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**EUROPEANISING ADVISORY EXPERTISE:
The role of ‘independent, objective and transparent’
scientific advice in agri-biotech regulation**

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Abstract

Since various crises of food safety in the European Union (EU), institutional reforms have been designed to regain public confidence in regulatory decisions and their expert basis. By Europeanising advisory expertise, the European Food Safety Authority (EFSA) was also meant to help harmonise ‘science-based regulation’ and thus facilitate EU decisions. In evaluating agri-biotech products during 2003-2005, however, the EFSA procedure extended previous expert disagreements rather than overcome them. EFSA was designed to demonstrate that expert advice would be ‘independent, objective and transparent’; yet tensions arose between expert experience versus independence, between transparency versus objectivity, and between harmonisation versus precaution. These conflicts have been shaped by the dominant problem-diagnosis, which favours a narrow expert consensus within a specific policy view. Alternative problem-diagnoses suggest that expertise should instead be pluralised, so that norms and uncertainties become more explicit. Pressure for EU reform manifests tensions between the dominant and alternative problem-diagnoses.

Outline

Acknowledgements	2
1 Introduction: European expertise in crisis.....	3
2 Europeanising advisory expertise: policy and analytical perspectives.....	3
2.1 Europeanising advisory expertise through ‘functional separation’	3
2.2 Divergent problem-diagnoses for advisory expertise	5
3 EFSA’s origins and tasks	6
4 Agri-biotech regulation: more precautionary and harmonised?	7
5 Independent expertise?.....	8
6 Objective and transparent advice?.....	9
6.1 Enacting objectivity	9
6.2 Enacting transparency.....	11
6.3 Pluralising expertise?.....	12
7 Conclusions: Tensions of expert roles and problem-diagnoses.....	13
Table 1: Diagnosing EU Policy Problems for Expert Advice	15
References	16

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Seminar at the STS Department, Kennedy School of Government, Harvard University, chaired by Prof. Sheila Jasanoff, on 18 May 2005.

1 Introduction: European expertise in crisis

Risk regulation and its expert basis have faced a crisis of public credibility in the European Union (EU). Since the mid-1990s, the BSE crisis has been compounded by other food safety controversies, e.g. around dioxins, additives and growth promoters. These crises undermined public trust and extended national regulatory differences, which impeded the EU internal market.

In response, EU and national authorities have developed institutional reforms. These have aimed to demonstrate publicly that regulatory procedures would address public concerns, consumer interests and scientific uncertainty. Reforms have sought to Europeanise advisory expertise, through new bodies and procedures to accommodate or adjudicate between diverse views among national experts.

As a specially contentious sector, agri-biotechnology provides an extreme test case for the results of EU reforms. In this case the putative remedy, designed to avoid or overcome regulatory conflicts, turned out to extend them. To analyse why, this article addresses the following questions:

- i. Since agri-food safety issues and advisory expertise became controversial in the mid-1990s, how have the EU's policy problems been diagnosed? How have these diagnoses informed policy changes and institutional reforms? (See sections 2 and 3.)
- ii. What have those general reforms meant for the agri-biotech sector in particular? What has been their outcome for the official aim that expert advice should be 'independent, objective and transparent'? (See sections 4-6.)
- iii. What are the policy implications of this outcome for Europeanising advisory expertise? (See the concluding section 7.)

As a method for answering those questions, an EU-wide research project first analysed relevant documents, e.g. policy statements, legislative frameworks and risk assessments for specific GM products. This analysis then informed the questions for semi-structured interviews with key individuals (regulators, expert advisors, companies and NGOs). In particular they were asked how regulatory-advisory procedures address scientific uncertainty, expert disagreements, national-EU conflicts, and links between risk assessment and risk management. This article is based mainly on the EU-level study (involving approximately 20 interviews), as well as the EU-wide context from the seven national studies. The interview material influenced the analysis and selection of detail here. (See also Acknowledgements section.)

2 Europeanising advisory expertise: policy and analytical perspectives

European integration, itself a contentious project, has assigned changing roles to EU-level advisory expertise. This section surveys analytical perspectives on those roles: first, strategies to enhance the cognitive authority of advisory expertise; and second, diverse diagnoses of the policy problems facing such expertise.

2.1 Europeanising advisory expertise through 'functional separation'

European integration has linked the EU internal market with standard-setting in various ways. Named after a prime architect, the 'Monnet method' envisaged a low-politics process, avoiding the most contentious issues. A few hundred Commission staff would set thousands of national experts to work at technical standard-setting, as a means to achieve an internal

market (cited in Weale, 1999: 44). This project was initially seen as a technical-administrative task of lowering trade barriers, also known as negative integration, but such a strategy encountered limitations. As an alternative, Europeanisation has generally meant efforts towards positive integration through a standard-setting process (Joerges, 1997, 1999).

Trade barriers often resulted from member states devising their own product standards for health and safety. EU policy saw these regulations as potentially justified, unlike some national trade barriers designed to protect specialty products, e.g. beer or cheese. But attempts at mutual recognition had little success in avoiding trade barriers in the 1980s, so Commission policy sought to harmonise standards, especially for product safety issues. The relevant expertise was available mainly at national level; member states were reluctant to transfer powers concerning such politically sensitive matters to the Commission without being allowed a role in decisions. So in the 1990s the Commission sought to establish a European-wide scientific expertise acceptable to all participating national experts (Vos, 1997: 138-39). These new expert bodies advised EU regulatory committees, which in turn shared decision-making authority with the Commission.

At the same time, the 1990s EU policy agenda sought to 'complete the internal market' in a more extreme sense than before. It meant recreating Europe as an artificially 'free', deterritoralised space for the smooth mobility of labour, capital and goods. This aim needed at least a mutual recognition of regulatory standards among member states through EU procedures; yet such EU competence could 'reveal differences in standards and practices across Europe' (Barry, 2001: 82-84). Such national differences have arisen even in relatively uncontroversial sectors, thus indicating an 'uneven geography of Europeanisation' (Perkins and Neumayer, 2004: 884).

Given those expert disagreements in the 1990s, EU-wide regulatory conflicts led to numerous court challenges, especially over food products. Sometimes these involved conflicts about how to interpret the precautionary principle. The European Court of Justice faced national regulatory differences – not only regarding claims for food safety, but also regarding uncertainties about evidence.

A series of food scandals, especially the 1996 BSE crisis, undermined official images of policy-neutral expertise at both national and EU levels. Expert advice had implicitly made policy assumptions, e.g. that real-world practices would follow risk-management guidelines (Jasanoff, 1997; Millstone and van Zwanenberg, 2001). To address its legitimacy problems, the EU now attempted to separate risk-assessment advice from risk-management decisions. In reorganising its scientific committees accordingly, the Commission aimed to obtain timely and sound advice, 'based on the principles of excellence, independence and transparency' (EC, 1997).

To pursue those aims, in 1997 all the expert advisory committees were transferred to DG 24 for Consumer Affairs, later renamed DG-SANCO. Formerly the relevant committees were hosted by the Directorate-General responsible for the corresponding legislation. The new arrangement was formalised as a policy: 'experts responsible for scientific risk assessment should be kept functionally separate from those responsible for risk management' (e.g., EU Council, 2000). Formerly, governments had nominated prospective members of the committees; now such individuals were invited to nominate themselves for consideration and were asked to declare any material interests, e.g. sources of research funding, in an effort to enhance expert independence.

That plan for expert independence was meant to support 'science-based regulation', a global discourse which prevails in international agreements. These give EU decision-makers

incentives to align their own practices with that of the WTO, especially ‘by grounding their own food safety measures more solidly in a science-based regulatory approach...’ This alignment aims to avoid trade retaliation, while also creating scope for precaution within WTO procedures (Skogstad, 2001: 496, 498).

2.2 Divergent problem-diagnoses for advisory expertise

In keeping risk assessment functionally separate from risk management, the EU was attempting to enhance public credibility. According to an EU report on governance, regulatory responsibilities often seem blurred:

“It is often unclear who is actually deciding – experts or those with political authority. At the same time, a better-informed public increasingly questions the content and independence of the expert advice that is given” (CEC, 2001: 19)

This general problem has divergent diagnoses, each with a corresponding to an institutional remedy (see Table 1). According to the dominant diagnosis, regulatory procedures may lack public credibility if advisory expertise involves disagreements, subjectivity, policy influence, etc.; as the corresponding remedy, the EU should harmonise expertise so as to provide consensual objective advice. According to alternative diagnoses, however, narrow expertise poses a problem:

“While being increasingly relied upon, however, expertise is also increasingly contested.... ‘Traditional’ science is confronted with the ethical, environmental, health, economic and social implications of its technological applications (Liberatore, 2001: 6).

[Decision-making needs] ... expertise that embraces diverse forms of knowledge (plurality). Expertise should be multidisciplinary, multi-sectoral and should include input from academic experts, stakeholders, and civil society (ibid: 3). [It needs] a ‘track record’, explaining how evidence was produced and used, including accounting for minority views and making explicit the uncertainties” (ibid: 20).

Pluralising expertise would mean incorporating various interactive and conflictual forms of expertise within formal procedures. Advisory procedures need to develop ‘an approach that makes apparent the possibility of unforeseen consequences, to make explicit the normative within the technical, and to acknowledge from the start the need for plural viewpoints and collective learning’ (Nowotny, 2003: 153).

These divergent problem-diagnoses imply different remedies: harmonising expertise for ‘science-based regulation’, versus pluralising expertise for uncertainty-based regulation, as juxtaposed in Table 1 (see last row). The former diagnosis prevails in documents from the European Commission, its scientific advisors and some policy analysts. Alternative diagnoses come from some Commission staff members and EU-funded reports. By analogy to those divergent remedies, knowledge-production in the European Environmental Agency has a tension between two models: Europe as an emerging superstate needing harmonisation across cultures, versus Europe as a civil society evaluating uncertainty and contingency (Waterton and Wynne, 2004: 91-92).

[Insert Table 1]

Critical analysts identify a further tension between transparency and objectivity. ‘Increased transparency in risk decision-making has made it apparent to all stakeholders that risk analysis is not a purely objective process as it has been previously portrayed’ (Frewer, 2002: 16). Expert advisors ‘work hard to enact objectivity’. Often ‘competing performers actively work to “backstage” some bits of information, while “front-staging” others’, thus downplaying diverse views (Hilgartner, 2003: 14, 18). In enacting objectivity, then, expert procedures may shape and limit transparency.

All those perspectives on advisory expertise can help to analyse recent EU institutional changes.

3 EFSA's origins and tasks

After the EU's 1997 reforms of advisory expertise, some participants began to regard the new arrangements as problematic. According to leading members of EU-level expert committees, their role was hindered by the lack of in-house scientific expertise at DG-SANCO, and often their own advice conflicted with national expert views (James et al. 1999: 8). Even after functionally separating risk assessment from risk management, problems continued because 'the current risk assessment process... has negligible input from those dealing with issues of risk management, on practical options for change or on the validity or effectiveness of control measures'. Therefore the overall procedure needed 'to ensure articulation between these two components of the risk analysis process'. Moreover, public-interest groups had little access to the process and judgements which formed expert advice (ibid: 43). This problem-diagnosis suggested the need for greater transparency, with systematic links between advisory expertise, risk managers and stakeholders.

As another problem, various European and national expert committees conduct risk assessments, often with different outcomes, so that expert advice readily becomes a political tool within EU-national conflicts. 'The legitimacy and the autonomy of the European Commission, and indeed its *rappports de force* with the EU member states, are thus being displaced to the arena of scientific expertise' (Dratwa, 2004: 13). Given expert disagreements, moreover, 'This is the source of much confusion and tends to undermine the credibility of the risk assessment process.' So the EU should take firm steps 'to harmonise the process', argued the EU's Scientific Steering Committee (SSC, 2003a).

All those problem-diagnoses informed proposals to create an independent agency for EU expert advice, largely along the lines of harmonising expert advice for 'science-based regulation' (Table 1). In its 2001 White Paper on Food Safety, the Commission outlined its plan for a European Food Safety Authority (EFSA). Equipped with its own in-house expertise, EFSA was designed to achieve a greater cognitive authority for accommodating and/or challenging national expert bodies.

EFSA was intended to link scientific objectivity with public credibility and regulatory harmonisation, through a positive integration of national regulatory criteria. According to the new legislation: 'In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data'. A related aim was to harmonise regulatory criteria, even precaution: 'it is necessary to adopt a uniform basis throughout the Community for the use of this [precautionary] principle', which 'has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed' among EU member states (EC 2002a: 2).

This strategy sought public confidence through 'independent' expert advice, somehow standing above policy. According to the Commission, establishment of EFSA was 'generally regarded as the most effective way to address the growing need for a solidly science-based policy and to increase consumer confidence' (EU Food Law News, 2000). The EFSA structure was aimed 'to protect the scientific integrity of expert advice'. According to the relevant Commissioner, the independence of EFSA 'will ensure that scientific risk assessment work is not swayed by policy or other external considerations'. Moreover, he stated, 'the Authority's reputation for independence and excellence in scientific matters appertaining to food will put an end to competition in such matters among national authorities in the Member States' (Byrne, 2002: 4-5). Thus, when EFSA communicates its results, 'The information will be objective, reliable and easily understandable for the general public' (CEC, 2002a).

While functionally separating risk assessment from risk management, the new structure was also designed to link those roles at a policy level. A Management Board would include representatives from the four stages of the agro-food chain, i.e. farmers, food producers, retailers, consumers. In addition an Advisory Forum would be drawn from the member states. EFSA was expected to draw upon various national strengths in expertise, consider the diversity of agro-environmental conditions, judge the quality of evidence and thus consider all relevant uncertainties within risk-assessment procedures (based on various interviews, 2002-2003).

This ambitious plan gained wide stakeholder support by accommodating various aims and agendas. In establishing EFSA, the European Commission found (or even created) trans-European institutional partners with shared understandings of policy problems, especially the need to gain public confidence. New arrangements involved a wider range of EU-level stakeholders, especially consumer groups; their role pluralises the policy process, while weakening corporatist relations with business and farmers (Smith et al., 2004). In this way, the EU sought ‘an overall commitment to a stronger “top-down” and standard European approach to both the assessment and management of risks’, as a means to harmonise both those roles at the EU level (ibid: 563).

4 Agri-biotech regulation: more precautionary and harmonised?

As a specially contentious issue for the EU, agri-biotech regulation has undergone pressure for greater precaution and harmonisation, especially since the late 1990s. At the June 1999 meeting of the Environment Council, many national Competent Authorities (CAs) had declared that they would not consider further requests for commercial authorisation of GM products until new conditions were fulfilled: ‘Given the need to restore public and market confidence’, the EU must first adopt new measures – e.g., full traceability and labelling of GM crops across the agro-food chain, and risk-assessment criteria which are more transparent and based on precaution (FoEE, 1999: 3). In addition, some member states banned GM products which had already gained EU approval. Through this *de facto* moratorium, the EU-level regulatory procedure was effectively suspended.

The suspension drove EU policy towards a more explicit treatment of scientific uncertainty. The 1990 Directive on the Deliberate Release of GMOs was revised along more stringent lines, with the precautionary principle in its preamble. Henceforth risk assessment must encompass a broader range of potential effects; and potential risks may not be disregarded simply on grounds that they would be unlikely (EC, 2001). For implementing the Directive, expert guidance set relatively more stringent criteria for evidence, e.g. the quality necessary for a peer-reviewed journal (SSC, 2003b).

In the same period, the Commission gained support for proposals to centralise regulatory decisions and expert advice. It had long promoted the slogan, ‘one door, one key’, i.e., a single procedure for authorising a GM product for all commercial uses at once. Under the 2003 GM Food & Feed Regulation, which replaced previous laws for GM agri-food products, EFSA centralises the administrative procedure for circulating product files among member states and for checking applicants’ risk assessments. EFSA was asked to standardise evaluation criteria across member states: ‘In order to ensure a harmonised scientific assessment of genetically modified foods and feed, such [risk] assessments should be carried out by the Authority [EFSA]’ (EC, 2003: 4). This remedy largely means harmonising expert advice through ‘science-based’ regulation (see again Table 1, final row).

Amid continuing conflict over agri-biotech, the Commission proposed a ‘strategic vision’ for biotechnology.. In its view, regulatory oversight ‘is the expression of societal choices’ –

through rules which ensure that market mechanisms function effectively through for consumer preferences (CEC, 2002b: 14, 15). Overall its policy aimed ‘to enable Community business to exploit the potential of biotechnology while taking account of the precautionary principle and addressing ethical and social concerns’ (CEC, 2003: 6, 17). By putting a great burden on ‘science-based regulatory oversight’, this framework raised the stakes for official accounts of science and precaution.

EU-level bodies have provided expert advice on GM products. Before 2003 such advice came from the EU’s two Scientific Committees on Plants and on Food. In early 2003 EFSA replaced all the former scientific committees with new ones, including a single integrated Scientific Panel on GMOs (henceforth ‘the GMO Panel’). As more GM products were proposed for EU-wide commercial authorisation in 2003-2004, disagreements arose among member states. Their more cautious approaches were rejected by EFSA’s opinions, which thereby continued the earlier conflicts, thus leaving the Commission with little national support to approve GM products. Conflicts arose around EFSA’s design to provide ‘independent, objective and transparent’ expert advice, role, as analysed in the next two sections.

5 Independent expertise?

Despite EFSA’s design and claims for independence, this has been widely questioned. Criticisms have come from consumer organisations and national governments, as well as from environmental organisations which oppose agri-biotech. The rest of this section examines the claim for independence – from material interests, member states and policy influences.

As regards dependence on material interests, EU expert committees on agri-biotech have included no one employed by industry since the 1997 EU reforms. But it has been difficult to avoid all industry links, especially because research institutes and academic departments have become more dependent upon industry funding. Before EFSA’s establishment, some members of the EU’s Scientific Committee on Plants (and on Food), held a research contract with industry. When EFSA’s GMO Panel was established in May 2003, direct financial interests became more marginal.

As regards independence from member states, earlier selection procedures were changed. Until 1997 national governments had nominated all prospective members of scientific committees. Since then, prospective members have nominated themselves for potential selection by the Commission. Nevertheless NGOs have suspected that governments lobby for preferred members, thus continuing some dependence. EFSA’s independence came under similar scrutiny. As mentioned earlier, the EFSA Management Board included representatives from the four stages of the agro-food chain, among other members, especially national regulators of food safety. Consumer organisations filed an official complaint about the EU Council’s procedure in appointing the Management Board’s membership. As a key criticism, ‘the presence of so many national officials will make it more difficult for the Authority [EFSA] to win the confidence of consumers and “serve as a point of reference by virtue of its independence”’ – as stated in EFSA’s own policy (BEUC, 2004: 6). Here NGOs questioned EFSA’s independence from national influences.

Also contentious was the relevant experience which could improve expert advice without biasing the results, especially through policy influences. EFSA’s GMO Panel included members of some national agencies or advisory committees which were evaluating the same GM products. The GMO Panel judged that such an overlap would not be a conflict of interest, except where the member had a risk-management role in their own country (EFSA GMO Panel, 2003).

GMO Panel members were asked to declare any interest on any agenda item that may arise, with the option of absenting themselves for that item. Given overlaps between their roles at EU and national levels, several members often abstained from a decision. Yet such members participated fully in the discussion.

For all those reasons, EFSA's independence was questioned by environmental NGOs (FoEE, 2004). Such doubts were raised more widely:

“The GMO Panel is very influential in defining relevant science. In the light of this influence and the role it is meant to play, it is questionable if it was a good idea to have national regulators as independent experts on the panel” (personal communication, national expert, 2004).

EFSA's Executive Director rejected the criticism, partly on grounds that the quality of scientific expertise depends on ‘prior experience’ in advisory-regulatory procedures (Podger, 2004). When invited to discuss their concerns with the GMO Panel, environmental NGOs attacked Panel opinions for bias towards the agbiotech industry. Moreover, the NGOs pointed out, three Panel members were overt supporters of an industry-funded pressure group lobbying for less stringent regulation (FoEE, 2006).

The selection criteria for expertise has had an implicit policy agenda. In the late 1990s, some EU-level expert committee members saw ‘political bias’ in national regulatory procedures which had been influenced by anti-biotechnology pressure groups. They saw themselves as protecting scientific risk assessment from such bias (according to interviews with committee members during 1998, cited in Levidow et al., 2000: 201).

Apparently ‘bias’ has meant suspicion towards safety claims. Among the members of EFSA's GMO Panel, some were known for publicly expressing pro-biotechnology views, while none were known for challenging safety claims about GM products; no such person was included in the nominations list after the Commission filtered the original self-nominations by scientists. According to some participants, moreover, the above selection criteria would help EFSA's procedures to remain distant from the political arena, so that its advice would provide a ‘rational peer review’ of national procedures. Consequently, the claim for expert independence has been contentious.

As a further source of bias, panel members have been selected also for a willingness to reach consensus on their advice (interviews with members of EFSA Management Board and Advisory Forum, 2003-2004). The outcome has been regarded as a policy bias by environmental NGOs. They have criticised the absence of minority views within the expert committees' advice since the 1990s.

6 Objective and transparent advice?

As more GM products were proposed for EU-wide commercial authorisation under the revised Directive in 2003-2004, disagreements arose among member states. This section examines how EFSA's GMO Panel has handled national disagreements. Its role has manifest tensions between the official aims that expert advice should be transparent and objective, as well as between the official aims of precaution and harmonisation.

6.1 Enacting objectivity

Claims for ‘objective’ advice depend upon an official separation between science and policy, often related to a ‘functional separation’ between risk assessment and risk management, respectively. For the European Commission, this framework implies a strict boundary on the remit of expert advice, for at least two reasons. First, risk assessment should not depend upon risk-management practices or assumptions, for which regulators should take responsibility. Second, EFSA aims ‘to protect the scientific integrity of expert advice’ (Byrne, 2002); this leaves ambiguous whether expert advice could or should remain free of policy judgements.

Overlaps between risk assessment and risk management have been widely acknowledged as unavoidable, even as helpful, provided that these ‘grey areas’ are made transparent as policy issues. According to a survey of participants in EFSA procedures across all food sectors, expert advice should provide multiple options, especially because unitary advice could be readily used by risk managers in a political manner:

“Key agenda point for science is to ensure that the grey area between risk assessment and risk management is covered; this should clearly be an EFSA accountability. It was felt that the risk managers should be explicitly aware of a number of options so as to avoid too much ‘politics’ in the management process” (FPA, 2004: 28).

In the agri-biotech sector, EFSA’s GMO Panel has effectively covered the ‘grey areas’ as if they were scientific issues. The Commission has assigned staff members to handle the ‘interface’ between risk assessment and management issues, yet their task has been marginalised by EFSA’s broad opinions: ‘In theory, it is good to have a functional separation between risk assessment and risk management, but a strict separation doesn’t work in practice. (interview, member of EFSA’s GMO Panel, 2004). Indeed, EFSA has generally given unitary advice, incorporating normative and risk-management issues. Such advice has provoked dissent from member states adopting more stringent criteria, as in the following two examples.

Member states have disagreed about which antibiotic-resistance marker (ARM) genes should be permitted in GMOs, given that ARMs could spread to pathogenic microbes, thus jeopardising the clinical efficacy of the corresponding antibiotics. In response to those disagreements, the GMO Panel’s evaluation involved ‘taking into account the limited availability of alternatives’ for biotechnologists. Ultimately it advised that specific ARMs should be banned in GM crops, while others should be permitted; the permitted ARMs corresponded to the ARMs most commonly used in GM plants (EFSA GMO Panel, 2004a). Thus this advice made risk-management judgements about which antibiotics should be preserved for clinical use and which ones were expendable, as well as judgements about needs of biotechnologists.

Member states have also disagreed about how to identify and manage uncertain risks. For the import of GM rapeseed, any spillage could generate feral populations, spread its genes to related plants, lead to more herbicide sprays and thus cause environmental damage, etc. Some CAs requested control measures to prevent and monitor any seed spillage. But the GMO Panel found no grounds for any risks. According to its opinion, an EUPermit for rapeseed import would not allow its cultivation, thus implying that spillage would have no environmental consequences; segregation issues anyway lay beyond its remit.

Thus EFSA’s opinions have rested upon normative judgements about acceptable or relevant effects and assumptions about risk-management measures. Such judgements absorb uncertainties into unitary, prescriptive advice, as if it were objective.

6.2 Enacting transparency

Some GMO Panel members describe their group opinions as ‘scientific value judgements’. Their transparency is enacted through EFSA’s information disclosure, consultation procedures and responses to national objections.

Since the late 1990s, national Competent Authorities (CAs) have developed more stringent criteria for evidence of safety. They have criticised GM product files on grounds that routine tests used poor-quality or inappropriate methods, yielded anomalous results, or were otherwise inadequate. Implicitly such criticisms make precautionary judgements on research methods as well as on empirical results; they evaluate scientific ignorance – i.e., uncertainty about overlooking hazards, not only about clarifying an identified hazard. Their demands for more rigorous evidence have circulated among CAs; the national rapporteur for a product file sometimes anticipates, accommodates or stimulates similar requests from other CAs (Levidow et al., 2005).

The GMO Panel has accepted ‘reasonable’ national requests for more rigorous information, while rejecting requests which would unreasonably burden companies or delay procedures (according to interviews with Panel members, 2003-04). In one case the GMO Panel issued a split opinion about the need for extra lab tests. EFSA itself declared that they would be necessary (EFSA, 2004), thus avoiding further disagreements among Panel members and member states.

Apart from that one case, the GMO Panel’s opinions have generally declared that the available information is adequate for a risk assessment, and that the GM product is as safe as its non-GM counterpart. The Panel’s opinions have scrutinised different types of evidence in an asymmetrical way – by raising methodological uncertainties about evidence of risk, far more than about evidence of safety. Its opinions generally have framed scientific uncertainties in such a way that they can be resolved by extra information, or can be readily managed, or can be deemed irrelevant to any risk. Thus EFSA’s safety claims provide a seamless link with EU regulatory approval of GM products.

Tensions arise between objectivity and transparency. GMO Panel members have sought to reach consensual advice for various reasons – so that its advice can straightforwardly inform regulatory decisions, and so that expert disagreements do not alarm the public or serve as ammunition for objectors.

“Ultimately it is important to show 100% agreement within the Panel. A minority opinion would be unhelpful to the public because it suggests there may be a question about safety” (interview, GMO Panel member, 2004).

From their wide-ranging internal discussions, the GMO Panel selects arguments which can best gain internal consensus, can be scientifically most defensible, and can minimise external criticism. These arguments form the basis of published opinions, which thus enact transparency through selective disclosure.

EFSA’s opinions serve a policy agenda of EU regulatory harmonisation, which often conflicts with national precautionary approaches. Each EFSA opinion briefly explains why it claims to accommodate, resolve or reject national objections, generally on grounds that they have no basis in scientific risk assessment. According to some Commission staff and expert advisors, national governments try to justify their dissent or delay towards GM products in scientific terms:

“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” (Scientific Panel member, interview, 2004).

Consequently, national objections could be dismissed as ‘political’ dissent by citing EFSA’s advice. However, it may not always be straightforward to distinguish between scientific and political reasons for expert disagreements (interview, Commission staff, 2005).

Uncertainties in risk assessment have remained implicit in EFSA opinions. According to EU statutory guidelines, ‘the overall uncertainty for each identified risk has to be described’ (EC, 2002: 32). The Panel’s published opinions have not explicitly characterised ‘uncertainty’, consistent with the conclusion that no risk is identified for a GM product. In a stakeholder consultation held in spring 2004, EFSA’s GMO Panel was asked to provide a more explicit analysis of uncertainties in risk assessment. In revising its guidance document for applicants, EFSA requested a ‘risk characterisation’ that would explain uncertainties about data and about assumptions, especially in extrapolating across contexts. Moreover applicants should explain ‘the scientific basis for different options to be considered for risk management’ (EFSA GMO Panel, 2004b: 46-50).

6.3 Pluralising expertise?

Persistent conflicts in the EU regulatory procedure eventually intensified a legitimacy crisis. During 2004-2005, each time a Commission proposal to approve a GM product went to the EU regulatory committee of member states, few gave support and many voted against (FoEE, 2005). Nevertheless the Commission often granted approval, while citing EFSA’s favourable advice.

By early 2006 member states were publicly attacking that procedure. They proposed that EFSA use scientific opinions available from national bodies; they warned EFSA that its own opinions must be seen to be ‘scientifically objective’. Even the UK, which generally voted in favour of GM products, asked that EFSA’s opinions be ‘more robustly argued and more clearly explained’ (Anon, 2006). These pressures intensified a dilemma: regulators depend on expert advice but cannot credibly delegate responsibility for adjudicating expert disagreements.

After much internal debate within the Commission, it announced a policy shift in April 2006. Previously it had operated as if the problem were national objections to safety claims, while treating EFSA as a High Court. Now it diagnosed the problem as expert disagreements arising from EFSA’s procedures and advice. The Commission proposed practical improvements ‘to improve the scientific consistency and transparency for decisions on GMOs and develop consensus between all interested parties’. Its proposals included the following:

“In the scientific evaluation phase:

to invite EFSA to liaise more fully with national scientific bodies, with a view to resolving possible diverging scientific opinions with Member States;

to invite EFSA to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities....

to invite EFSA to clarify which specific protocols should be used by applicants to carry out scientific studies...

In the decision-making phase:

The Commission will also address specific risks identified in the risk assessment or substantiated by Member States by introducing on a case by case basis additional proportionate risk management measures in draft decisions to place GMO products on the market, as appropriate; and

Where in the opinion of the Commission a Member State’s observation raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer back the question for further consideration” (CEC, 2006).

In other words, if EFSA does not adequately justify its advice, then the Commission may reject it or impose extra management measures to deal with uncertainties in risk assessment. The Commission proposals were pushing EFSA to go beyond a minimal internal consensus. Around the same time, EFSA itself issued a guidance document along similar lines regarding transparency (EFSA, 2006: 3). However, truly greater transparency would elaborate the Panel's value judgements, thus potentially undermining the enactment of objectivity.

7 Conclusions: Tensions of expert roles and problem-diagnoses

Since various crises of food safety in the 1990s, EU institutional reforms have been designed to regain public confidence in regulatory decisions and their expert basis, as means to stabilise an EU-wide market in agri-food products. EFSA was meant to Europeanise advisory expertise through arrangements acceptable to national expert bodies. EFSA took a top-down, standard EU-wide approach (Smith et al., 2004), along with more in-house scientific expertise and stakeholder involvement. EFSA's centralised advice was meant to strengthen the political authority of the Commission for regulatory decisionmaking *vis à vis* national bodies (Dratwa, 2004). These reforms were guided largely by a problem-diagnosis that national politics had been distorting expert advice and undermining its independence: therefore expert advice should be harmonised to guide 'science-based regulation'.

In procedures for evaluating agri-biotech products during 2003-2005, however, expert disagreements extended regulatory conflicts from the late 1990s. National experts continued to dissent from EFSA's advice. Commission proposals to approve GM products gained little support from member states. The prevalent harmonisation strategy aggravated EU-national disharmonies rather than reduced them. This conflict inadvertently helped agri-biotech opponents to intensify public distrust in safety claims and in the EU regulatory procedure.

EFSA was designed to demonstrate that expert advice would be 'independent, objective and transparent', but tensions arose among those aims – between expert independence and expert experience, between transparency and objectivity, as well as between harmonisation and precaution. More specifically:

- Expert independence versus expert experience: By comparison to 1990s expert bodies, financial 'conflicts of interest' became relatively marginal in EFSA's GMO Panel. But its membership had a great overlap with involvement or prior experience in similar roles at national level. Critics identified this overlap as a source of bias, while EFSA defended its own arrangements as an appropriate use of relevant experience. Panel members had been selected to avoid anti-biotech 'political bias', and to provide a 'rational peer review' of national expert advice, but soon their policy independence was questioned.
- Transparency versus objectivity: While expert advisors acknowledge 'scientific value judgements' in their advice, EFSA has enacted objectivity through an internal expert consensus on unitary, prescriptive advice (cf. Hilgartner, 2003). Sometimes its advice has depended on normative judgements, despite the EU policy on 'functional separation' of risk assessment from risk-management decisions. From all the considerations which arise in the Panel's discussions, its advice has selectively 'front-staged' the most internally consensual and scientifically defensible arguments, thus selectively enacting transparency. Thus claims for objectivity and transparency remain in pervasive tension.
- Harmonisation versus precaution: EFSA's procedures were meant to help harmonise regulatory criteria, even precaution, but EFSA's advice hardly accommodated the precautionary approaches developed by member states. National objections challenged normative judgements and scientific ignorance which underlie safety claims. Such conflicts

manifest a dynamic tension between harmonising risk-assessment criteria and exploring uncertainties through precaution.

Thus a narrow expert consensus generated expert disagreements, intensified regulatory conflict and jeopardised the legitimacy of EU decisions. In response to this pressure, the European Commission eventually shifted its policy. No longer simply accepting EFSA's safety claims, it asked EU-level expert advice to accommodate national dissent through greater transparency about uncertainties, as a means towards greater 'scientific consistency', i.e. harmonisation.

Such reform could mean pluralising expertise, along the lines of the alternative problem-diagnosis, so that uncertainties and norms become more explicit (see again Table 1). Advice could also make explicit the normative within the technical (cf. Nowotny, 2003: 153). Not simply a remedy, however, such reform could aggravate the inherent tensions – between transparency and objectivity, as well as between harmonisation and precaution. Indeed, the dominant diagnosis for EU policy problems remains in tension with alternative ones.

Fundamentally, such difficulties of advisory expertise arise from the overall policy framework. The European Commission relies upon 'science-based regulation' for societal decisions about agri-biotech (CEC, 2002b: 14). This contentious technological development provokes public controversy, in turn generating more expert disagreements. Those systemic conflicts pose dilemmas for how to Europeanise advisory expertise in a way which can legitimise regulatory decision-making.

Table 1: Diagnosing EU Policy Problems for Expert Advice

	Prevalent diagnosis of problem	Alternative diagnoses of problem
Problem/issue		
Sources of advisory-regulatory conflict	politics influencing national regulatory expertise, distorting any scientific basis (Majone, 1996)	a narrow expert consensus favouring a specific policy view, implicitly 'advocating a cause' (Roqueplo, 1995)
Sources of expert in/dependence and illegitimacy	expertise dependent on material interests, national patronage, politics, etc. (EC, 1997)	an implicit, hidden tension between independence vs expertise, which depends on relevant experience (Oxera, 2000; EP, 2000; Liberatore, 2001)
Expert-policy relation	expert advice under policy influence (Byrne, 2002)	pretence of policy-free expertise (Levidow and Marris, 2001; Millstone et al., 2004; Jasanoff, 2005); or a gap between expert advice and policy issues, e.g. risk management (James et al., 1999; Setbon, 2001)
Public suspicion of official expertise	divergent expert advice within or across expert advisory bodies (SSC, 2003a)	expert advice for a merely negative, free-trade or technocratic harmonisation, which denies or excludes cultural meanings (Barry, 2001; Zito, 2001; Waterton and Wynne, 2004)
Uncertain risks	failure to resolve expert disagreements and/or scientific uncertainty (CEC, 2000)	assumptions which frame ignorance and deny scientific uncertainty (Stirling, 1999; Funtowicz et al., 2000), especially through a positivist approach to science (Christoforou, 2003)
Sources of uncertainty	data gaps which can be filled by extra information or better methods (CEC, 2000)	diverse cognitive frames for scientific research, causal models, risk manageability (Stirling, 1999; Waterton and Wynne, 2004)
Socio-ethical issues	lie outside risk regulation and so may need extra procedures and consumer choice (CEC, 2002b)	implicitly lie within expert advice but are represented as 'science' (Carr, 2002); wider societal issues being marginalised or else reduced to risk management (Rayner, 2003)
Transparency	inadequate communication of scientifically objective risk from expert advice (CEC, 2002a; Ballantine, 2003)	concealment of social assumptions about control over risks, limits of scientific knowledge, etc. (Marris et al., 2001); practical tensions between transparency and objectivity (Frewer, 2002; Hilgartner, 2003)
Remedy for the above problems	harmonise expert advice for science-based regulation	pluralise expert advice for uncertainty-based regulation

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Note: All EFSA documents are normally cited as 'EFSA', but the list below distinguishes between documents from a specific Panel (EFSA GMO Panel), from EFSA per se, and from its Executive Director (Podger, 2004). 'CEC' denotes a Commission view, while 'EC' denotes a statutory decision binding on the European Union.

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