Science and Public Policy, volume 32, number 4, August 2005, pages 261–276, Beech Tree Publishing, 10 Watford Close, Guildford, Surrey GU1 2EP, England

European Union

European Union regulation of agri-biotechnology: precautionary links between science, expertise and policy

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Despite various institutional reforms in the European Union (EU), regulatory procedures for genetically modified (GM) products are still held up by disagreements among experts; claims about a product's safety often correspond to a narrower account of precaution than broader counter-claims from objectors. In the EU, we argue, these conflicts have given practical meaning to the concept of precaution, rather than any explicit interpretation of an* a priori *principle. Through dynamic tensions between the various claims and accounts of precaution, EU regulatory-expert procedures have identified and addressed more scientific uncertainties than before. Yet decisions about GM products still face legitimacy problems, because they arise fundamentally from the great burden placed on science as the basis for societal choices about agri-biotechnology.

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This paper arises from a research project, 'Precautionary Expertise for GM Crops' (PEG), funded by the European Commission, Quality of Life programme, socio-economic aspects, during 2002–2004 (contract no QLG7-2001-00034). The authors are grateful to their research partners and other colleagues, in particular, Theofanis Christoforou, Jim Dratwa, Hervé Martin, Sylvie Mestdagh, Prof Tim O'Riordan, Sujatha Raman, Suzy Renckens, Linda M Smith, Armin Spoek, Andy Stirling, Professor Joyce Tait and Rene von Schomberg.

AGRI-BIOTECHNOLOGY HAS remained deeply controversial in Europe, especially when it is used as a symbol of wider issues. For proponents, genetically modified (GM) crops offer hope for a more environmentally benign, sustainable and economically competitive agriculture. For opponents, these products pose threats of globalisation undermining democratic sovereignty, environmental resources and consumer choice.

Stakeholders have sought to promote or prevent market access to GM products. This conflict has been played out in various arenas, for instance, attempts to carry out, block or even destroy field trials of GM crops; national bans on GM products that had already gained EU-wide approval; court hearings on the legal status of regulatory decisions and of protest actions; food-chain operators under pressure to label products as 'GM' or else to substitute alternative ingredients; member states voting on whether to approve new GM products; public debates over alternative forms of agriculture and R&D priorities; and mass-media reports on such issues.

In all those arenas, 'precaution' has been widely invoked, often to justify blockages or alternatives to agbiotech, though sometimes to justify safety claims. Not surprisingly, precaution itself has become a contentious concept. Indeed, its usage has been criticised as merely rhetorical, especially as a pretext for political agendas. Nevertheless precaution has been widely accepted in Europe for dealing with uncertain risks.

Precaution became more explicit in 1999, when the EU-level regulatory procedure was blocked. At

 0302-3427/05/040261-16 US$08.00 © Beech Tree Publishing 2005

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the June 1999 meeting of the Environment Council, many member states declared that they would not consider further requests for commercial authorisation until new conditions were fulfilled, "given the need to restore public and market confidence". According to declarations they signed, the EU must first adopt measures to ensure full traceability and labelling of GM crops across the agro-food chain, and risk-assessment procedures must be more transparent, based on precaution.

The subsequent regulatory delays have been often called 'the *de facto* EU Council moratorium' — a misnomer for a period of intense activity. Policy makers worked on new legislation to meet the demands of member states; they continued to ask companies for more rigorous data to demonstrate product safety. Meanwhile, institutional reforms have included more stringent laws, broader expert bodies and stakeholder involvement.

On that new basis of national and EU arrangements, regulatory procedures resumed to consider proposals for approving GM products in 2003. To analyse those new procedures and their policy role, this article discusses the following questions:

- To help reach regulatory decisions, how did the EU redesign advisory expertise and statutory procedures?
- What conflicts arose over the basis for evaluating and commercialising GM products?
- How did those conflicts involve different accounts of precaution, implicitly or explicitly?
- How did the EU's new arrangements help to deal with those conflicts, by comparison to arrangements in the late 1990s?

The questions can be illuminated by analytical perspectives on expertise and precaution. These are surveyed in the next section and are cited again for their relevance in the conclusion. Overall, this EU-level analysis draws on extensive documentary sources and numerous semi-structured interviews, as referenced in our report (Levidow *et al*, 2005); it also draws on national studies cited here.

Analytical views on expertise and precaution

EU-level scientific expertise has become more important and controversial through its role in European integration. Such expertise has been designed to overcome or reconcile national regulatory differences that may block internal trade within the EU. Institutional reforms have involved conflicting models of expertise, science, regulatory standards and the EU itself. Precaution has offered a flexible means to deal with such conflicts, through more explicit approaches to scientific uncertainty. This section surveys analytical perspectives on EU expertise and then on precaution (especially from the June 2003 special issue on 'Democratising expertise' of this journal), for their relevance to the case study of agbiotech.

Expertise for European regulatory integration

Not very long ago, European regulatory procedures generally reached decisions by giving deference to expert claims:

> "European officials and the public tend to accept as 'science' any issues that their technical advisory committees are prepared to treat as science. There is apparently little concern that policy issues will illegitimately be decided by scientists under the guise of technical decision-making," (Jasanoff, 1987, page 225)

Such images of objective, policy-free expertise were undermined by several crises, culminating in the 1996 BSE (bovine spongiform encephalopathy or mad cow disease) crisis. Beforehand, UK expert

Before the BSE crisis, UK expert advice had downplayed important uncertainties about the disease and about weaknesses of preventive measures: experts aimed to give advice that would be politically acceptable to regulators, while avoiding public alarm about any risks

advice had downplayed important uncertainties about the disease and about weaknesses of preventive measures. This advice was presented as purely scientific, yet it was framed by policy assumptions and commitments. Experts aimed to give advice that would be politically acceptable to regulators, while avoiding public alarm about any risks (Millstone and van Zwanenberg, 2001).

The European Commission likewise covered up the problem, for fear that public concern about the BSE problem would endanger the European beef market, according to a report by the European Parliament (1997). Subsequent revelations led to a legitimacy crisis that was often diagnosed as a 'democratic deficit'. In particular, EU regulatory procedures were illegitimately equating expert advice with science, as a basis to pre-empt or conceal political decisions.

In response to that crisis, the EU attempted to enhance the public accountability of expert advice and of its policy use. From 1997, new procedures sought to separate expert advice from policy, by separating responsibility for risk assessment from risk-management decisions. Eventually this meant a new regime for food safety, which has been analysed as a strategy to regain legitimacy: "Supra-state regulators can overcome their democratic deficit by being more transparent, providing more opportunities for public participation, giving reasons for their decisions, and exercising less technical or administrative discretion", argues a political scientist (Skogstad, 2003, page 5).

Under a 2002 food law, the European Food Safety Authority (EFSA) was created as an independent body that would help set 'science-based' standards for risk assessment. In establishing EFSA, the European Commission involved representatives of industry and non-governmental organisations (NGOs) as partners with a shared understanding of policy problems, especially the need to gain public confidence (Smith *et al*, 2004).

Such reforms have featured a tension between two tendencies: transferring authority from national to EU-level expert bodies and the Commission (sometimes called centralisation), versus strengthening EU regulatory committees, which represent member states. Their role has remained essential for democratic legitimacy, argues Christian Joerges (1997, pages 221–222): Assuming that:

> "the Europeanization of markets requires institutional structures which ensure both the effectiveness and the legitimacy of risk assessments, then we are bound to strive for institutional solutions which transcend the boundaries of our constitutional States without replacing these States with a Europeanized equivalent."

Within regulatory committees, decision-making has featured conflicts of authority, especially over 'political' issues that may warrant a broader procedure beyond technical expertise. For example, decisions are often justified as "adaptations to technical progress". Yet "the difficulty of distinguishing between political and technical questions also provides an opportunity to those who might wish to reduce political questions to technical ones" (Landfried, 1999, page 181). Amid such strategies, the regulatory committees have considered normative issues in a deliberative way. Participants face pressures to address disputes through claims for the common good, rather than invoke sectional or national interests. This process has been called a 'deliberative supranationalism', that is, inter-governmental deliberation without a central state authority (Joerges, 1999, pages 315, 319).

The European integration project has needed at least a mutual recognition of different regulatory standards among member states through EU procedures. Yet such efforts often "reveal differences in standards and practices across Europe", argues Andrew Barry (2001, pages 82–84). Regulatory standard-setting for technology should be understood as a cultural policy, yet EU institutions tend to treat such issues as merely technical ones, while presupposing or designing a European cultural unity that can readily overcome such differences (Barry, 2001, page 65). EU institutions reduce public concerns to biophysical risk, in turn reduced to science, as if this were the only public meaning of 'risk' issues. Such a framing ignores public concerns, for instance, about limits of scientific knowledge, commercial forces influencing science, and public accountability for the forces driving innovation (Wynne, 2001).

Precaution and uncertainty in expert judgements

In mainstream policy language, precaution is variously criticised or defended with reference to 'science', for instance, its limitations or capacity for predicting risks, respectively. Beyond such arguments, moral–ethical issues arise in using and generating scientific knowledge for risk assessment. Precaution incorporates two kinds of normative obligations: prudential ones in seeking to anticipate potential harm, and moral ones in judging the adequacy of available knowledge.

> "The conflicts over precaution concern the nature of the relationship between the norm's prudential and the moral components … Should the capacity of current scientific knowledge define the baseline for moral action, so that we ought to act preventively only when we can scientifically foresee the harms that may ensue from inaction?" (Jasanoff, 2003, page 229).

That question has become contentious because 'science-based risk assessment' generally downplays long-term systemic effects, and also socio-cultural values underlying science. Precaution can highlight the limits of available knowledge, thus implying a

moral obligation to test and strengthen the epistemic basis of safety claims (Jasanoff, 2003).

Indeed, precaution implies a different model of science as a basis for risk assessment. By contrast to a positivist model, "it is more accurate to view science in general and scientific research in particular as products of a technical and sociological process that involves both objective and subjective observation", argues a European Commission staff member. Scientists should apply technical precaution in risk assessment:

> "it is of paramount importance for risk assessors to explain in detail any kind of scientific uncertainty they encounter in any step of their analysis and the techniques, assumptions and values they employ to eliminate or reduce it."

When evidence shows credible scientific disagreements among experts, this can establish uncertainty about risk, especially under EU law and policy frameworks. Risk managers may exercise regulatory precaution in such cases of uncertainty about potential harm, without having to establish a direct causal link to potential harm (Christoforou, 2003).

Such harm depends on 'the chosen level of protection', that is, a norm of unacceptable effects; that level may be implicit, explicit and/or controversial. There is an interplay between predictive and normative uncertainties: "the uncertainty of the science is related to the uncertainty of what still could count as acceptable in terms of health and environmental effects" (von Schomberg, 2006).

Moreover, uncertainty depends on the questions that are asked and the process that generates them. Precaution can justify uncertainty, not simply *vice versa*. For agbiotech in the late 1990s, "the risk controversy was constituted by divergent accounts of the relevant scientific uncertainty" (Levidow, 2001). Precaution offers a stronger means to raise new questions and thus to identify unknowns.

Precaution can highlight various unknowns in risk assessment, argues Andy Stirling. There may be ambiguity in the choice of framing assumptions, for instance, about causal pathways of potential harm, and thus the basis for generating and evaluating evidence. Uncertainty may also involve epistemic ignorance — 'what we don't know that we don't know'. Assessors make value choices about how to frame unknowns and indeterminacies, so there cannot be a definitive version called 'sound science'. As an alternative, a deliberative process among stakeholders can highlight ambiguity and ignorance, so that framing assumptions can be made more transparent and deliberative:

> "In acknowledging that the problems of scope, incommensurability and ignorance in risk assessment are otherwise intractable, active stakeholder engagement in the appraisal process becomes a matter of analytical rigour." (Stirling, 1999, page 20)

Therefore the term 'uncertainty' can be misleading, for instance, as if it always meant an uncertain probability of known harms (Wynne, 1992). Unknowns go beyond that concept: 'uncertainty' means inadequate knowledge to predict the likelihood of discrete outcomes. 'Ambiguity' means that outcomes remain poorly defined, for instance, because divergent framing assumptions preclude a single definitive account. In cases where both types of unknowns are great, this means uncertainty about our uncertainty, that is, ignorance (Stirling, 1999, page 26; 2003, pages 42–46). By recognising and addressing such unknowns, precaution can inform knowledge-generation. By considering a wider range of options, "a precautionary process extends the knowledge base for risk appraisal" (Stirling, 2003, page 53).

Risk assessment also involves assumptions about human behaviour — "how society must be organised so that the technology will behave in accordance with established risk assessments". Such assumptions play an ambiguous role in the "grand social experiment" of negotiating technologies (Wynne, 1995, page 31). In scaling up new technologies, "real-life experiments" are designed to test assumptions about behaviour and its effects (Krohn and Weyer, 1994).

To enhance policy-relevant knowledge in general, important expertise lies beyond official organisations, and often citizens become engaged in deliberative processes of science-related governance issues. Their involvement can benefit government: for example, public trust in decision-making can be restored, and participants are more likely to accept the outcome, argue Funtowicz *et al* (2000).

Although such expectations of trust or consensus may be over-ambitious, there are other reasons for broader participation and public debate on risk issues. For example, often expert knowledge addresses the wrong question, thus missing relevant aspects. Although wider participation can be helpful, "the main purpose of a public debate is not to eliminate the conflict, but possibly to clarify what [the] conflict is really about" (de Marchi, 2003, page 172). The rest of this paper draws on those perspectives to analyse recent changes in EU agbiotech regulation and in expert advisory arrangements, especially their role in handling regulatory conflicts.

Policy context of EU agbiotech regulation

Since the mid-1990s, conflicts have intensified within the EU-level regulatory committees responsible for decision-making on GM products. Some member states sought to translate public concerns into regulatory criteria, for example, through relatively broader definitions of harm to be prevented and scientific uncertainties to be managed. However, these proposals were rejected by other member states and the European Commission, which were effectively harmonising regulatory criteria through

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narrow standards, thus facilitating approvals of GM products (Levidow and Carr, 1996).

Stimulated by public protest against agbiotech, several governments blocked the EU regulatory procedure in June 1999, in declarations later known as the EU Council *de facto* moratorium. In response, EU institutions developed a new policy framework, incorporating more diverse accounts of expertise and scientific uncertainty:

> National regulators (and advisors) are flexibly redefining the 'adverse effects' to be assessed, translating broader cause–effect uncertainties into technical criteria, and discussing these measures at the EU level. Such flexible standards can be understood as an integral part of the harmonisation process, rather than as a failure to achieve a universal norm (Levidow and Carr, 2000, page 205).

The revised Deliberate Release Directive (2001/18), which named the precautionary principle as its basis, had stronger precautionary features than its predecessor. It mandated public access to information, as a basis for public consultation and comment on GM products before any regulatory decision. The Directive required a broader risk assessment, linked with market-stage monitoring to manage uncertain risks: "It is important not to discount any potential adverse effect on the basis that it is unlikely to occur" (EC, 2001, page 20). According to extra guidelines, moreover, "the overall uncertainty for each identified risk has to be described" (EC, 2002a, page 32).

For food products in general, in 2003, the EU also established a new expert body, the European Food Safety Authority (EFSA). In 1997, the Commission had already restructured advisory expertise to establish a "functional separation between risk assessment and risk management". EFSA's design went further by providing clearer links between those roles. The EFSA Management Board represented bodies across the agro-food chain, including consumer organisations, while its Advisory Forum included mainly representatives of expert advisory or regulatory bodies of member states.

EU-level expertise was also designed to provide an authoritative form of science. EFSA panels were "to act independently of any outside influence". According to the DG-SANCO Commissioner, objective scientific advice would be kept separate from policy considerations; this procedure aimed to inform "a solidly science-based policy and to increase consumer confidence" (Byrne, 2002).

As another policy aim for EFSA, centralised expert advice would help to harmonise risk assessment and even precaution. According to the 2002 food law establishing EFSA, "it is necessary to adopt a uniform basis throughout the Community for the use of this [precautionary] principle" (EC, 2002c, page 2). In case of disagreements with other expert bodies of member states, EFSA would resolve these or else clarify their basis in a joint document (EC, 2002c, article 30).

According to a later law for agbiotech regulation in particular, EFSA had a role "to ensure a harmonised scientific assessment of genetically modified foods and feed" (EC, 2003, page 4). EFSA would also give an opinion on each GM crop proposed for cultivation, in cases where member states disagreed about the environmental risk assessment. Some governments anticipated that centralisation would marginalise national expertise and contexts. For example:

> "Denmark questions whether EFSA would have a sufficient competence to cover the natural and environmental differences in the EU regions." (Økonomi-og Erhvervsministeriet, 2001)

> "The European procedure should include multidisciplinary expertise with the specific strengths of each national advisory committee … Before the moratorium, we used to acknowledge our own gaps in expertise and rely on the expertise of other member states, which complemented each other. This is my hope of a democratic expertise for Europe." (interview, national regulator, 2002)

EFSA's structure had a single integrated Scientific Panel on GMOs. After prospective members nominated themselves, the list had been successively shortened by the Commission and the EFSA Management Board. Implicitly, the selection criteria sought to enhance 'rationality' and avoid 'political bias'. Of the nominees originally considered, some were publicly known as favourable, while none had publicly criticised safety claims for GM products. After the Panel was chosen, environmental NGOs criticised its composition as biased, partly on those grounds, and partly on the grounds that many members had national roles as expert advisors or as regulators evaluating the same GM products. When NGOs argued that this overlap undermines expert independence (FoEE, 2004), EFSA replied that relevant expertise depends on prior experience.

As a policy framework for the agri-biotech sector, EU statements have emphasised scientific evidence as the basis for societal decisions, while acknowledging that non-scientific issues are also relevant. According to the Commission, technological progress carries socio-ethical implications that "cannot be adequately addressed within the narrow context of regulatory product approvals" (CEC, 2002). Consequently, EU procedures need transparency, accountability and participatory approaches.

According to the Commission, nevertheless, risk regulation "is the expression of societal choices": rules should ensure that market mechanisms function effectively, so that safe products are available to accommodate consumer preferences (CEC, 2002, page 14). Moreover, "science-based regulatory oversight" aims "to enable Community business to exploit the potential of biotechnology while taking account of the precautionary principle and addressing ethical and social concerns" (CEC, 2003b, pages 6, 17). Thus EU policy has defined agri-biotechnology as an expert scientific issue, involving precaution, though kept separate from socio-ethical issues.

Precautionary meanings and policy roles

Among companies, regulators and their expert advisers in the agbiotech sector, there has been a general reluctance to draw explicit links between their practices and precaution, except to make a political point in justifying a policy or decision. Nevertheless various practices may be informed by precaution. This section sketches general precautionary accounts and their role in EU policy debate, so that subsequent sections can analyse how practices compare to those accounts.

General accounts of precaution

Official definitions leave considerable scope to interpret precaution. According to a declaration from the 1992 UNCED conference in Rio: "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" (UN, 1993). This concept was extended through more stringent language by the EU. According to EU food law, wherever "the possibility of harmful effects on health is identified but scientific uncertainty persists", authorities may adopt "provisional risk management measures necessary to ensure the high level of health protection chosen in the Community" (EC, 2002c, page 9).

In 2000, the European Commission issued a communication on how the precautionary principle should be interpreted and implemented. It aimed to guide member states so as to deflect international criticisms that the EC's precautionary approach served as an unfair trade barrier, for instance, regarding animal hormones or agri-biotechnology. It linked precaution with scientific uncertainty, which can arise from the methods for generating knowledge; such methods include the choice of variables, measurements, samples, models and causal relationships (CEC, 2000, pages 13–14).

According to the communication, the precautionary principle can be triggered only by reasonable grounds to expect "potentially dangerous effects" that jeopardise the "chosen level of protection". On that basis, recourse to restrictive measures is justified only until extra scientific information is obtained to allow a more complete risk assessment. "However, this is not always linked to the time factor, but to the development of scientific knowledge" (CEC, 2000, page 19).

Emphasising criteria for a trigger, this account has been portrayed as a common understanding across EU institutions. Yet different and broader accounts can readily be found in key EU documents and expert practices. Diverse accounts are even more apparent among other bodies.

Table 1 provides a heuristic device for analysing how expert advice and regulatory practices correspond to different accounts of precaution. The text in the left-hand column paraphrases Commission documents, while that on the right comes from other sources (such as the European Parliament, the Economic and Social Committee, expert advisers, member states and stakeholder groups). Their statements may overlap more than the table indicates. It

Table 1. Accounts of the precautionary principle (PP) in the EU

Narrow accounts	Broader accounts
Prior risk assessment	
The burden of evidence is inherently shifted, from demonstrating risk, to demonstrating safety	The burden of evidence depends on the questions asked: asking the right questions needs stakeholder involvement
When doing a risk assessment, scientists apply caution — not to be confused with precaution	Precautionary risk assessment should identify uncertainty and ignorance about potential risks
Trigger for PP	
PP can be triggered only by an objective scientific evaluation, indicating reasonable grounds to expect potentially dangerous effects (or established scientific uncertainty)	PP can be triggered also by initial suspicions about risk
	PP can justify measures to control undesirable effects (including potentially dangerous ones)
Scope of action	
Analyse policy options — regulatory action versus inaction — eg through a cost–benefit analysis	Provide the means to demonstrate that alternative solutions are less harmful
	Establish a dialogue on social issues, eg what options are desirable and feasible

encompasses accounts of 'precaution' and 'the precautionary approach', as well as 'the precautionary principle'. Narrow versus broad approaches to risk assessment in general have been outlined by Stirling (1999, pages 29–31). These accounts should be seen not as fixed types but rather as points on a continuum, or even as dynamic tensions within regulatory procedures.

Contending policy agendas

There are links between policy agendas and different accounts of precaution. When EU-level regulatory procedures for GM products resumed in 2003, contending policy agendas included:

- Agbiotech opponents (for instance, environmental NGOs and many farmers): GM products are 'genetic pollution', impose unpredictable or unacceptable hazards, deny consumer choice of non-GM products, and increase farmer dependence on multinational companies. Less-intensive agricultural methods provide more benign alternatives and more appropriate comparators for GM products in risk assessment, than conventional agriculture. On precautionary grounds, the EU Council moratorium must be maintained until safety is shown.
- European Commission: EU regulatory procedures must be implemented in a scientific, rational manner. According to objective, independent advice from EU experts, there is no evidence of risk or uncertainty for GM products awaiting a decision. Precaution may be applied as a management measure in cases of established scientific uncertainty about potentially dangerous risks. This policy will enable Community business to exploit the potential of biotechnology, while taking account of the precautionary principle. Such regulatory procedures are also necessary for complying with EU and international treaty obligations.
- Agbiotech industry: Europe will gain environmental, agronomic and economic benefits by commercialising GM crops. Risk assessments for our GM products show that any risks are negligible, for instance, because the evidence demonstrates safety, or because any uncertainties can be managed at the commercial stage. If regulations impose precautionary measures, they should be proportionate to the risk. Consumers should have the right to choose GM products as well as non-GM ones. Regulatory delays deprive Europe of the benefits.

Not surprisingly, agbiotech opponents have espoused broader accounts of precaution, emphasising unknown risks, while proponents have espoused relatively narrow accounts. Regulatory authorities and their expert advisers have developed practices that correspond to more diverse, flexible accounts of precaution. Analogous policy framings of precaution have arisen at the national level (for instance, Boschert and Gill, 2005; Marris *et al*, 2005; Toft, 2005).

NGOs have played a role in reinforcing, publicising and sometimes stimulating more rigorous approaches by regulatory authorities. In that sense, stakeholder involvement has been important for analytical rigour in risk assessment (compare with Stirling, 1999). In consultation procedures, NGOs have also demanded resources for alternative solutions to agricultural problems; in this way, their participation highlights what the conflict is really about (compare with de Marchi, 2003), though without the means to address its fundamental sources. Member states and NGOs have raised similar uncertainties about risk assessment, though their agendas differ.

Since the late 1990s, mainstream consumer groups have argued that a more transparent and rigorous risk assessment is essential to gain public confidence in regulatory procedures. Many of their specific criticisms have been accommodated in extra data requirements, especially for GM food safety (Schenkelaars, 2005). Partly through those regulatory changes, consumer groups have accepted the safety of GM foods already approved.

By contrast, environmental NGOs have emphasised uncertain, irreversible risks. In making detailed criticisms of GM product files, they have pursued several aims: to arouse public suspicion, to justify regulatory blockages, and to demonstrate that their opposition has a scientific basis (for instance FoEE, 2004). Groups representing small-scale farmers have also opposed agbiotech, sometimes by supporting attacks on field trials of GM crops as a 'contamination' threat to non-GM crops (CPE, 2002).

When EU regulatory procedures for new GM products resumed in 2003, the files submitted by companies underwent many stages of scrutiny, by a national Competent Authority (CA) as EU-wide rapporteur, by other CAs, and by EFSA's Scientific Panel on GMOs. This procedure has accommodated some objections, while generating further conflicts, which involve different accounts of precaution. The next three sections elaborate each element of Table 1 in turn, although its three elements may be related in

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practice. Each section starts with general accounts of precaution, as a basis for comparing expert practices in the agri-biotech sector.

Prior risk assessment

Precaution in general

In industrial sectors that require a risk assessment and prior approval of each product, especially when similar products have not yet shown evidence of harm, this requirement establishes a precautionary framework. According to narrow accounts of precaution, such a requirement inherently shifts the burden of evidence: the burden lies with applicants to demonstrate safety, not simply with others to demonstrate risks. However, in risk assessment, scientists apply caution, not to be confused with precaution, which applies only to the risk-management stage.

In relatively broader accounts, precaution is relevant to risk assessment as well as to risk management. Precaution means seeking to identify unknowns and ignorance, while questioning assumptions and extrapolations. Research may be needed to improve the available knowledge, for instance, by devising more reliable methods to test complex causal pathways and by obtaining more rigorous evidence that could reduce dependence on assumptions. Truly reversing the burden of evidence depends on how questions are asked in risk assessment. The involvement of diverse stakeholders, including critical scientists and NGOs, can help ensure that as many relevant questions as possible are addressed.

Precaution for agbiotech

In line with broader accounts, some national CAs seek to identify uncertainties explicitly within risk-assessment procedures for agbiotech products. For example, they identify methodological weaknesses, unreliable extrapolations from existing knowledge, or optimistic assumptions in evidence. Partly in response to public protest, some member states have funded more research on ecological uncertainties, for instance, transgene introgression in France, herbicide effects in the UK and Denmark, and Bt toxin effects in several countries. For the latter risks, more sensitive research methods were adapted through interactions between the EU and USA (Murphy *et al*, 2006).

In response to the applicant's risk assessment, CAs identify inadequacies in the evidence, as a basis to request more reliable or complete information. When a CA initially regards a company file as satisfying statutory requirements for a risk assessment, other CAs have raised objections. Often disagreements concern the adequacy of evidence, for instance, molecular characterisation or toxicological tests.

As regards possible health effects, some CAs criticise product files on the grounds that routine tests have used poor-quality or inappropriate methods, have yielded anomalous or suspicious results, or have not been carried out on hybrids (only on the GM parental lines). Some CAs have requested new risk research and/or extra control measures to manage uncertain risks. They have sought more knowledge to establish a 'normal' baseline of conventional products for comparison with GM products.

Given those disagreements, EFSA has been asked to make its own judgement. In each case, EFSA's GMO Panel has generally argued that the evidence is adequate for a risk assessment, and that the GM product is as safe as the corresponding non-GM product. The EU procedure has generated extra information that can accommodate some objections, for instance, as regards molecular characterisation and extra toxicity tests. Panel members have justified some extra requirements as necessary to 'confirm safety' or 'reduce uncertainty', thus leaving ambiguous any perception of hazard. However, in some cases the Panel has accepted weak evidence or anomalous results as adequate.

In particular, conflicts have ensued over the practical meaning of substantial equivalence for assessing GM food safety. EU-level experts recast this 1990s concept as a 'comparative approach' for identifying any differences between a GM crop and its non-GM counterpart. According to the EFSA Panel's guidance document, risk assessments should clarify "the baseline used for consideration of natural variations" (EFSA GMO Panel, 2004). However, expert disagreements emerged over the normal baseline, especially for toxicological tests (see Box 1).

Statutory guidelines specify that "the overall uncertainty for each identified risk has to be described" (EC, 2002a, page 32). Panel opinions generally have not done so, having identified no risk. Panel opinions criticise weaknesses in evidence of risk but rarely do likewise for evidence of safety, thus indicating an asymmetrical scrutiny. Panel members acknowledge that data evaluation involves "scientific value judgements" and see these as precautionary issues:

> "Precaution is an integral part of risk assessment. Panel members are aware of uncertainties, eg lack of data, incomplete data, poor quality of data and extrapolations from data. These are issues of debate within the Panel … If we feel that a file is incomplete, then we will ask for further experiments or look at other information sources. The GMO Panel in its discussions has covered the issue, even without using the word 'uncertainty'." (interview, member of EFSA's GMO Panel, 2004)

The Panel received requests to make uncertainty explicit, especially in responses to its April 2004 draft guidance document for applicants. According to the revised document, a "risk characterisation" should explain uncertainties about data and about assumptions. For example, this can mean uncertainties in

Box 1. Shifting the burden of evidence

For several generic issues, there have been disagreements about how to assign or shift the burden of evidence. This depends on how questions are asked about the available knowledge and unknowns, for example, in looking more for similarities than differences between a GM product and its non-GM counterpart. Given conflicts among CAs, EFSA's GMO Panel gave opinions on these issues during 2003–04.

Normal variations?

Substantial equivalence depends on comparing a GM food to a normal baseline, which in turn depends on 'normal variations'.

> "The concept of substantial equivalence has been used and abused by some people. The concept can be interpreted to mean a comparison only to the parental (non-GM) material. But we need to look at a GM product in the context of the entire species, which may have a huge variation. If a GM product falls within that range, then perhaps there is no risk. If it does not, then we need to ask what risk there may be." (interview, member of EFSA GMO Panel, 2004)

How to interpret variations has been contentious, featuring ambiguity about test methods and potential hazards. After testing whole GM grain on animals, some results have been apparently abnormal. From retrospective data analysis, companies have indicated a wider 'normal range' of variation in test animals fed on conventional grain, so that the GM grain tests need not indicate any risk. Such safety claims have led to expert disagreements that concern ambiguity about test methods, reliable knowledge and potential hazards.

In the case of Monsanto's GT73 rapeseed, GM-fed rats had higher liver weights in one of three animal tests. The company retrospectively found a greater normal variation across all the tests, as grounds to accept the original tests as adequate for risk assessment. The EFSA GMO Panel did likewise, while citing safety results of tests on other animals. However, UK experts in feed safety criticised this basis for comparing the results and opposed approval of the product.

In the case of Monsanto's MON 863 maize, French experts criticised abnormal test results in GM-fed rats. The German CA submitted a critical report by Arpad Pusztai. The company retrospectively documented great normal variations at the relevant stage of animal development. On such grounds, the EFSA GMO Panel argued that the test results were statistically significant but not biologically significant and thus adequate for a risk assessment. Some national experts remained sceptical; as one remarked:

> "There are few reliable peer-reviewed studies on food safety. Given the data on significant differences between parent lines and the GM lines, and the scientifically questionable integration of historical controls to keep the data within the 'normal' variation, this seems to be urgent. How do we get a consensus or define when 'significantly different' is 'biologically not relevant'?" (personal communication, national expert, 2004)

Extra toxicity tests on GM hybrids?

Expert bodies have disagreed about the need for extra lab tests on GM hybrid crops, implicitly concerning ignorance about unknown hazards. For a cross between Bt 11 field maize and conventional sweet maize, in 2000, the Scientific Committee on Food had regarded the product as safe, while acknowledging some weaknesses in the overall company data. Some CAs demanded whole-food sub-chronic toxicology tests on the hybrid, as a means to predict any harmful effects, for instance, from an unknown novel protein. The Commission proposed and granted approval without the extra data, and without an opinion from EFSA. Few member states voted for approval.

For the first-ever hybrid of two GM crops in the EU regulatory procedure (MON 863 x 810), many CAs argued that whole-food toxicology tests must be done on the hybrid itself, while other CAs accepted tests on the two parent lines of the hybrid as adequate. EFSA's GMO Panel published a split opinion, with some members arguing the need for "confirmatory data" to demonstrate safety. This opinion potentially left great scope for further disagreements among CAs, for instance, about the predictability of hypothetical effects.

Instead, EFSA itself declared that the extra tests would be necessary. According to a staff member, "EFSA has a responsibility to reach a conclusion on risk assessment, so therefore EFSA decided to request the disputed study" (interview, 2004). This outcome provided a stronger basis for regulators to reach a decision and for the GMO Panel to reach consensual opinions in future cases, especially given that many more GM hybrids have been submitted under the GM Food and Feed Regulation.

extrapolating from animals to humans, or from small-scale tests to large-scale contexts, while considering "the robustness of ecosystems". Moreover, applicants should explain "the scientific basis for different options to be considered for risk management" (EFSA GMO Panel, 2004, pages 46–50). In future, this wording could stimulate more transparency in framing uncertainty and assigning a burden of evidence.

Trigger for the precautionary principle

Precaution in general

Accounts differ over what should be the trigger criteria for a decision to apply the precautionary principle (PP), understood as special measures to manage uncertain risks. According to a narrow account, the PP can be triggered only by reasonable grounds to expect 'potentially dangerous effects' that jeopardise the 'chosen level of protection' or acceptable level of risk. According to broader accounts, the PP (that is, special risk-management measures) can be triggered by initial suspicions or inadequate evidence about uncertain risks. In these accounts, precaution is seen as a process and approach, not simply as decision criteria to be triggered.

The trigger for precautionary measures also depends on views about what counts as 'the chosen level of protection'. This means judgements about what is an unacceptable risk or adverse effect. Some member states interpret this broadly to encompass 'undesirable' effects, not only 'dangerous' ones. Under EU law and international agreements, each

jurisdiction may define its own appropriate level of protection.

Precaution for agbiotech

As in relatively broad accounts, many EU member states understand and practice precaution as an overall process, especially for the agbiotech sector (for instance, Oreszczyn, 2005, for the UK case). Some CAs have implemented or proposed measures for managing uncertainties, often on grounds of suspicion or inadequate evidence, not necessarily evidence of risk. Such measures accommodate undesirable agronomic–environmental effects that were not previously (or universally) evaluated as 'harm' or 'adverse effects'. These include the spread of herbicide-tolerant weeds, insect resistance to Bt, and inadvertent mixtures of GM material with non-GM products.

As an example of managing uncertainty, Bt insecticidal crops have undergone market-stage monitoring for potential effects such as insect resistance and harm to non-target organisms. Since 1998, Spain has used national laws to require such efforts (Todt and Luján, 2000; Tàbara *et al*, 2004). For similar products awaiting EU authorisation, companies have undertaken to monitor commercial use for the development of insect resistance. Some member states have proposed additional requirements, for instance, to monitor non-target harm or to establish buffer zones for preventing it (for example, Toft, 2005, for the Danish case).

Some national procedures evaluate 'undesirable' effects as well as 'dangerous' ones. In Denmark, undesirable effects explicitly include GM admixtures with conventional products (Toft, 2005). Among EU member states, segregation from non-GM products has become a general issue for grain imports. For GM rapeseed import, some CAs have demanded extra measures to prevent and detect any spillage (see Box 2).

As national CAs express those uncertainties, EU expert advice has absorbed them into requests for extra information and into its own consensual advice on safety. EFSA's published opinions generally indicate no uncertainty that would trigger extra risk-management measures, beyond companies' proposals for managing insect resistance to Bt. Conflicts have continued over the basis for suspicion about uncertain risks, as appropriate grounds to impose management measures, thus indicating a tension between narrow and broad accounts of precaution (see Box 2).

For some GM products, regulators make further judgements about how to monitor and discipline human practices that matter for agro-environmental effects. For cultivation of herbicide-tolerant oilseed rape, the applicant (Bayer) proposed measures for farmers to control the spread of herbicide-tolerant weeds. As the CA acting as EU-wide rapporteur, Belgium expressed doubt that such controls would be feasible, as a reason ultimately not to support approval for cultivation. Thus the company did not achieve its regulatory aims by incorporating a relatively broader account of precaution.

As an explicitly precautionary measure, the UK sought to simulate farmers' commercial behaviour through four-year farm-scale evaluations. These aimed to clarify the effects on farmland biodiversity from spraying GM herbicide-tolerant crops, by comparison to spraying their conventional counterparts. From the results, the Government proposed to authorise commercial use of Bayer's GM herbicide-tolerant maize, though with extra restrictions to protect farmland biodiversity and to segregate GM crops. In response, the company withdrew its application, on the grounds that the restrictions made the crop 'uneconomic' (Oreszczyn, 2005).

Different accounts of precaution can be seen in efforts to segregate GM crops in cultivation, given the prospect that GM material may be inadvertently mixed with non-GM crops. For crop segregation, Commission recommendations sharply distinguish environmental from economic harm. For the latter, any rules must be justified as proportionate to the context and the economic problem (CEC, 2003a). That Commission policy had been revised to accommodate Wales' statutory rules on isolation distances for GM crops. Eventually Carinthia revised its draft law on coexistence to accommodate the Commission's criteria (Torgersen and Bogner, 2005).

Going further, many regional authorities have entirely blurred any distinction between economic, agricultural and environmental harm, in ways corresponding to broader accounts of precaution. Taking up NGO arguments, many authorities have declared that co-existence would be impossible, while counterposing alternative forms of agriculture. They have linked 'GMO-free zones' with 'quality' labels on food products. Their Europe-wide association sees GM crops as a threat to "sustainable and organic farming and to regional marketing priorities for their rural development" (FFA, 2005; AER/FoEE, 2005). They continue plans to establish 'GM-free zones', contrary to Commission policy.

Scope of action

Precaution in general

According to narrow accounts, the PP involves considering the practical consequences of inaction or action, in the form of risk-management measures. The relative merits of these options can be evaluated by a cost–benefit analysis that goes beyond economic criteria (for instance, CEC, 2000, page 4). According to broader accounts, the precautionary principle involves considering a wider range of options, for example, supporting the development of alternative products and processes that bear less risk

Box 2. Triggering risk-management measures?

For several generic issues, there have been disagreements about whether uncertain risks warrant management measures, sometimes called 'applying the precautionary principle'. Some disagreements implicitly concern 'the chosen level of protection'; the higher the level, the greater the uncertainty and so the greater warrant for restrictions. Given conflicts among CAs, EFSA's GMO Panel gave opinions on these issues during 2003–04.

Antibiotic-resistance marker (ARM) genes

Antibiotic-resistance marker (ARM) genes have been used to identify and select the GM plant in the lab. Their use has been criticised for potentially undermining the efficacy of therapeutic antibiotics, if they were to spread from a GM crop to pathogenic microbes. Most expert advice judges this scenario as unlikely, but some CAs have regarded the possibility as unacceptable, on grounds that all antibiotics must be preserved.

The GMO Panel stretched its role on this generic issue in April 2004, by making normative judgements about essential ARMs and dispensable antibiotics. It judged that biotechnologists lacked practical alternatives to the ARMs most commonly used. It also judged which antibiotics have the greatest clinical importance, as grounds for the EU to phase out the corresponding ARM genes. Its opinion became a reference point for disagreements among member states, which were trying to reach a common view in the CAs' working group on ARMs. Some CAs proposed that all ARMs be phased out, corresponding to a broader account of precaution.

Post-market monitoring

The Directive requires case-specific monitoring (CSM) to confirm any assumptions about adverse effects in the risk assessment, except in cases where no risks are identified (EC, 2002b). In all cases, the Directive requires "general surveillance" for potential risks not identified. Member states have regarded general surveillance as less meaningful than CSM, which would experimentally test a specific cause–effect hypothesis. Some CAs have sought CSM to test safety assumptions based on inadequate evidence. By contrast, EFSA's GMO Panel has understood CSM as mandatory only for assumptions that harm would happen — for which it saw no evidence. Indeed, according to its guidance document, CSM is necessary only when a risk assessment already has evidence of "expected adverse effects". So the Panel held workshops instead on scientific methods for general surveillance, seen as a potential substitute for requiring CSM.

In the case of Bt insecticidal maize, companies undertook to monitor commercial use for emergence of insect populations resistant to Bt, but some CAs proposed CSM for non-target harm too. Some CAs argued that the available test data did not adequately encompass European species and environments (FoEE, 2005b). Some cited a lab experiment indicating possible harm to earthworms (Zwahlen, 2003a; 2003b).

In its risk assessments of Bt maize, the EFSA GMO Panel raised uncertainties about whether that experiment had demonstrated a causal relationship between the Bt toxin and harm to earthworms. More generally, its opinion emphasised methodological difficulties in detecting any non-target harm in the field, as extra grounds for why CSM would not be cost-effective. In its view, non-target harm should be relegated to general surveillance.

In further comments, Panel members raised doubts about the likelihood and extent of any harm in the field, as in these two views:

> "The weight difference between the Bt and non-Bt treatment was not very strong in the lab, and was absent in the field experiment. It's also a matter of precaution to avoid publication of false-positive results. The difference found in the Zwahlen study could be a sampling error." (interview, Panel member, 2004)

> "In the experiments by Zwahlen *et al*, the effect was apparently not dramatic in the sense that a whole population was lost from the habitat. And the system is resilient enough to return to normal after the Bt exposure. Even if the Bt caused the weight loss, apparently it has an ephemeral character." (interview, Panel member, 2004)

Thus the burden of evidence was shifted back to those who would require CSM.

Inadvertent spillage or mixtures of GM rapeseeds

For the import of GM oilseed rapeseed, member states anticipated that any spillage could lead to admixture with conventional oilseed rape and/or extra herbicide sprays for weed control. Taking up an argument from NGOs, Italy proposed extra controls to avoid interbreeding between GM grain and wild *Brassicas*, on grounds that their country was a centre of diversity for *Brassica* crops. Such governments sought rigorous statutory monitoring and controls to prevent spillage. From the company's standpoint, however, it could not feasibly accept such a responsibility at ports and processing plants.

According to the Panel's opinion, GM rapeseed would be as safe as its non-GM counterparts, and EU authorisation anyway would permit seed import only, not cultivation. Moreover, the Panel accepted the company argument that import and processing occurs in industrial areas, making it unlikely that germination would transfer genes to other *Brassicas*. The Panel's advice thus assumed that spillage would not happen and/or could not cause environmental harm; in any case, segregation issues lie beyond EFSA's remit. Citing EFSA's safety advice, the Commission omitted any extra controls in its proposal for product approval. Few member states voted in favour; sceptical views expressed a broader account of precaution, as regards uncertainty about control measures and consequences of non-compliance.

GM-free zones vs co-existence

In 2002, Upper Austria declared a 'GM-free zone' to protect organic crops and environmentally sensitive areas. Here Austria was blurring the distinction between environmental and economic harm, while treating the latter as an undesirable effect, thus corresponding to broader accounts of precaution. In response, the Panel ruled that Austria had presented no new evidence of environmental risk to justify the regional ban. Citing that advice, the Commission rejected the ban, while noting that segregation could be achieved by other means, through coexistence measures under Commission policy (CEC, 2003a). Also the Commission agreed to amend the Deliberate Release Directive so that "Member states may take appropriate measures to avoid the unintended presence of GMOs in other products" (EC, 2003a, page 20).

or offer clearer environmental benefits. Broader accounts promote dialogue about social issues, for example, about what options are desirable and feasible.

Precaution for agbiotech

In the agri-biotech sector, member states consider various types of regulatory inaction versus action, for example: requests for extra scientific information; demands for market-stage monitoring; and liability for inadvertent admixtures with conventional products. As reasons for or against imposing extra requirements, governments and their expert advisers may consider consequences such as: greater regulatory burdens on companies; greater public trust in expert advice; and biophysical effects of a product.

When NGOs take part in stakeholder discussions, they criticise regulatory criteria as too lax, while emphasising the need for alternative agriculture innovations. Some member states have opened up discussion of policy options for GM crops and alternatives for sustainable agriculture more generally. Illustrating broader accounts of precaution, such practices can be seen in several countries, for instance, in the Netherlands, Germany and the UK. Innovation systems independent of large agribusiness companies was a prominent theme in the French national workshop of our project; likewise possible futures for 'multiple agricultures' were linked with precaution in our EU-level workshop.

Sustainable agriculture has diverse, contradictory meanings: agbiotech proponents make eco-efficiency claims for GM crops, while critics demand less-intensive alternatives. For example, sustainable agriculture has been associated with 'quality' production, such as *prodotti tipici* (local specialty products) in Italy and organic methods in Austria. From their anti-agbiotech policy frameworks, the Italian and Austrian national regulatory procedures have framed scientific uncertainties in ways that make risk assessment more difficult for GM crops, for instance, by evaluating their benefits unfavourably *vis à vis* alternatives.

The UK Government's advisory committee has investigated methods for comparing environmental impacts of various cropping systems. In Germany, the Government initiated the *Agrarwende*, a turn in agricultural policy towards consumer interests and choices; new research has promoted alternatives to intensive agricultural methods (Boschert and Gill, 2005).

Consequences of regulatory inaction or action lie beyond the formal remit of EFSA's GMO Panel. Nevertheless, its members consider whether more laboratory experiments are warranted by uncertain risks, whether market-stage monitoring would be cost-effective, whether additional requests would unfairly burden companies, and whether restrictions would impede agbiotech innovation.

At a general level, the Commission has encouraged civil society involvement in influencing R&D programmes and as partners in EU-funded projects (for instance, IFOK, 2003). NGOs have been involved in some projects relevant to GM food safety. However, the Commission's Framework Programme VI has little scope for generating alternative R&D priorities for agricultural methods, and such alternatives have no link with EU regulatory procedures for agbiotech.

Sustainable agriculture has diverse, contradictory meanings: agbiotech proponents make eco-efficiency claims for GM crops, while critics demand less-intensive alternatives

Precaution underlying expert disagreements

Expert–regulatory conflicts involve precautionary issues, as the previous sections have demonstrated. Through dynamic tensions among different accounts of precaution, EU regulatory–expert procedures have identified and addressed more scientific uncertainties than before. Analysing those patterns, this section returns to the questions that were posed at the start of this article, especially how the new EU arrangements dealt with regulatory conflicts during 2003–04. The answers draw on analytical perspectives that were surveyed earlier.

Since the EU agbiotech regulatory procedure resumed in 2003, the new framework has provided greater scope to accommodate the conflicts that led to an impasse in the late 1990s. Risk-assessment criteria include some issues that were previously excluded as 'non-risk' issues or 'other' factors, for instance, agro-environmental effects of GM crops and inadvertent admixtures with non-GM crops. Extra guidelines mandate more rigorous criteria for evidence and an explicit treatment of uncertainty. As a means to deal with expert disagreements among member states, EFSA was meant to provide objective, independent advice, though some experts more modestly describe their opinions as 'scientific value judgements'.

EU-level regulatory procedures address diverse regulatory norms through a deliberative supranationalism, as in other regulatory sectors (Joerges, 1997). National CAs contribute to a Europe-wide expert network, by exchanging views on GM product files and on generic issues of risk assessment, especially in joint working groups. In this way, they contribute to a Europe-wide expert network. In criticising proposals to authorise GM products, some CAs may be acting on policies beyond agbiotech, fro example, to protect special forms of agriculture. Nevertheless,

they generally express their criticisms as plausible harm or inadequate scientific information, in terms that can be universalised, rather than as national economic interests. Indeed, such demands are taken up or accommodated by other member states.

Despite institutional reforms since the late 1990s, regulatory disagreements continue, for instance, over the criteria for evidence, definitions of harm and means to manage uncertain risks. The burden of evidence is shifted back and forth by asking questions differently from before. Broader precautionary approaches increase uncertainty, even in cases where more knowledge is available (on a similar GM product or risk issue) than before the *de facto* moratorium.

According to Commission guidelines, a more complete risk assessment depends on "the development of scientific knowledge"; yet additional knowledge undergoes critical scrutiny, highlighting more scientific unknowns. For the examples cited here, such unknowns can be analysed as forms of uncertainty, ambiguity or ignorance (as in Stirling, 1999). More stringent norms of harm have meant greater uncertainty about adequate knowledge to predict risks, for instance, as regards antibiotic-resistant marker genes or agri-environmental effects (compare with von Schomberg, 2006).

Also at issue have been control measures in commercial use, through operator self-discipline to follow rules in grain import or crop cultivation. In judgements on control measures — as necessary, adequate, feasible, and so on — experts seek to anticipate or design commercial use as an experiment, as in other cases of technological scale-up (compare with Krohn and Weyer, 1994). Some expert bodies have doubted that real-life commercial practices could be adequately disciplined to conform to the optimistic assumptions in risk assessments (compare with Wynne, 1995).

In its published opinions, EFSA's GMO Panel has specifically responded to objections from member states. Its opinions have framed scientific uncertainties in such a way that they can be resolved by extra information, or can be readily manageable, or can be deemed irrelevant to any risk. Often its advice involves judgements in a grey area between risk assessment and risk management, thus providing a seamless link with any decision on regulatory approval.

The Commission has staff members formally responsible for the interface between risk assessment and risk management, but EFSA has effectively carried out this task itself, by stretching its remit. For example, EFSA has judged what extra information is necessary, what potential effects would be unacceptable or relevant, and whether extra management measures are necessary.

Despite efforts to accommodate diverse views through EU-level expert advice, disagreements have continued among member states and with the Commission, which has used that advice to override dissent. Within expert–regulatory circles, the continuing conflicts have often been described as 'science versus politics'. Proponents and critics of safety claims have accused each other of being motivated by politics rather than science. However, it is more helpful to analyse expert disagreements as a dynamic tension among different accounts of precaution.

Precaution has been given its practical meanings through these conflicts, rather than through an explicit interpretation or application of an *a priori* principle. Formal safety claims — of the company, the rapporteur CA or EFSA — often correspond to a narrower account than that of objectors. Narrower accounts sharply define the risk problem and evidential criteria, thereby more readily justifying a regulatory decision. Broader accounts leave the risk problem more open-ended, while emphasising limits of available knowledge. The latter approaches can more flexibly accommodate issues from public–scientific debate but remain subject to an ever-increasing burden of evidence and/or managerial responsibilities.

Limits of 'science-based regulation'

For the agri-biotechnology sector the European Union has developd a precautionary framework to provide a more rigorous and transparent basis for regulatory decisions. In parallel, the European Commission has established the European Food Safety Authority (EFSA) to provide the Commission with objective, independent advice. As an EU policy framework for 'science-based regulation', statutory guidelines specify risk-assessment criteria, but expert bodies disagree over how to interpret them.

Views about what uncertainties are relevant or acceptable are informed by policy aims, in ways that correspond to different accounts of precaution. Policy actors play down or emphasise various uncertainties — to challenge evidence of risk or of safety, to justify their stances on a particular product, to pursue greater rigour in demonstrating safety, to mediate among conflicting views, and/or to delay politically awkward decisions.

EFSA faces a dilemma in reconciling diverse national views through its own expert advice, which may overlap (and/or conflict) with the policy remit of EU regulatory committees. In responding to conflicts among member states, EFSA has interpreted its remit flexibly. It has requested additional information from applicants, sometimes by stretching the official timetable. Its GMO Panel has consulted a wide range of other experts and stakeholders. EFSA has continued to consult CAs on product files, beyond the formal requirements of centralised legislation, that is, the GM Food and Feed Regulation: "We have learned from the past: there can be different views among member states, so it is better to know their scientific views sooner, before EFSA gives an opinion" (interview, staff member, 2004).

Risk assessment depends on a policy framework — a link increasingly discussed in international fora.

For food safety, Codex has mandated a "risk-assessment policy", which would make explicit the following judgements: the range of relevant impacts; criteria for evidence; and responses to scientific uncertainties (CAC, 2003, page 126). More generally, risk assessment makes assumptions that frame the relevant knowledge (Millstone *et al*, 2004).

Thus, expert advice involves risk-assessment policy, notwithstanding claims otherwise, for instance, that "risk assessment should not involve policy issues" (interview, EFSA staff member, 2004). Although EU advisory expertise has been designed to gain cognitive authority as objective science, specific advice involves moral–prudential judgements, for instance, about whether available knowledge is adequate (compare with Jasanoff, 2003). Precaution offers flexible means to address such issues that anyway arise in EU regulatory procedures, and to assign responsibility for possible consequences, by shifting or clarifying regulatory criteria.

Within EFSA's GMO Panel, views differ about the policy role of their advice. One member expressed an expert strategy of acting both scientifically and politically at once:

> "Some governments are running strong political agendas on agri-biotech, sometimes by using scientific arguments. The EU has an agenda to separate science from politics, as a step towards transparency about the political basis of objections to GM products. Some countries have difficulty in defending their stances (in scientific terms). EFSA is like the High Court: after EFSA gives an opinion, it becomes more difficult for a country to return to its earlier risk assessment." (interview, member of EFSA's GMO Panel, 2004)

By contrast, others expressed

> "concern that the isolation of the safety assessment from other debates (socio-economical, biodiversity …) was somewhat artificial and that the EFSA 'safe' stamp could potentially be abused for political purposes to legalise GMOs (Panel members' views summarised in FPA, 2004, page 29).

Citing EFSA's safety advice, the Commission has sought to overcome EU regulatory blockages, partly to strengthen the EU case in the US-led trade dispute, and also to implement EU laws. It has attempted to push files for GM products through EU regulatory procedures and to lift national restrictions. However, during 2003–04 the Commission's proposals did not gain even a simple majority of member states, much less the qualified majority needed for straightforward approval (FoEE, 2005a). This low support indicates a gap between EU regulatory procedures and public–scientific concerns among member states, though few CAs explain why they withhold support from GM product approvals. The many abstentions may indicate conflicts among ministries within a national government. Under its legal authority, the Commission has approved some of those GM products.

Ensuing conflicts have continued the EU's legitimacy problems from the late 1990s blockages. Meanwhile, the sources of those problems are obscured by prevalent policy language. It makes many assumptions, such as: that 'science-based regulation' can find an objective expert basis for decisions; that precaution and socio-ethical issues remain external to risk assessment; and that risk assessment can be functionally separated from risk management.

The analysis here offers alternative understandings of the problem: regulatory conflicts involve different ways to link science with policy, corresponding to different accounts of precaution. Through dynamic tensions between those various accounts, EU regulatory–expert procedures have identified and addressed more scientific uncertainties than before. However, EU decisions about GM products still encounter legitimacy problems, because they arise fundamentally from the great burden placed on science as the basis for societal choices about agri-biotechnology.

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Note: All reports from the PEG project are available at <http://technology.open.ac.uk/cts/peg/index.htm>. The research drew upon numerous documents, especially company notifications for placing GM products on the market and CAs' assessment reports, all available at <http://gmoinfo.jrc.it/gmc_browse.asp>; also EFSA opinions on those products, available at <www.eu.efsa.int>.

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