EU agbiotech regulation

Relinking science and policy

This year has seen a crisis in the EU-level regulation of agbiotech products. The European Commission had previously cited safety claims from the European Food Safety Authority (EFSA) as an authoritative basis for "science-based regulation". The Commission subsequently approved GM products, despite objections from several member states and support from few others. This practice intensified regulatory conflicts and led to a policy impasse for the EU system. To overcome the impasse, the Commission announced procedural changes last April. This article analyses sources and implications of the changes.

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Harmonisation through EFSA?

The EU's recent difficulty has origins and analogies in the regulatory impasse of 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. 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 changes in EU policy and law towards a more explicit treatment of scientific uncertainty. The 1990 Directive on the Deliberate Release of GMOs was revised in 2001 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 disregarded simply on grounds that they would be unlikely.

In parallel with those legislative changes, the Commission gained support for proposals to centralise regulatory decisions and expert advice for GM agri-food products. Under the 2003 GM Food & Feed Regulation, the European Food Safety Authority (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', i. e. EFSA.

For all agro-food sectors, EFSA was meant to link scientific authority with public credibility and regulatory harmonisation. According to the 2002 food law: '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.

This strategy sought public confidence through 'independent' expert advice. 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'. 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'.

In such language, risk assessment was nearly equated with science, as if this involved no issues of policy, precaution or risk management – which would arise only after the stage of expert advice. That equation complemented the Commission's

own statements: that risk assessment should be functionally separate from risk management, i. e. as the responsibilities of different bodies; and that risk assessment involves only technical caution, not to be confused with precaution. Yet all those official separations soon became blurred in conflicts over EFSA's risk assessments.

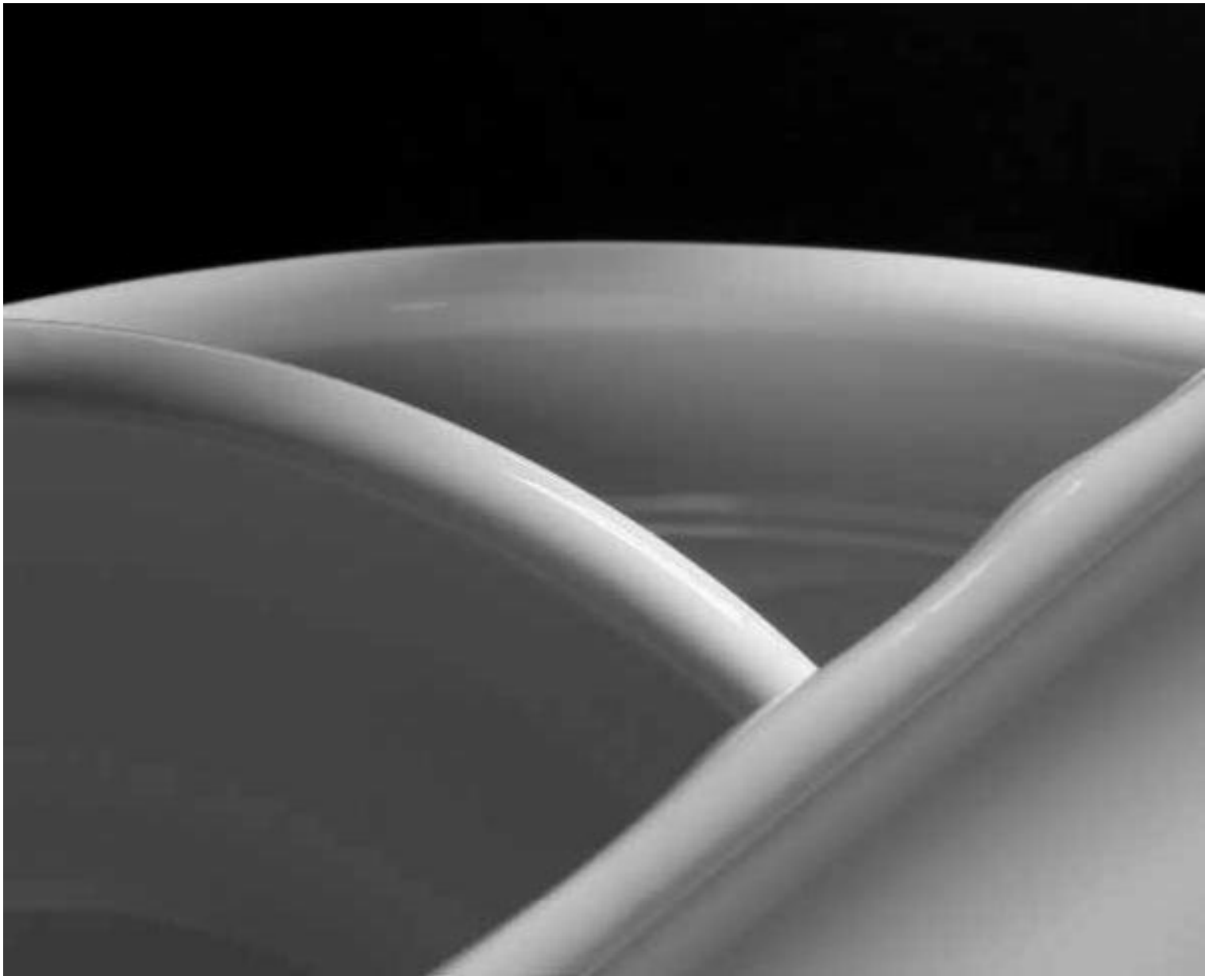
Regulatory-expert conflicts continue

When the EU regulatory procedure resumed in 2003-2004, disagreements again arose over GM products. Safety claims met objections from member states which were applying relatively broader forms of precaution, e. g. regarding the 'harm' to be prevented and evidence of safety (Levidow et al., 2005). However, EFSA generally accepted safety claims, with little extra evidence to persuade objectors, thus extending the regulatory conflicts of the late 1990s. Here follow some 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 was 'taking into account the limited availability of alternatives' for biotechnologists. In 2004 it advised that specific ARMs should be banned in GM crops, while others should be permitted; the latter corresponded to the ARMs most commonly used in GM plants. 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 of GM products in commercial use. 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, while assuming that a permit for rapeseed import would not allow its cultivation; segregation issues anyway lay beyond its remit.

Apart from disagreements over 'harm', CAs have criticised GM product files on grounds that the available evidence was inadequate. For example, routine tests used poor-quality or inappropriate methods. Such criticisms make precautionary judgements about scientific ignorance – i. e., un-



certainty about overlooking hazards, not only about clarifying an identified hazard. In its published opinions, however, EFSA's GMO Panel 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 scrutinised different types of evidence in an asymmetrical way – by raising methodological uncertainties about evidence of risk, far more than about evidence of safety. It accepted 'reasonable' national requests for more rigorous information, while rejecting requests which would unreasonably burden companies or delay procedures.

EU-level expertise extended the conflicts that it was meant to overcome. EFSA's 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. Citing EFSA's favourable advice, the Commission advocated approval and eventually granted it – despite many national objections and little support from member states. The Commission had undertaken not to act against a 'predominant majority' of member states in the EU Council but was now doing so.

Commission policy change

By early 2006 a legitimacy crisis emerged from those conflicts between the Commission and member states. Some were publicly attacking the EU decision procedure and its deference to EFSA's safety claims. They asked EFSA to use scientific opinions available from national expert bodies; they also 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'. These pressures intensified a dilemma: regulators depend on expert advice but cannot credibly delegate responsibility for adjudicating disagreements among experts.

After much internal debate within the Commission, it announced a policy change last April. Previously it had operated as if the main problem were national objections to safety claims. Now it diagnosed the problem as expert disagreements, partly 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 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.

The Commission proposals were pushing EFSA to provide greater transparency about value judgements and uncertainties in risk assessment. No longer accepting EFSA opinions as 'science', the Commission would now take some responsibility for risk assessment as a policy matter. If EFSA did not adequately justify its advice, then the Commission could reject it or impose extra management measures to manage uncertain risks.

Policy implications

What could the new policy mean in practice? As its explicit aim, the procedural change could accommodate more member states, persuade them to support approval of specific GM products, and thus facilitate Commission decisions. Yet the change may involve further difficulties in relinking science and policy through risk assessment. Here are three aspects:

- Objective, transparent advice? As expert advisors are pressed to justify their judgements about uncertainties, greater transparency in risk assessment could undermine official claims for objective advice. The Commission may become reluctantly drawn into such judgements, contrary to its plan that EFSA would provide authoritative opinions for 'science-based regulation'.
- Harmonising precaution? Commission interest in 'scientific consistency' extends a harmonisation agenda, which generates and highlights pervasive disagreements over scientific uncertainties. There remain tensions between harmonisation and precaution.
- Commercial experiments? When scientific uncertainties depend upon the precise conditions of product use, some member states have proposed risk-management measures, as in the case of rapeseed import. Such proposals implicitly design commercialisation as an experiment, by testing assumptions about the feasibility and acceptability of control measures. Yet the experimental design has been contentious (Levidow and Carr, 2007, forthcoming). Fundamentally, such difficulties arise from the overall policy framework. The European Commission relies upon 'science- based regulation' for societal decisions about agri-biotech (CEC, 2002: 14). In lieu of any other means for such decisions, public controversy generates more expert disagreements. There follow dilemmas for how to legitimise EU regulatory decisions by relinking science and policy.

References

Note: For full references see our 2005 paper below.

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