Channelling Agbiotech Controversy into Regulatory Conflicts

Research of the Open University's Biotechnology Policy Group

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Sources of European regulatory conflict

Since the late 1990s, European regulatory frameworks for agbiotech have been broadened to encompass more issues from the wider public controversy, thus potentially accommodating public concerns. At the same, those regulatory frameworks have become arenas of greater conflict. How and why? This overall question has been analysed in several research projects and publications of the Open University's Biotechnology Policy Group (see Box, p. 16). Early on, EU policy promoted biotech as an objective imperative of global economic competitiveness, requiring greater productive efficiency. Conversely, the technology was adopted as a symbol of progress for European integration. At least implicitly, this agenda accepted intensive agri-industrial production as an inevitable future, along with policies to establish that future. In the name of rules necessary for 'completing the internal market', EU policy promoted integration with global markets as the basis for biotechnological progress, economic prosperity and societal benefit. After a decade-long controversy over patent rights on 'biotechnological inventions', fiercely opposed as 'Patents on Life', 1998 EC legislation granted patent rights in principle, especially to transgenes inserted into GM crops. This provided an extra incentive for R&D to seek single-gene solutions using GM techniques. Meanwhile public-sector research was driven into greater dependence upon private finance or even upon their own entrepreneurial role, with incentives to prioritise molecular-level knowledge which can be patented; this meant less public accountability for R&D priorities in the agri-food sector.

Although the EU had special regulation of all GMOs, its procedures were initially used to normalise them as safe products which could freely circulate in the internal market. In the mid-1990s, safety claims accepted the normal hazards of intensive monoculture as a baseline of acceptability for GM crops, thus defining harm in a narrow way. The European environment was conceptually homogenised for treating agricultural land as an industrial resource. Under the 1997 Novel Food Regulation, GM foods could be readily approved as safe without a risk assessment, on grounds of substantial equivalence with a conventional counterpart. Through a technicist harmonisation agenda, Europe was being constructed as a smooth space for freely circulating agbiotech commodities. Expert accounts of safety generally served to minimise any role for public influence over the trajectory and regulation of agbiotech.

All these policy frameworks potentially made Europe safe for agbiotech – not simply as products, but also as an overall model for reordering future agriculture, science and markets. Early on, however, this 'inevitable' future was contested. Critics questioned the putative safety, benefits and ethics of further industrialising agriculture, which would thereby become more dependent upon commodity inputs from agrichemical companies. The 'mad cow' crisis became an opportunity to warn against inherent hazards of agri-industrial efficiency, as exemplified by GM agri-production. By the late 1990s these critical perspectives were gaining a mass audience and active support across Europe.

Since then, the EU's fundamental commitment to agbiotech has hardly been opened up to public deliberation. Instead, 'science-based regulatory oversight' remains 'the expression of societal choices' regarding biotechnology: EU rules should ensure that

OU Biotechnology Policy Group

The Biotechnology Policy Group at the Open University has conducted research which relates biotechnology to broader issues of agriculture, sustainability, technological change, precaution, regulation and governance. Most of the group's projects have focused upon the EU, its member states, the USA and interactions among those jurisdictions. For example:

- Trading Up Environmental Standards? Trans-Atlantic Governance of GM Crops, funded by the UK's Economic and Social Research Council (ESRC) during 2002-2004.
- Precautionary Expertise for GM Crops, funded by the European Commission during 2002-04.
- Risk-Assessment Policies: Differences Across Jurisdictions, funded by the European Science & Technology Observatory, Joint Research Centre, European Commission.

Our website has all project reports, a list of publications, and the text of recent or forthcoming papers. This Soziale Technik article draws especially on the following ones:

- Levidow, L., Carr, S., Wield, D. (2005) 'EU regulation of agri-biotechnology: precautionary links between science, expertise and policy', Science & Public Policy 32(4): 261-76
- Levidow, L., Murphy, J., and Carr, S. (2007) 'Recasting "Substantial Equivalence": transatlantic governance of GM food', Science, Technology and Human Values 32(1) forthcoming.
- Levidow, L. and Carr, S. (2007) 'GM crops on trial: technological development as a real-world experiment', Futures 39(4), forthcoming.
- Levidow, L. and Boschert, K., 'Coexistence or contradiction? Agricultural biotechnology versus alternative agricultures in Europe', Geoforum, forthcoming

Also available is a book: Murphy, J. and Levidow, L. (2006) Governing the Transatlantic Conflict over Agricultural Biotechnology: Contending Coalitions, Trade Liberalisation and Standard Setting. London: Routledge.

market mechanisms function effectively, so that safe products become available to accommodate consumer preferences (according to Life Sciences and Biotechnology: a Strategic Vision for Europe, European Commission, 2002).

By default, the wider controversy has been translated and channelled into conflicts over regulatory criteria. Regulation bears the burden of societal unease and opposition towards a contentious technological development, in lieu of any other formal means to make societal choices. That pattern can be illustrated through three case studies below, drawing upon publications from the Biotechnology Policy Group at the Open University. For more detail, see the papers on our website, http://technology.open.ac.uk/cts/bpg.htm.

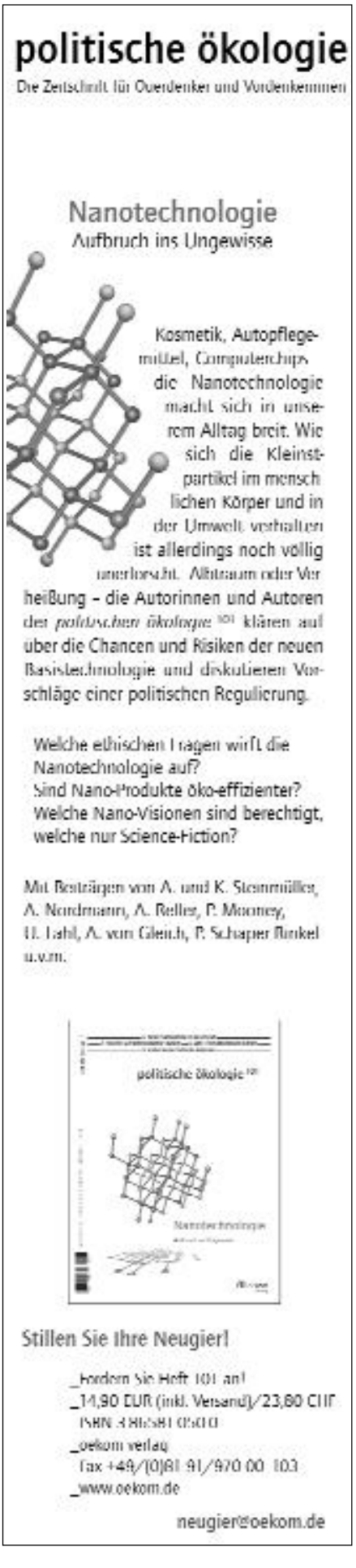
Recasting Substantial Equivalence

Since the early 1990s 'substantial equivalence' has been developed as a means to compare a GM food with a conventional counterpart for safety purposes. The concept was designed to compare a GM food with a conventional counterpart by evaluating any unintended differences – i. e., other than the novel protein, which anyway underwent safety tests. As a scientific basis, the concept emphasised physico-chemical tests to detect any differences.

The 'substantial equivalence' concept was formalised by the Organisation for Economic Cooperation and Development (OECD). According to its 1993 report on Safety Evaluation of Foods Derived by Modern Biotechnology, the precise techniques involved in genetic modification 'should enable direct and focused assessment of safety where such assessment is desired'. On this basis, the report promoted a straightforward comparison between a GM food and a familiar one.

Although proponents did not claim a 'scientific' status for substantial equivalence, the concept was used to portray the appropriate test methods as merely technical issues, separate from policy issues. Moreover, the concept was used to justify fast-track procedures which minimise or avoid any statutory requirement for a risk assessment – especially under US regulatory procedures, as well as the simplified procedure in the EU's Novel Food Regulation. In this way, the concept served a policy agenda: trans-Atlantic regulatory harmonisation of GM food, and thus trade liberalisation among the major trading partners for GM products. For all those reasons, the substantial equivalence concept became a vulnerable target for criticism. When agbiotech overall became more controversial in the late 1990s, opponents publicly ridiculed substantial equivalence as deceptive and biased. The concept was turned into an ominous symbol of 'globalisation' – political pressures driving safety claims.

Eventually the 'substantial equivalence' concept was recast through international bodies, e. g. the EU-US Consultative Forum



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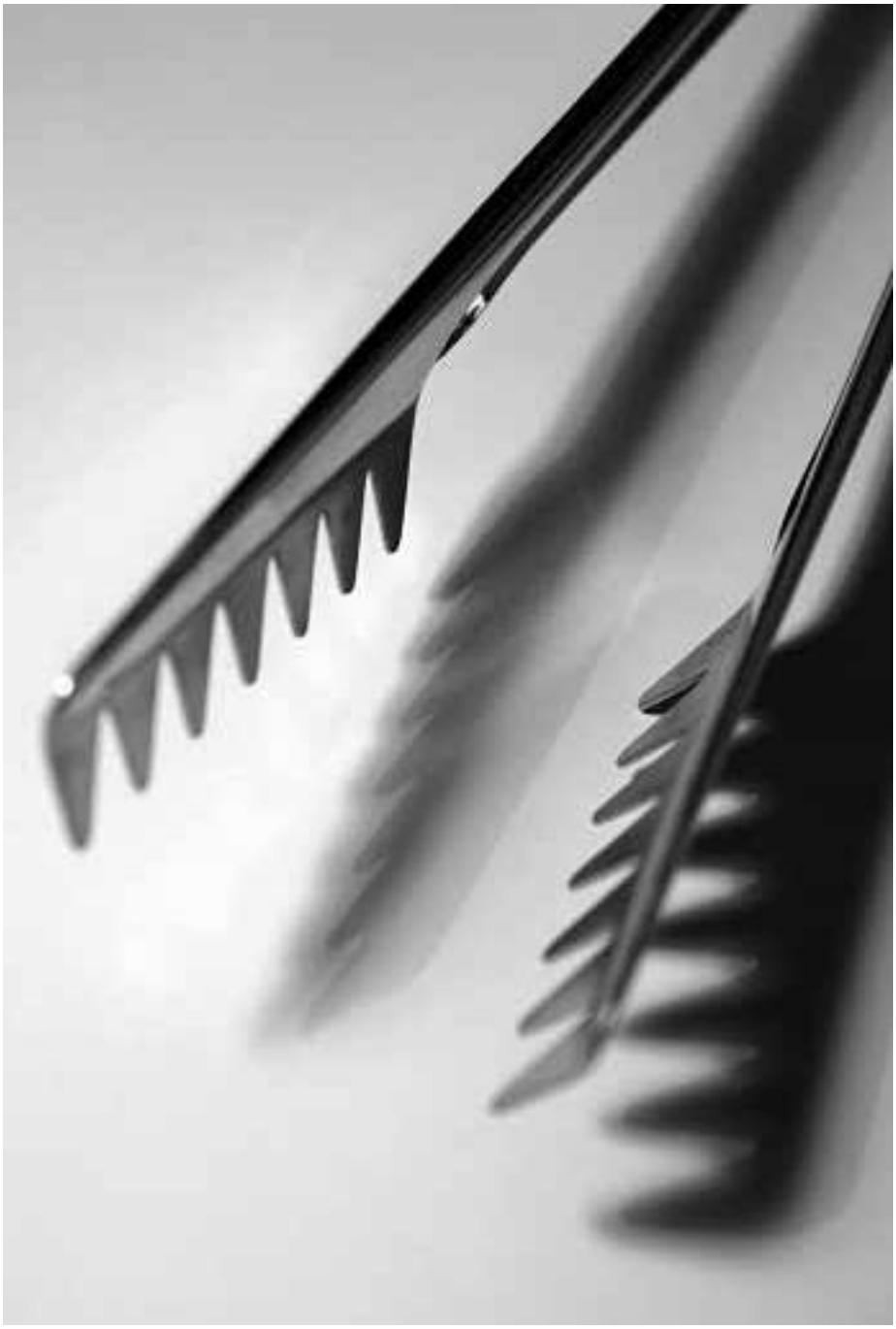
on Biotechnology, as well as the Codex Alimentarius Commission. Substantial equivalence was redefined to search more systematically for differences between a GM food and a conventional counterpart. Compositional analysis was now designated as 'a starting point in the risk assessment', not as an endpoint – as if it always had this more humble meaning. This shift opened up the evidential criteria to policy debate, including wider stakeholder views.

In the late 1990s the European role of substantial equivalence became increasingly controversial. The EU's 1997 Novel Food Regulation had a simplified procedure, not requiring a risk assessment for a GM food deemed substantially equivalent to a conventional counterpart. In the late 1990s the simplified procedure reached a breaking point, as more member states opposed it. Consequently any simplified procedure was omitted from the 2003 Regulation on GM Food and Feed, replacing the Novel Food Regulation for such products. Since then, European expert practices have been addressing more scientific uncertainties, but disagreements have continued over criteria for evidence. 'Substantial equivalence' necessarily plays a policy role, in at least two senses – by defining the evidential criteria for a risk assessment, and in representing those criteria either as merely technical or as policy issues too. For both reasons, substantial equivalence has been controversial and unstable. The EU system still faces difficulties in stabilising a scientific basis which can legitimise safety claims for GM food.

GM crops on trial

EU regulatory procedures were designed – and initially used – to normalise GM products. However, critics stigmatised them as abnormal, especially regarding their agri-environmental roles and effects. A metaphor of suspected crimes, 'GM crops on trial', has been extended into public debate and EU-wide regulatory procedures for commercial authorisation.

The agbiotech debate features contending moral frames about GM products conserving or degrading nature. From their eco-efficiency frame, proponents have diagnosed the problem as agro-economic inefficiencies which GM crops can remedy; they have framed any unintended effects as routinely manageable problems of safe products. By contrast, agbiotech opponents have emphasised apocalyptic threats – e. g., of uncontrollable risks, intensive agricultural methods and farmer dependence on multinational companies. In these ways, eco-efficiency versus apocalyptic frames favour different future scenarios for linking nature, society and technology (see picture, p. 18). Moreover, agbiotech opponents have framed risk in successively broader ways, thus expanding the charge-sheet of suspected crimes for which GM crops should be kept on trial. Their discourses have emphasised three ominous metaphors: 'superweeds' leading to a genetic treadmill, thus aggravating the familiar pesticide treadmill; broad-spectrum herbicides 'sterilising' farmland biodiversity; and pollen flow 'contaminating' non-GM crops. They have also cast doubt on whether preventive measures would be reliable, realistic or morally responsible. In these ways, they have sought to undermine safety claims; indeed, they have cast the entire technological development as immoral, thus challenging eco-efficiency discourses of societal benefits.



Governments have mediated between eco-efficiency and apocalyptic frames, especially by translating the three ominous metaphors into measurable, manageable effects. More national authorities took up those risk issues, which readily became European ones through interactions between activists and regulators. Governments defined harm more stringently, thus generating more uncertainty about whether GM crops could cause harm.

For the commercial stage, regulators re-

Eco-efficiency frame: GM crops as a double-helix money-tree sprouting banknotes
Credit: UK Department of Trade & Industry, 1991

quested more knowledge about operator behaviour and diverse agri-environmental conditions – contexts which could not be standardised in advance. Risk assessments increasingly made assumptions or prescriptions about the operator behaviour necessary to avoid harm. The commercialisation stage was now anticipated and designed as a real-world experiment. Such designs would test assumptions about human practices as well as their environmental effects.

Conflicts arose about whether operator behaviour could be feasibly reorganised around the necessary social discipline to prevent harm, and thus about how to design a technological scale-up. Potential control measures became contentious in European regulatory procedures during 2004. GM crops have been kept continuously on trial in three related ways: contending risk discourses which attribute moral meanings to the agricultural environment, safety tests which simulate commercial use, and special measures which assign greater responsibility to commercial operators. All these elements intersect in regulatory conflicts over how to anticipate and design commercial use as a real-world experiment.

Coexistence or contradiction?

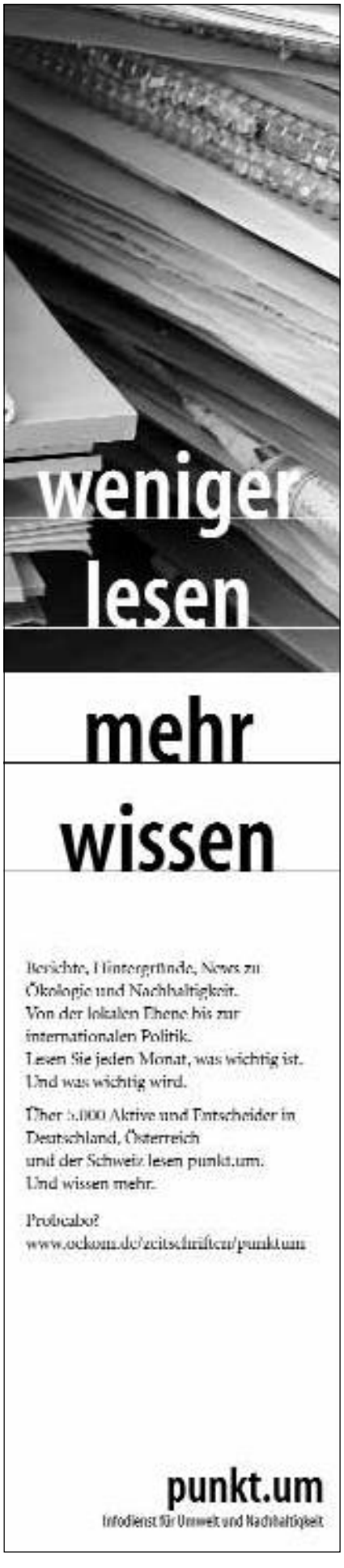
Agricultural biotechnology has intersected with a wider conflict over the meaning of sustainable agriculture, especially in Europe. From an agri-industrial paradigm, GM crops are promoted as eco-efficient tools for more safely sustaining intensive agricultural methods. Relatively more industrialised farmers seek access to GM crops as a more efficient means to compete in the bulk commodity market. From an agrarian-based rural development paradigm, opponents warn against various uncontrollable risks of agbiotech, while counterposing high-quality or high-skill agri-production as a truly sustainable future.

Debate has ensued over whether GM crops simply offer an additional option or rather threaten other agricultures, especially organic crops. In this asymmetrical conflict, alternative agricultures face an existential threat from the agro-industrial paradigm and so seek total segregation or even exclusion of GM crops in particular. Environmentalist groups, organic and many small-scale farmers have advocated 'GM-free zones'. To promote agricultural diversity, the European Commission has elaborated a policy on 'co-existence' between GM, conventional and organic crops. This officially aims to ensure that farmers can freely choose among those production systems, which would develop side by side. Within this framework, segregation measures could ensure that any 'adventitious presence' of GM material remains below the threshold for labelling products as GM. Specific national rules could assign a burden of responsibility for segregation, as well as liability to compensate any economic loss incurred by non-GM crops.

Despite the official language of free choice, any rules limit the choice of some farmers more than others, thus favouring one agri-paradigm over others. In response to criticism, Commission guidance has accommodated widespread demands that GM farmers should bear the economic burden of segregation measures. But some draft rules have sought to minimise any 'adventitious' presence, on grounds that this term should mean only those admixtures which are technically unavoidable. The Commission has rejected such rules for imposing a disproportionate burden, which could deter or preclude GM crops.

Through 'GM-free zones', moreover, some regional authorities have sought to brand, structure and market their territory for economic competitive advantage. Rural space is redesigned for green, high-quality agri-production; this agenda aims to enhance the market value of diverse local agri-products and other environmental assets. Any prospect of nearby GM crops is framed as a threat to local genetic resources and regional marketing strategies.

Thus 'coexistence' policy has become yet another arena for contending agricultural paradigms, which may not readily co-exist in practice. Wherever a rural development paradigm gains local support, its alternative agricultures are in contradiction rather than coexistence with GM crops. ■



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