the basis of what they tell opinion-poll surveys, e.g. about what products they would buy. Many people do not accept GM technology, so consumer choice becomes more important, but preferences may be more varied than simply non-GM, e.g. products of Integrated Crop Management (ICM). Public choice means listening to concerns through consultations, not simply referendums. Many people feel uneasy that technological developments are 'messing with nature', so ways are needed to address such concerns, which go beyond transparency about science and regulation.

7 Topic mapping diagrams

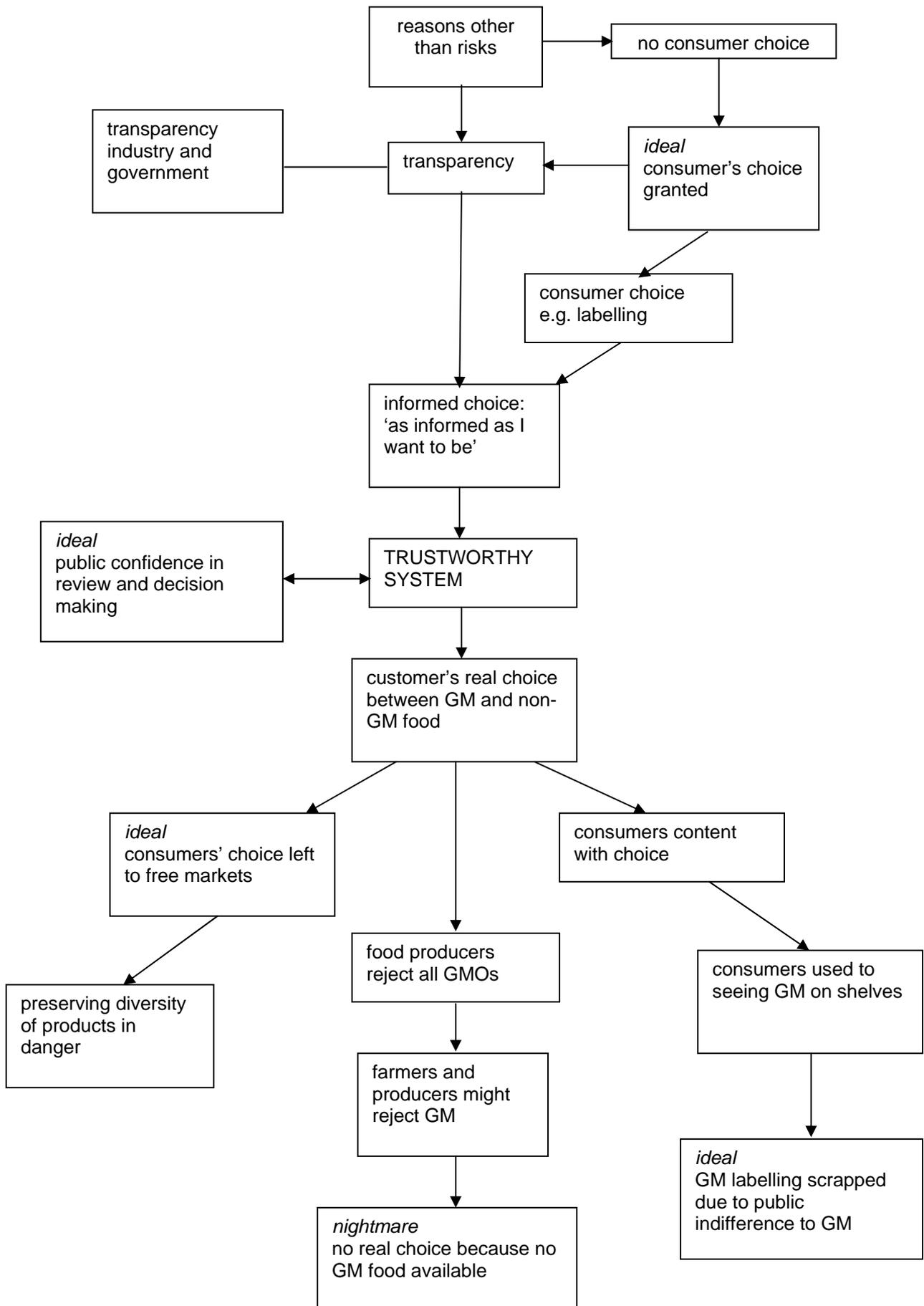
7.1 Multiple agricultures



7.2 Regulation and legislation



7.3 Societal and consumer choice



8 Overlapping themes

The discussions on all three topics took up familiar themes, looking at various aspects of the near future. Across the topic groups were some common themes – e.g., precaution, trust and differentiated agriculture.

8.1 Precaution

Albeit with no consensus on its meaning, precaution was often mentioned as a basis for better policies – e.g., for different ways to design risk research and agricultural systems, or as a basis for consumer choice to influence such systems, and even for consumers to share responsibility for them. According to some participants, the Precautionary Principle was seen as a big concept for doing battle with the USA, especially around GM crops, but as too big for EU citizens to use. In public debate, EU policy has been widely seen through the prism of the US-EU dispute, e.g. as submission or defiance towards the USA, rather than as European judgements about the meaning of precaution. So there was a need to make precaution into a routine tool, useable for regulatory and consumer practice.

Such comments intersect with the relatively broad accounts of precaution in the introductory talks and in some policy documents cited there (e.g. European Parliament, Economic and Social Council). These contrast with narrow accounts that see precaution as a special case, which can be triggered only by specific conditions.

8.2 Trust

'Trust' emerged as an important theme in at least two of the three topic groups. Participants discussed public mistrust in the decision making system at present and the need to create a more trustworthy system for the future. This would require further institutional changes, e.g. greater transparency of decision-making, and potentially open-ended demands for information on how products are made. As an element of a trustworthy system, some advocated transparency about the extra-scientific criteria involved in regulatory decisions, though some disagreed that these were (or should be) involved.

8.3 Differentiated agriculture

All participants supported the current EU policy commitment to co-existence (of GM, conventional and organic agriculture), but some saw this as potentially conflicting with more complex categories of agriculture. Examples of differentiated categories included the following:

- i. Multiple agricultures beyond the tripartite stereotypes
- ii. 'Good GMOs', e.g. medicinal crops
- iii. Integrated Crop Management, as an approach which could involve GM or conventional crops.

In general, 'multiple' meant diverse types of crops or cultivation methods – by contrast to the policy concept of multifunctional agriculture, which emphasises alternatives to cultivating crops.

9 Observations on the process

For all three topics, discussions tended to centre on familiar themes, looking at aspects of the near future. The Multiple Agricultures topic stimulated the most creative discussion, partly because it established a specific and plausible future scenario. The

other two topics were more difficult as a basis for constructing chains of causes and consequences. This was partly because they started as topics, rather than policy scenarios, and the topics did not become much more specific during discussion.

Why not? One facilitator offers the following hypothesis for why these topics provided less stimulus for discussion: 'It was too demanding for participants to imagine possible future developments, assess whether they would favour them, defend them against other group members, and arrive at consistent scenarios together with the other participants – a process which would require homogenising diverse views. Participants became puzzled: either they seemed to expect to build scenarios from likely developments, or else to 'backcast' developments from scenarios seen as either ideal or nightmarish. Thus it was no wonder that they stayed within single issues, which seemed easier to handle.' If that explains the dynamics, then it would be all the more difficult for a facilitator to shift the group discussion from a topic to a specific scenario.

In those two groups – on Regulation and Legislation, and on Consumer and Societal Choice – more difficult disagreements arose, perhaps due to the group composition rather than inherent features of the issues. For the topic of Societal and Consumer Choice, some members attempted to discuss how the entire society could participate in decision-making, but this idea was criticised, e.g. by asking how ordinary people could legitimately challenge the judgements of elected officials during their term of office. Such objections were bypassed by abandoning societal choice as a focus for discussion and instead focusing on choices of individual consumers.

The introductory talks and opening question emphasised precaution. This theme arose to some extent in the post-it notes but was marginal in the diagrams of possible futures. This marginal role has several possible reasons. Precaution itself may be marginal to the mindset of most policy actors around GM crops. Precaution may be seen as implicitly involved in the issues under discussion, rather than as a special measure to be taken. And/or participants disagreed about the meaning of precaution and were reluctant to record disagreements.

Indeed, when members of a group disagreed about a key point, resulting in a lively discussion (e.g. about the definition or relevance of precaution), they tended not to record the points made. There was a tacit assumption that only agreed points should be recorded, or perhaps a tendency to avoid contentious points. Some participants were reluctant to express critical views or lacked the confidence to do so. Consequently, the post-it notes and diagrams omitted important views held by participants, even though the organisers had encouraged everyone to express and incorporate any disagreements. As an example of such silencing, one participant who expressed anti-GM views was isolated by a strong group view to the contrary and so left the group.

As another kind of silence, there were few new ideas from Commission officials, though the participants did not include the officials most centrally involved in the sector of GM crops. This sector is seen as a political 'hot potato', which may discourage new people from becoming involved. At the workshop, ideas came mainly from national regulators and companies.

After each group completed the diagrams of possible futures, participants were invited to discuss implications for their own roles, but few responded. Possible reasons include the following: because little time remained, because the diagrams were not sufficiently specific about potential futures, and/or because people were reluctant to talk publicly about the implications for their own role.

After the small-group discussions, the carousel procedure gave participants a welcome change and a means to hear about the other discussions and to generate extra ideas. This created a new group dynamic, thus reviving discussion.

In retrospect, what resulted from the open-ended method of the workshop? The initial question for discussion, with its idea/nightmare contrast, was intended to generate elements of possible futures which may be seen as desirable by some participants but not by others (and vice versa). This method aimed to highlight any normative

differences, e.g. views of desirable futures, and thus to generate a broader range of plausible scenarios. Implicitly, this method assumed that descriptions of the future are separable from value judgements about their desirability.

In the workshop process, however, such differences in values and norms rarely arose – partly because of the group composition, and perhaps because diverse views were homogenised by the group effort to devise scenarios. Minority views were often marginalised rather than incorporated into more imaginative scenarios. Consequently, although the diagrams are ostensibly neutral descriptions of plausible futures, they tend to express the dominant values of the participants. (Indeed, a similar process happened in some national workshops – e.g. France, Germany and the UK – first in the imbalance of the group composition, and secondly in the discussions.)

The experience gained can be used for learning to improve future exercises of this type. For example, organisers could take the following measures.

In planning such a workshop:

- discuss with prospective participants what they might hope to gain from the experience, in terms of their roles and needs *vis à vis* the topic at hand (for example, in Austria government officials were keen to meet to discuss policy change options, and in Germany NGOs were keen to discuss the practical implications of precaution)
- devise a thematic focus which can attract specific constituencies, even if not representing the full range of relevant policy actors.

In structuring the event:

- encourage people to write down their thoughts on a topic individually, before working together as a group, so as to avoid group suppression of some viewpoints
- use techniques that encourage participants not to dismiss unusual or extreme views but rather to view them as an aid to creative thinking
- focus discussion on a specific scenario or ‘policy future’, not simply a topic
- suggest how participants could record and incorporate disagreements into the diagrams
- suggest a timescale further into the future, to facilitate creative thinking beyond currently obvious forces and issues
- give facilitators more guidance on the above points, as well as agreeing with them in advance various prompts for the discussion.

10 Using the results

The PEG project has been using the workshop results to plan the rest of our work, in several ways. Key points were presented and discussed at the partners’ two-day meeting held immediately after the workshop. Many PEG partners had contributed to the workshop, e.g. by acting as facilitators or note-takers, and they subsequently contributed ideas for how to analyse the results. Discussion included the following points and questions for further research:

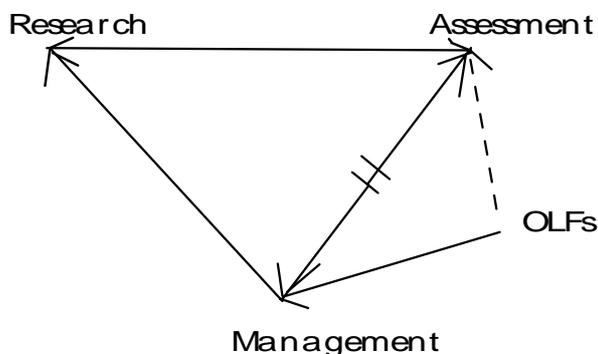
- Science-based decisions

Workshop participants disagreed about whether regulatory decisions could or should be based entirely on science, i.e. whether other factors could be legitimately included. This disagreement relates to our research on how ‘science’ is defined in practice. How do regulatory procedures draw boundaries between scientific and extra-scientific criteria? Between expertise and mere opinion? How does precaution help to open up that question?

- Risk assessment/management

In the workshop discussion, ideal regulatory practices were described as a continuous triangle between risk research, regulation and management; this means that risk assessment and management have a mutual dependence. Such a complex view has relevance to debates on appropriate regulatory procedures. Several member states have adopted EU policy on 'the functional separation of risk assessment and management', i.e. so that different bodies are responsible for the two functions. Sometimes this is understood as excluding risk-management or normative judgements from expert advice, yet such an absolute separation has been criticised as unrealistic or illusory. 'Other legitimate factors' (OLF) are often discussed as if they lay outside risk assessment, yet closer scrutiny can reveal extra-scientific judgements within risk assessment. (See Figure 1, resulting from subsequent discussions among the PEG partners.) What are the mutual interactions between risk research, assessment and management?

Figure 1. Perceived links between risk research, assessment and management, and between these and 'other legitimate factors' (OLFs)



- Co-existence

In the workshop discussion, adventitious presence of transgenes was identified as an important problem which links gene flow, the agro-food chain and thus consumer choice. Research on gene flow acquires an extra significance for management measures needed to achieve co-existence. For modelling gene flow and devising such measures in an agricultural context, what expertise is being developed?

- Precaution

Precaution arose at many points in the workshop discussion but generated disagreements and so remained marginal to the cause-consequence diagrams. For example, participants disagreed about whether precaution makes a difference to regulatory science. At the same time, precaution was mentioned as a general perspective on innovation choices as well as regulation, and as a basis for individual as well as societal responsibility.

These aspects of the workshop confirmed our sense that precaution may have important but implicit roles in European developments on GM crops. In that context the European Commission does not mention precaution, yet it is widely invoked to oppose GM crops, as well as to defend a different approach here than in the USA. How do understandings of precaution shape regulation and mediate conflicts? Conversely, how do regulatory conflicts shape different understandings of precaution?

11 References

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12 Project documents

Related documents from this project are downloadable at the website of the Biotechnology Policy Group, Open University, <http://www-tec.open.ac.uk/cts/peg/index.htm>

Eventually the website will include reports of the EU-level and national studies from this research project.

Appendix I. Attendance list

Name	Organisation
Participants	
Jan Staman	Rathenau Institute, Netherlands
Martine Delanoy	Health Ministry, Belgium
Mark Cantley	European Commission, D-G Research
Ioannis Economidis	European Commission, D-G Research
Jim Dratwa	Harvard University
Guy Deregnaucourt	Environment Committee, European Parliament
Andrew Barnard	European Commission, D-G Enterprise
Patrick Rudelsheim	PERSEUS bvba, Belgium
Halima Khan	Cabinet Office, UK
Sebastien Goux	Health Ministry, Belgium
Jonina Stefansdottir	Environmental & Food Agency of Iceland
Jean-Francois Sarrazin	Bayer CropScience, Belgium
Eva Claudia Lang	Ministry for Health & Women, Austria
Hilde Willekens	Syngenta International AG, Belgium
PEG partners	
Jesper Toft	Roskilde University, Denmark
Joyce Tait	Edinburgh University
Helge Torgersen	Institute of Technology Assessment, Austrian Academy of Sciences
David Tabara	Universidad Autonoma de Barcelona (UAB), Spain
Christophe Bonneuil	INRA STEPE, France
David Wield	The Open University
Sue Oreszczyn	The Open University
Susan Carr	The Open University
Stephanie Ronda	INRA STEPE, France
Karin Boschert	Institute of Sociology, University of Munich
Piet Schenkelaars	Schenkelaars Biotechnology Consultancy, Netherlands
Joseph Murphy	The Open University
Les Levidow	The Open University
Marlene Gordon	The Open University
Facilitators	
Mark Yoxon	INFORM
Mo Shapiro	INFORM

Appendix II. Agenda

Time	Item & Brief Description
09.30	<i>Coffee</i>
10.00	Introduction
10.15	European GM crop issues Les Levidow - Research Fellow - The Open University
10.25	Current changes in the EU regulatory system on GM crops Patrick Rudelsheim - General Partner - PERSEUS bvba, formerly Bayer CropScience
10.35	Overview on how the day is to be run.
10.50	Using the question, ' <i>For GM Crops and the implementation of the Precautionary Principle in the European Union, what are the key elements of your ideal and nightmare futures?</i> ' Participants generate their ideal and nightmare futures. A facilitated group activity.
	Consolidating and Prioritising Participants prioritise which futures they think most need further discussion in the afternoon.
13.00	<i>Lunch</i>
14.00	Brief presentation by a member of the project team on futures exercises.
14.10	Facilitated groups draft a cause and consequence map for the policy futures requiring further discussion. Participants select the futures they wish to explore.
15.00	Implications – Participants are asked to consider the implications of the outcomes for their own particular role.
15.50	Presentations: short presentations from each group, using a carousel method.
16.40	Summing up Jan Staman - Director of the Rathenau Institute, Netherlands
16.50	Close
17.00	Drinks Reception

Two professional facilitators will run the workshop in conjunction with members of the project team.

Appendix III. Three talks

1. Les Levidow: European GM crop issues (introductory talk) Research Fellow, The Open University

Today's exercise is not about predicting the future or gaining consensus.

Rather, it aims to hear all views about plausible futures which may be desirable or undesirable, from the standpoint of the various participants. In that spirit, the briefing document surveyed current issues on how GM crops may be regulated and the relevance of precaution. Institutional views were drawn from documents and interviews. My talk will touch on such issues through simple pictures (see Figure 2).

Trans-Atlantic conflict

Since the late 1990s US maize shipments have been blocked because they may contain GM varieties not approved in the EU. The USA and EU have disagreed about who has the burden to demonstrate that such non-approved varieties are present or absent. The delay in decision-making on their approval comes from the overall *de facto* moratorium which was formalised by the EU Environment Council in June 1999. As a precondition for resuming the regulatory procedure, member states demanded a more transparent procedure for risk assessment, as well as rules for traceability and labelling. In their view, a precautionary approach provides guidance for such regulatory changes and procedures. What is meant by precaution?

Precaution as dialogue

According to the Economic and Social Council, often decisions must be taken on the basis of uncertain and extremely complex data rather than scientific certainties – i.e. on a precautionary basis. Consequently, risk assessment must be fostered as part of the negotiation mechanism on social issues. Its actual role in society is to provide the bases for dialogue. According to the European Parliament, precaution means that risk assessment should emphasise and investigate unknowns. The Precautionary Principle (PP) can be triggered by initial suspicions or empirical assessments, not only after comprehensive studies have been done. Precaution can generate alternative solutions: objectors should demonstrate that the alternatives are less harmful than the product to be replaced.

Precaution as rules

According to the Commission, the PP is a special case triggered by scientific grounds for uncertainty about risk which may exceed the chosen level of protection. The PP applies mainly to risk management of such uncertainty, e.g. by seeking additional scientific information for a more complete risk assessment. Precautionary measures must satisfy criteria of proportionality, non-discrimination, consistency and a cost-benefit analysis of technological options. In the Commission's view, moreover, the PP has been unwarranted for GM crops so far – except in one case (a GM potato), where the available information was inadequate for a risk assessment. For products awaiting a decision, expert advice has found no evidence of any potentially negative effects on the environment or human health, so those cases cannot justify recourse to the PP, argue Commission officials.

Precaution as evidence of safety

Likewise industry has regarded regulatory delay in approvals as not justified scientifically or legally. Indeed, delay severely jeopardises confidence in the EU regulatory system, they argue. According to some risk assessments, the safety conclusion is based on scientific evidence rather than on assumptions, and thus is precautionary.

Proposals for commercial authorisation

GM crop applications have been accumulating since the late 1990s. Many companies have added information to accommodate the requirements of the revised Deliberate

Release Directive (DRD). Scientific advisory committees have set out more stringent requirements for evidence of safety: how will these be satisfied?

Uncertainties about risk

Various risks have been addressed by research projects funded by the Commission or by member states, but arguments continue on key issues, even among regulatory officials. For antibiotic-resistance markers, which ones should be phased out? How soon? If Bt crops generate resistance in insects, would this count as an adverse effect under the DRD? Likewise for the spread of herbicide-tolerant weeds through volunteers or pollen flow? What measures are necessary to prevent these effects? For evaluating potential harm from GM crops, and from broad-spectrum herbicides, what should be the comparator? What form of conventional agriculture? or relatively less intensive methods?

Heading towards what future?

The choice of comparator relates to more basic issues of intensive agricultural models. Towards what future is European agriculture being led by GM crops? Will this mean greater or less sustainability? What is meant by sustainability?

Herbicide effects

Such abstract questions become more concrete in the case of herbicide-tolerant crops and their herbicide implications. Controversy includes the following questions: Will such crops encourage or reduce dependence on herbicide usage? Will broad-spectrum herbicides replace the ones previously used? If so, will they lead to greater or less biodiversity in agricultural environments? That last question is being tested in large-scale trials in the UK: look for the dead ladybirds (Figure 2, lower left-hand corner)! In Denmark, environmental policy is to use groundwater as drinking water without any treatment. Yet glyphosate has been found 1m below the ground, so this has generated debate on what restrictions to place on its use. Will it be approved for spraying on glyphosate-tolerant crops?

Monitoring

The DRD has means to accommodate uncertain risks within commercialisation. A monitoring plan must be designed to confirm any assumptions in the risk assessment - unless the risk is shown to be negligible. Companies have responded to this request in various ways. Most claim that the risk would be negligible, though with somewhat different reasoning in each case. Some propose to carry out monitoring measures under the Directive, while others do not. How will member states respond to these proposals?

Co-existence and gene flow

Beyond the risk of adverse effects under the DRD, there are extra reasons to manage the prospect of transgenes flowing to other crops, since these could jeopardise the economic value of non-GM crops, especially organic ones.

Arguments continue over the mutual responsibility of farmers to avoid the adventitious presence of transgenes, the legal basis for enforcing any rules, and the scientific basis for feasible rules. How can co-existence be achieved?

Labelling rules

On what criteria should a 'GM' label be required? Draft regulations would require such a label on all products derived from GM grain. These process-based regulations have gained wide support, as means

- for tracing any harm back to its source in a GM crop (i.e. for precautionary aims); and
- for ensuring that consumers have an informed choice.

In response, industry has argued that only detectable GM material warrants a label. It has opposed the draft regulations, on several grounds

- because such a rule could not be consistently enforced and could lead to fraud; and
- because a 'GM' label will be perceived by consumers as a skull and crossbones.

How will the regulations be finalised, and how will they be implemented?

WTO dispute

In recent years, US threats of a WTO case have backfired politically, further antagonising the public against the USA and GM crops.

Such reactions have made it more difficult for the Commission to obtain legislative changes which would facilitate the grain trade. Its proposals have been criticised as concessions to the USA. Now that the US government has initiated a WTO dispute over GM crops, how may this lead the EU to accommodate or defy the USA? How will the dispute be cited as an argument in EU politics? What difference could it make to developments here?

Figure 2. 'Rich picture' representing key EU issues for GM crops (by Sue Oreszczyń)



2 Patrick Rudelsheim: Current changes in the EU regulatory system on GM crops (introductory talk)

General Partner of PERSEUS bvba; previously Global Head, BioScience Regulatory Affairs, Bayer Crop Science

The second decade (2000-2010) of GM crops in Europe is characterized by completion of the regulatory framework and scientific documentation of uncertainties and risk factors. Irrespective of the wealth of information and efforts, there seems to be no link between knowledge, regulation and decision-making. Current regulatory changes have no clear relation to the risk research which has been done. Uncertainty is perceived as more important than familiarity and the proven safety track-record of GM crops. Other elements are as influential, e.g. wider visions for European agriculture or EU-US trade conflicts. Consequently, legislative proposals and decisions are often questioned as responses to pressure rather than inspired by safety concerns.

Taking the precautionary principle as the cornerstone for the regulatory approach, its implementation should be weighed with care. It leads to a prior risk assessment and subsequent risk management, as implemented in the different EU regulations. In a more general interpretation it can lead to further research – public and private – in areas of uncertainty. Accepting that future new areas of concern may be identified, it is the basis of more general and long-term monitoring. Yet precaution also forces an evaluation of alternatives, including the scenario of not deploying the new opportunities, and this inevitably requires clarity on the baseline for comparison. Finally, as illustrated by this study, different actors may have divergent views on the precautionary principle. While such a key principle deserves continuous refining, that process should not confuse or delay decision-making.

The dilemma we face is to decide which of the two interpretations of the precautionary principle should prevail – namely, that the lack of risk confirmation should not preclude restrictive measures, or that the lack of safety confirmation should not hinder product use. As a way forward, regulatory developments have several precautionary objectives – e.g., addressing uncertainty, providing transparency of decision-making and predictable rules for R&D activity, non-discrimination against a specific technology, and measures proportionate to potential impact.

3 Jan Staman: summing up Director, Rathenau Institute

Initially I didn't believe in today's procedure, but we did a marvellous job. The carousel method was a nice way to focus the discussion at the end. Different discussions focused on similar issues. If there is public trust, then there is space for GM food. No one in our group objected to GM crops, e.g. as unethical.

Right now we have the Precautionary Principle as a big gun (or B-52) to bomb the USA, but we don't use it for our own practices, at a time when we need a more trustworthy system. We should get the Precautionary Principle as a normal principle of politics, internalised in the minds of the producers and consumers. This is what I learned from today.

Appendix IV: Briefing document

EU Regulation of GM Crops: What Role for Precaution?

Les Levidow

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SUMMARY

Amid continuing controversy over the commercialisation of genetically-modified (GM) crops, the European Commission is seeking ways to resolve outstanding regulatory issues and move beyond the *de facto* moratorium. Pressure to find policy solutions has intensified as a result of the growing number of GM products awaiting marketing approval, and the initiation of a US-led complaint to the World Trade Organisation about the restrictions placed on GM trade by the EU.

The Precautionary Principle (PP), which underpins the EU's approach to GM crops, can be seen as providing opportunities to find ways through the regulatory impasse, but those opportunities will depend on how the PP is interpreted and implemented. This briefing document, which is based on research for an EU-funded project called 'Precautionary Expertise for GM Crops (PEG)', provides examples of views and practices relating to precaution gathered from EU-level bodies, member states and companies.

Official definitions of the PP broadly state that uncertain risks can justify temporary measures to avoid potentially serious or irreversible harm. The European Commission has tried to establish an EU-wide common understanding of the PP by means of an official communication, but other understandings exist, even among EU institutions. Organisations may refer to 'precaution' or 'the precautionary approach', sometimes interchangeably with the PP. The language of precaution may be used strategically, for example to promote a particular stance on products or to mediate conflicts.

Precaution may be viewed, for example, as:

- Justified only for exceptional cases, triggered by specific scientific uncertainties
- Allowing time to gain more or better scientific answers
- Enabling a process of social negotiation
- Ensuring that alternative technological solutions are considered.

The European Commission believes that use of the PP should be strictly limited. It argues that the PP's use is generally unwarranted for GM crops so far, because its Scientific Committee on Plants has found no evidence of risk for the GM products currently awaiting a marketing decision. Similarly, the biotechnology industry argues that regulatory delays cannot be justified scientifically.

Other bodies argue that precautionary measures are justified. For example, in 1999 the EU Environment Council stated that decisions should be suspended until there is a more transparent risk assessment procedure and until rules on traceability and labelling are established; precaution would provide guidance for such regulatory changes. Consumer organisations make similar demands. Farmer organisations want measures to avoid GM contamination of conventional seed, to assign responsibility for co-existence, and to avoid liability for adverse impacts. Environmental organisations want

more funding for risk research but believe that GM field trials pose unacceptable risks. They want government funding for research into alternatives to GM crops.

In EU member states, various practices are linked to precaution. For example, the Netherlands government holds that scientific risk assessment is itself precautionary. Its expert advisors frequently ask companies to provide better evidence regarding health risks of GM food and feed. In Germany the competent authority (CA) has initiated a public debate about GM crops and, with the Belgian CA, is advising Bayer on its plans for market-stage monitoring. The German government has established a new biosafety research programme. In the UK, the CA has funded farm-scale trials to compare the impact of GM and conventional crops on farmland biodiversity, in consultation with environmental groups. In Denmark, the CA requests information on how herbicide-tolerant crops may affect overall herbicide use. A debate has begun there about glyphosate residues in groundwater, which may have implications for glyphosate-tolerant GM crops. Thus member states generally understand precaution to mean identifying and clarifying uncertainties, sometimes in discussion with stakeholder groups.

Companies are responding in various ways to the extra requirements of the revised Deliberate Release Directive, for example the requirement for case-specific monitoring of commercial use for possible adverse effects. Monsanto, for its glyphosate-tolerant oilseed rape and beet and Bt cotton, argues that no specific risks have been identified or that risks are effectively zero, so no monitoring is necessary. Pioneer, for its Bt maize, concludes there would be 'no significant risks' for non-target organisms so does not propose to monitor those organisms. However, Pioneer acknowledges 'a limited potential' for the target pest to develop Bt resistance and so has drawn up monitoring and risk management plans to safeguard the product. Bayer, for its glufosinate-tolerant oilseed rape, has proposed plans for monitoring the occurrence, impact and management of glufosinate-tolerant volunteer plants and weeds, even though it believes the crop poses negligible risks.

Other issues relating to commercialisation that still have to be resolved include how to define 'adverse effects' in risk assessment (what baseline to use), how to phase out antibiotic-resistant marker genes, how to devise workable rules for traceability and labelling, and what measures are needed to allow the co-existence of GM and conventional crops.

Now that the US government has initiated a case against the EU under WTO rules, understandings of precaution may become more important. US pressure on the EU could lead to commercial authorisation of more GM products, or could instead strengthen demands for greater precaution and thus result in further delays.

EU Regulation of GM Crops: What Role for Precaution?

1 Introduction

European conflicts over GM crops have generated many difficult policy issues, for example:

- How should the EU deal with the controversy and go beyond the de facto moratorium?
- What is the relevance of precaution?
- How could various accounts of precaution help to deal with the conflicts in practice?

Such questions become more compelling as European authorities try to deal with several product files awaiting decisions, amid pressures for extra conditions and a US-led challenge to the EU at the WTO.

This document surveys EU-wide views on precaution in general, its relevance to uncertain risks of GM crops, and practical issues around regulatory procedures. It draws on a current research project, 'Precautionary Expertise for GM Crops', which is analysing how current European practices compare with various accounts of the precautionary principle. It looks at new institutional arrangements which may help to accommodate conflicting views and wider public concerns. The document mainly draws on the EU-level part of the study, with some material from national studies. It sketches views based on documents and interviews.

2 Precaution in general

In official accounts of the Precautionary Principle (PP), uncertain risks can justify temporary measures to avoid potential harm. For example:

Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation
(Principle 15 from Rio UNCED conference, 1992).

... precaution is normally applied by risk managers in case of established scientific uncertainty that risk assessors cannot reduce, eliminate or quantify (European Commission, reply to US FDA, 2000).

For implementing the Precautionary Principle (PP), an EU-wide common understanding has been sought by the European Commission, especially through its 2000 Communication on the PP. However, 'uncommon' understandings are readily apparent, even among EU institutions. Many organisations speak of 'precaution' or 'the precautionary approach', often interchangeably with the PP. This is a source of potential confusion, since often the same term is used in different ways, while different terms are used in similar ways.

All these 'precautionary' terms play various roles in informing regulatory procedures, expertise and social participation and may offer opportunities to deal with conflicts. A survey of 'precautionary' understandings can help to identify practical roles for precaution which lie beyond the formal scope of the Commission Communication. Examples of the views of EU-level organisations are paraphrased below.

European Commission

PP is a special case triggered by scientific grounds for uncertainty about any risk which may exceed the chosen level of protection. The PP applies mainly to risk management of such uncertainty, e.g. by seeking or requiring additional scientific information for a more complete risk assessment. Precautionary measures must satisfy criteria of proportionality, non-discrimination, consistency and a cost-benefit analysis of technological options. Triggered in such a way, the PP is distinct from the 'caution' normally applied in risk assessment.

Parliament

The PP can be triggered by initial suspicions or empirical assessments, not only after comprehensive studies have been done. Risk assessment should emphasise unknowns, e.g. the margin of uncertainty and the degree of ignorance. Trade agreements cannot be invoked to restrict precaution: the SPS Agreement places the burden of evidence on WTO Members, and not only on the Member which blocks a product. Precaution can generate alternative solutions: objectors should demonstrate that the alternatives are less harmful than the product to be replaced.

Economic and Social Committee

As well as gaining new knowledge for risk assessment, precaution means staging a wide-ranging social debate on what is desirable and what is feasible. Risk assessment must be fostered as part of the negotiation mechanism on social issues. Its actual role in society is to provide the bases for dialogue. The advancement of democracy requires new decision-making processes. Decisions will have to be taken on the basis of uncertain and extremely complex data rather than scientific certainties.

Scientific Steering Committee

Quality of life encompasses a state of complete physical, social and mental well-being. Beyond traditional risk assessment and management, quality of life criteria have already been included in the process in a non-systematic way via the precautionary principle and by considering public concerns, for example in issues such as BSE, GMOs and pesticides.

NGOs

Precaution should emphasise unknowns in risk assessment and enhance participation. Asking the right questions needs the involvement of stakeholders. Uncertainty may be not only preliminary but systemic, e.g. because of ignorance or indeterminacy: there are areas where more time and research may never allow for adequate certainty. Decisions on the acceptability of technologies and activities, as well as on the intensity of their control, requires a mechanism to identify the preferences of society.

Overview

These views indicate that there are diverse accounts of precaution, for example:

- as an exceptional case triggered by special circumstances, or as a general approach to risk assessment;
- as a consequence of inadequate information, or as a means to test its
- adequacy, e.g. by ensuring that all relevant questions have been asked;
- as a more rigorous approach by government officials, and/or as a social negotiation process;
- as a means to consider alternative technological solutions -- e.g., through cost-benefit analysis and/or through social preferences.

Each of those accounts can be used strategically, for example to justify a particular stance on products, or to mediate among conflicting views.

3 Precaution for GM crops: EU-level views

These views about precaution in general may limit or open up opportunities for dealing with conflicts over GM crops. A central question is how (or whether) the EU should move beyond the recent indecision on further commercial authorisations. Some views of EU-level organisations are paraphrased here, mentioning 'precaution' only when it was explicit:

EU Council

Decisions should be delayed until extra conditions are satisfied. In June 1999 most member states signed one of two statements with these common features: for new authorisations of GM crops, decisions should be suspended until the EU establishes a more transparent procedure for risk assessment, as well as rules for traceability and labelling. The PP (or precautionary approach) provides guidance for such regulatory changes and procedures. Some member states also demand clearer rules on liability.

Scientific Committee on Plants

There is no evidence of risk to human health or the environment from products awaiting a decision on commercial authorisation. For Bt maize, any non-target harm would be less than from agrochemical methods; and measures already proposed for Insect-Resistance Management (IRM) would be adequate to delay resistance. For herbicide-tolerant oilseed rape, the prospect of herbicide-tolerant weeds would arise more from volunteers than from out crossing; a stewardship programme is needed to manage this (agronomic) problem.

European Commission

The PP has been unwarranted for GM crops so far. Risk assessment should follow a case-by-case basis. The EU has never applied the PP to GM crops, except in the Avebe potato case, where the available information was inadequate for a risk assessment. For products awaiting a decision, expert advice has found no evidence of any potentially negative effects on the environment or human health, so those cases cannot justify recourse to the PP.

Its use must be strictly limited by evidence of risk or uncertainty, otherwise the PP may more readily come under challenge in international fora.

Biotech industry

Regulatory delay in approvals is not justified scientifically or legally, and severely jeopardises confidence in the EU regulatory system. Industry's risk assessment is based on scientific evidence rather than on assumptions.

Consumer NGOs

Commercialisation requires extra measures. Consumer NGOs do not challenge the safety of GM foods already approved, but point out that scientific risk assessment depends on the questions that scientists are to answer. So consumer NGOs want public transparency regarding the questions which are asked (or not asked) by scientific experts. Traceability and labelling are essential for consumer choice, e.g. to make their own judgements.

Environmental NGOs

Field releases should be stopped. Proof of safety is needed before commercialisation. Precaution requires more resources for risk research but field trials impose uncertain and unacceptable risks. Regulatory reform should start by analysing the agro-environmental problem, e.g., sustainability. Government should fund alternatives to both agrochemicals and GM crops. For all these reasons, environmental NGOs argue that the EU has not applied the PP to GM crops.

Farmers' organisations

The EU needs measures to ensure that adventitious presence of GM material does not undermine non-GM crops, since this would be an adverse effect. Also, COPA-COGECA wants rule for assigning responsibility for co-existence and for avoiding liability for farmers. CPE believes that because of important knowledge gaps, there is

no safe basis to release GMOs, so destroying field trials is a way to implement the precautionary principle.

4 National practices as precaution

Within EU member states, precaution is regarded as a general approach or process, not simply as a special case to be triggered. National debates and policy documents refer much to precaution but little to the Commission Communication. In a general sense, precaution means identifying and clarifying uncertainties about potential harm, in ways which sometimes involve discussion with stakeholder groups. When invited to participate in risk-assessment discussions, however, NGOs generally emphasise the need to develop alternative agricultural methods which they regard as more benign or sustainable.

Below are some brief examples of initiatives by national Competent Authorities (CAs) for the Deliberate Release Directive. Each example provides an explicit practical account of precaution, specific to national issues.

Netherlands

According to the Netherlands government, its risk assessment of GM products is based on scientific evidence rather than on assumptions, and thus is precautionary. In responses to files to market GM grain, Dutch experts on novel food and feed highlighted weaknesses in the available evidence about health risks.

They criticized inadequate data on the compositional equivalence of the GM crop to a non-GM crop, as well as from animal feeding studies on toxicological effects. They requested and obtained better evidence from companies. NGOs have welcomed the transparent and stringent approach to evaluation to novel foods but their main concerns are about how agricultural options relate to sustainability. In response to the environmental risk assessment of GM crops, NGOs have criticised the advisory committee (COGEM) for accepting poor-quality data and a comparative baseline of conventional agriculture, demanding instead a comparison to sustainable agriculture.

Germany

In the late 1990s the German government proposed a three-year large-scale cultivation and monitoring programme of GM crops, as part of a voluntary delay in commercialisation. This programme was to include research on gene flow from herbicide-tolerant oilseed rape, as a precautionary measure to gain knowledge for improving the risk assessment. However, the overall plan was changed when responsibility for GM crop regulation was shifted to the new Consumer Protection, Agriculture and Food Ministry, headed by a Green Party representative. The new Ministry initiated a *Diskurs grüne Gentechnik*, a debate on GM crops and the appropriate agro-environmental criteria for their commercialisation. The monitoring programme proposed previously was abandoned, though a new biosafety research programme was launched as part of the SDP-Green coalition agreement. Industry designed their own cultivation and monitoring programme for testing maize in agricultural practice. Among Ministries, arguments continue over whether adequate knowledge is available to justify commercial authorisation and what uncertainties need to be clarified beforehand. Meanwhile the German CA has cooperated with the Belgian CA for advising Bayer Crop Science on plans for market-stage monitoring of its herbicide-tolerant oilseed rape, as part of Bayer's request for commercial authorisation.

UK

In the UK nearly two-thirds of land is in agricultural use and is seen as a central part of the environment. In the late 1990s controversy arose over how GM herbicide-tolerant crops would affect herbicide usage and thus farmland biodiversity. Advisory bodies warned that broad-spectrum herbicides could 'sterilise' the countryside, turning agricultural fields into 'green concrete'. As a precautionary measure, the UK's CA (DEFRA) has funded farm-scale trials which aim to clarify effects on biodiversity. These trials compare such effects in GM crop fields and in adjacent non-GM crops. They were designed in consultation with stakeholder groups, which asked that the non-GM comparator should include fields which undergo relatively little spraying. The trials

themselves have generated further controversy, for example on possible 'contamination' of conventional crops, and on methodological issues which could limit the utility of the results. For example, the results would have statistical significance only for large differences in farmland biodiversity; yet some people may regard small differences as ecologically significant.

Denmark

Since the mid-1990s Denmark's CA (then the EPA) has requested an evaluation of how GM herbicide-tolerant crops may affect overall herbicide usage in the long term. As an impetus for this request, Danish environmental policy has sought to achieve substantial reductions in herbicide usage, partly because agriculture is regarded as part of the environment, and partly so that groundwater can be used directly as drinking water. Recently glyphosate was found in groundwater, so debate continues over the appropriate restrictions on its use, and this may bear upon an eventual decision about whether to permit glyphosate sprays on Roundup-Ready fodderbeet. Another uncertainty is how such herbicides may affect farmland biodiversity. To minimise any harm, voluntary guidelines ask farmers to limit and delay spraying; experiments have found that such practices can enhance weed flora and arthropod fauna, e.g. in the case of glyphosate-tolerant fodder beet. Concerns remain about whether farmers will follow such guidelines, and whether regular annual spraying will kill weeds before they can produce seeds.

5 Marketing applications

Under the revised Deliberate Release Directive, 19 products are awaiting decisions on commercial authorisation. Most are for grain import only, for several reasons. One is that with this modest request, political difficulties around the environmental risk assessment can be avoided. Another reason is that successful authorisation could overcome legal difficulties around imported grain containing traces of GM varieties not yet approved by the EU. This in turn would facilitate North American exports of grain, e.g. for use as animal feed, and thus GM seed sales to US farmers.

The revised Directive offers means to accommodate environmental uncertainties within commercial use of a GM crop. It requires case-specific monitoring to verify any assumptions in the risk assessment regarding prospects for a product to cause 'adverse effects'. According to subsequent guidelines: 'Where conclusions of the risk assessment identify an absence of risk or negligible risk, however, then case-specific monitoring may not be required.' For relevant risks, the guidelines mention insect resistance and the spread of herbicide-tolerance. The Directive also requires general surveillance for unanticipated risks.

Applicants have given various responses to the requirement for case-specific monitoring. In most cases, they claim that any risk is effectively zero or negligible, though this assessment may depend upon measures to manage uncertain risks. In the latter cases, the risk assessment is linked with a monitoring plan, which requires extra kinds of expertise. Below are some examples of company responses to monitoring requirements for marketing applications awaiting decisions under the revised directive.

Monsanto

Monsanto argues that their products warrant no monitoring under the Directive. A Monsanto product, *oilseed rape tolerant to glyphosate* (Roundup), is requested for grain import only. According to the company, its risk assessment is based on scientific evidence rather than on assumptions, so there are no grounds to require case-specific monitoring. This account of precaution is made explicit by the Netherlands CA in its assessment report. Nevertheless the UK Competent Authority (and some NGOs) have criticised the risk assessment for inadequate information.

Glyphosate-tolerant beet products have been submitted to Germany and Denmark for all uses including cultivation. According to the risk assessment of the fodder beet by DLF-Trifolium and Monsanto, no specific risks have been identified. The crop can

hybridise with weed beet, but glyphosate-tolerant hybrids would gain no selective advantage (in the absence of glyphosate) and thus would cause no environmental harm. So risk-management methods would be no different than for conventional fodder beet. Also, farmers' switch from selective herbicides to glyphosate allows a delayed application, which could enhance biodiversity in agricultural fields. The risk assessment assumes that glyphosate usage could not worsen biodiversity because conventional beet fields are currently kept weed-free. For all these reasons, the company proposes no statutory monitoring.

For *Bt cotton*, submitted to Spain, Monsanto's risk assessment says that scientific data show that the risk of non-target harm is effectively zero. Pests may gain resistance to Bt, but such an effect would be only an agronomic problem. On those grounds, no monitoring is proposed under the Directive, though the company plans to monitor fields for insect resistance on a voluntary basis.

Pioneer

Pioneer proposes to monitor for insect resistance. For a *Bt maize* product, submitted to Spain jointly by Pioneer and Mycogen, the risk assessment identifies two potential adverse effects. From the results of various studies, it concludes that the product would cause 'negligible' environmental impact resulting from potential interactions with non-target organisms. On such grounds of 'no significant risks', non-target organisms warrant no monitoring. The risk assessment acknowledges 'a limited potential environmental impact' for insect resistance to the Bt toxin. To ensure that the product poses negligible risk, 'appropriate monitoring and risk-management plans have been developed and proposed in the context of product stewardship'.

Bayer

Bayer proposes to monitor gene flow and farmers' practices. For Bayer's *oilseed rape tolerant to glufosinate* (Basta), in files submitted to Germany and Belgium, the risk assessment identifies two potential adverse effects: glufosinate-tolerant volunteers and weeds, the latter from outcrossing. Overall risk is assessed as nil, 'taking into account the risk management strategies'. On that basis, the company proposes case-specific monitoring to confirm its assumptions about the occurrence, impact and management of those potential effects. It aims to demonstrate that these are fully manageable in a practical way in farmers' fields.

Implementing the plan will require complex arrangements across institutions. Bayer mentions various 'expert networks' essential for the plan. The company realizes that it will need good communication, cooperation and shared responsibility with farmers. It will license the glufosinate-tolerance system to seed companies, rather than own and market the seed directly, so another layer of responsibility will need to be integrated in the monitoring plan.

6 Other issues

Commercialisation may depend upon other issues which are ambiguous in the Directive or which lie outside its formal scope.

The DG-Environment Biotechnology Unit hosts Working Groups of CAs to discuss some of these issues, which include agro-environmental effects, antibiotic-resistant markers, traceability and labelling, and co-existence.

Agro-environmental effects

Like the original Deliberate Release Directive, the revised one allows broad scope for judgements on what potential effects would count as an 'adverse effect' if they were to happen, as well as judgements on the evidence needed to evaluate their likelihood. Examples include the potential spread of Bt insect resistance and herbicide-tolerance. Some companies and member states have requested clarity on the norms or baselines for unacceptable effects, as guidance for doing the risk assessment. But it is difficult for regulators to set general criteria, especially on an EU-wide basis.

Antibiotic-resistance markers

The safety of antibiotic-resistance marker (ARM) genes has been under debate since the mid-1990s. Under the revised Directive, authorities must take a view 'to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment'. Some member states have interpreted this requirement as an eventual ban on ARMs in products to be commercialised, or even for field trials. Some, for example the Netherlands and Denmark, have asked companies to exclude all ARMs, even those which did not previously generate controversy. Excluding ARMs is easier for products with a herbicide-tolerance gene, which can also serve as a marker for identifying GM plants in the lab.

However, many of the 19 products awaiting an EU decision were constructed with an ARM. When CAs act as rapporteur for a product, they attempt to anticipate possible objections or requests from other CAs. For a Monsanto maize with an ARM which the German CA regards as safe, for example, it is proposing a time-limited registration until 2004.

Traceability and labelling

Traceability and labelling rules are mentioned in the Preamble to the Directive but are not elaborated there. Such rules have two main purposes: to facilitate monitoring of any adverse effects and linking these with a specific product; and to allow an informed consumer choice on whether to buy food derived from GM crops. The monitoring purpose explicitly involves precaution, by acknowledging uncertainty in risk assessment. Consumer choice has an implicit precautionary rationale, in so far as consumers may regard safety as uncertain.

Consumer choice depends upon specific criteria for labelling. Within the Commission's original framework of process-based labelling, compromises are being reached on two controversial criteria for adventitious presence of GM material in food. In cases where the operator can demonstrate efforts to avoid such presence, the following thresholds are now being proposed:

- 0.9% for EU-approved GM material
- 0.5% (for a three-year transitional period) for GM material not EU-approved but favourably evaluated as safe by an EU scientific committee.

An allowance for non-approved GM material has gained support for many reasons, e.g. to ensure that the overall agro-food chain is not disrupted by illegal traces of GM material.

These proposals will be considered when drafted regulations go to a second reading at the Parliament plenary in early July.

Industry maintains its previous arguments that process-based labelling would be unwarranted and unworkable, especially for the trans-Atlantic grain trade. They fear that consumers will interpret a 'GM' label as 'a skull and crossbones', which may lead retailers to exclude GM ingredients.

Co-existence

Given the possible spread of GM volunteers or pollen, there have been long-standing arguments about whether transgene flow would irreversibly transform the environment or 'contaminate' conventional crops. As a response, the term 'co-existence' expresses compromise measures to ensure freedom of choice to produce GM and non-GM crops. Some environmental NGOs have argued that co-existence would be difficult or impossible. Industry, national governments and many farmers' organizations seek feasible measures to make it possible.

The debate involves several issues: the mutual responsibility of farmers to avoid adventitious contamination, the role of government in these arrangements, and the legal basis. Member states have requested clarification on these issues. For example, can adventitious presence be regarded as environmental damage, or only as an economic problem? In that regard, the UK has invoked Article 16 of the Directive to justify statutory requirements for isolation distances, as requested by Wales, to provide an environment where non-GM crops can be grown.

According to a March 2003 proposal from the DG-Agriculture Commissioner, Franz Fischler, the EU would best be involved in coordination and advice only, so that each national authority could specify measures appropriate to its conditions. Authorities could develop or clarify legislation to provide liability for economic damage from adventitious presence. For new legislation, the constitutional basis could be Article 37 of the EC Treaty, which authorises managing an economic risk from agriculture. The Directive cannot be used to regulate adventitious GM presence because it would not be environmental harm, Fischler argues. On that basis, local authorities may not simply use a ban to declare entire areas 'GM-free', as proposed in some member states, e.g. Austria.

This proposal has drawn mixed responses. The farmers' association COPA welcomed the commitment to address liability in the case of economic loss to non-GM farmers. According to several environmental NGOs, however, the Commission was 'dodging its responsibility' to prevent genetic contamination in agriculture.

EU and national studies have analysed the feasibility of co-existence measures, on the basis of thresholds in current draft legislation for GM labelling. Current cultivation practices may be adequate to ensure co-existence for many crops, but extra measures would be needed for the three major crops awaiting commercialisation - maize, beet and especially oilseed rape - in which case extra costs may be incurred. The feasibility and costs to farmers will depend upon factors which lie somewhat beyond their control, for example GM thresholds in non-GM seeds, and the local extent of GM cultivation.

Feasibility studies have developed predictive models which incorporate several types of knowledge, including information on seed banks, gene flow, cultivation practices, cropping systems and landscape patterns. There are proposals to test and refine such models by obtaining more data, for example from intermingled farming patterns, scaled up production, outcrossing at longer distances, and monitoring the efficacy of isolation measures. In such ways, co-existence extends expertise already developed for the risk assessment and risk management of GM crops.

7 WTO case against the EU

When the US government initiated a WTO case against the EU in May 2003, this step carried out a familiar threat. In the past, such threats have backfired by intensifying European resentment towards both the USA and GM crops, thus making any accommodation more difficult. For example, when the Commission proposed rules which could simplify GM-labelling requirements for grain shipments, some member states and MEPs rejected such proposals as concessions to the USA. The Commission warned the US government that its threats were polarising the issues in Europe. Likewise the European biotechnology industry foresaw that a WTO case would be counter-productive for progress towards commercialisation.

The USA went ahead anyway, by attacking the EU Council moratorium as unjustified and unscientific, and even blaming Europe for blockages of food aid in Africa. In response, the European Commission criticised the US action as 'legally unwarranted, economically unfounded and politically unhelpful': indeed, they argued that there is no moratorium, given that EU regulatory procedures are operating. EuropaBio defended the EU regulatory system for GMOs as 'transparent and workable'.

This complaint to the WTO has high political stakes. Apparently the US government has aims going far beyond GM crops in the EU, for example to deter similar restrictions elsewhere in the world, and to weaken stringent or precautionary measures in other regulatory sectors. US pressure could push the EU system towards commercial authorisation of GM products; or else it could backfire, for example by strengthening demands for greater precautions and thus result in further delays.