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EXPLORING THE LINKS BETWEEN SCIENCE, RISK,  
UNCERTAINTY, AND ETHICS IN REGULATORY  
CONTROVERSIES ABOUT GENETICALLY MODIFIED CROPS

**ABSTRACT.** Just as a stream of genetically modified crops looked set to be approved for commercial production in the European Union, the approval procedure appears to have become bogged down once again by disagreements among and within member states. Old controversies have resurfaced in new forms. The intractability of the issues suggests that the regulatory procedure has had too narrow a focus, leaving outside its boundary many of the more fundamental aspects that cause people in the European Union most concern. Regulators have come under considerable pressure to ensure their risk assessment decisions are soundly science-based. Ethical issues have been deemed to lie beyond the scope of the regulatory procedure, as a matter to be considered separately by professional ethicists. Yet it has been suggested that all environmental controversies at root involve disputes about fundamental ethical principles. This paper examines how the ethical issues are currently suppressed or sidelined. It discusses how an appreciation of systems thinking and a check on the values that underpin decisions, using boundary testing questions, might contribute to a more constructive regulatory dialogue, with ethical issues considered as integral in a way that takes better account of people's concerns.

**KEY WORDS:** Biotechnology, critical systems heuristics, environmental ethics, regulation, risk

## 1. INTRODUCTION

### 1.1. *What's the Problem?*

Commercial production and use of genetically modified crops in the European Union is being held up by recurring controversy. After prolonged deliberation among member states, the European Commission has finally given its consent to the marketing of several genetically modified crops, including oilseed rape, soyabean and maize. It might have been assumed that with these consents, some of the earlier uncertainties and disagreements had been resolved, so that succeeding applications for marketing other very similar products would be approved without too much difficulty. In practice, this has been far from the case. More recent marketing applications have met with renewed disagreement among member states,



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TABLE I  
Status of EU marketing applications – February 1999

CA	Applicant	Ack.	Crop	Modification	EC consent
UK	PGS	Feb. 94	Oilseed rape	Hybrid, H	Feb. 96
UK	Monsanto	Dec. 94	Soyabean	H	May 96
Fr	Ciba-Geigy	Mar. 95	Maize	I, H, A	Feb. 97
Fr	PGS	July 95	Oilseed rape	Hybrid, H	Pending
Fr	PGS	July 95	Oilseed rape	Hybrid, H	Pending
UK	AgrEvo	Mar. 96	Oilseed rape	H, A	June 98
Fr	Pioneer Hi-Bred	Mar. 96	Maize	I, H, A	Pending
Fr	AgrEvo	May 96	Maize	H	Pending
Fr	AgrEvo	May 96	Maize	H	Pending
UK	Northrup King	June 96	Maize	I, H	June 98
Fr	Monsanto Eu	June 96	Maize	I, H	Pending
De	Hoechst Sch AgrEvo	July 96	Oilseed rape	H	Pending
Be	PGS	Jan. 97	Oilseed rape	Hybrid, H	Pending
Dk	Monsanto Eu	Oct. 97	Fodder beet	H	Pending
UK	Monsanto Eu	Dec. 97	Maize	H	Pending
NL	Dekalb Genetics	June 98	Maize	I, H	Pending

(Key: UK United Kingdom, Fr France, De Germany, Be Belgium, Dk Denmark, NL Netherlands; PGS Plant Genetic Systems, Sch Schering; Ack Acknowledged; H herbicide tolerant, I insect resistant, A Antibiotic resistant.)

so that there is now a back-log of products awaiting a decision from the Commission (Table I).

### 1.2. *What's the Response?*

The prevailing view in the UK, and in the European Commission, is that the objections being raised lie outside the regulatory remit. The chairman of the UK's advisory committee on releases to the environment (ACRE) has emphasised the need to keep the regulatory process focussed on safety:

The responsibility of advisory committees, such as ACRE, is to develop scientific procedures for assessing risks, consider risk assessments and advise whether the GMOs [genetically modified organisms] are at least as safe as the parents from which they are derived. Social, ethical and other issues arising from this technology should be debated elsewhere by those with the appropriate competence (DETR, 1998, p. 5).

To some extent, the ethical issues *are* debated elsewhere, by professional bioethicists. For example, in 1991 the European Commission set up the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB). The remit of this six (later nine) member group was to identify

and define the ethical issues raised by biotechnology, to assess from an ethical viewpoint the impact of the Commission's activities in the field of biotechnology, and to advise the Commission on the ethical aspects of biotechnology (EC, 1996). The group's advice so far has been limited and bland. For example, when asked to advise the Commission on the ethical issues surrounding the labelling of foodstuffs, its opinion was: 'Modern biotechnology, as a technique, used in food production, cannot be regarded in itself as ethical or non-ethical' (EC, 1996, p. 18).

Since December 1997, GAEIB has been expanded to form a new 12-member group, the European Group on Ethics in Science and New Technologies. This has a broader remit, for example encompassing information technology, although biotechnology will continue to be an important focus. Its main purpose is stated to be to foster debate among legislators, interested parties, and the general public (EC, 1998).

In the UK, the usual practice when the Government needs ethical advice is to set up ad-hoc committees of inquiry (Vines, 1994). For example, in 1992, the Minister of Agriculture, Fisheries and Food set up the Polkinghorne Committee to look at the ethical concerns surrounding food products derived from transgenic organisms, including concerns about the transfer of human and other animal genes to food products. Its report was published in 1993 (HMSO, 1993). To help overcome the piecemeal approach of such temporary ad-hoc committees, in 1991 the Nuffield Foundation funded the setting up of a bioethics council, to define ethical questions raised by medical and biological advances and to try to anticipate public concern. A working party of this committee has recently issued a public consultation document on genetically modified crops, which takes a much more open-ended and broad view of the issues than the Government-initiated committees (Nuffield Council on Bioethics, 1998). However, it has no formal link into the regulatory procedure.

### 1.3. *Why is This Response Inadequate?*

As commercial use of genetically modified crops and foodstuffs becomes a reality, the existing regulatory system is proving inadequate to deal with the issues that most concern people. The risk assessment procedure is hampered by the need for regulators to present their decisions as soundly science-based, which leads them to focus on a narrow range of possible effects. In practice, because of the uncertainties, risk assessment depends as much on professional judgements about the relevance, plausibility, and acceptability of effects as it does on scientific evidence. The disagreements among member states show that professional judgements can differ (for a detailed analysis of the differences, see Levidow et al., 1996, 1997).

There are at least two significant criticisms that can be levelled at the view that value-driven ethical questions lie beyond the regulatory remit. The first is that science-based decisions are not value free. For example, value judgements are involved in deciding what impacts to include and leave out of the risk assessment, and what counts as environmental harm. Even for impacts that can be fairly confidently predicted to occur, such as the spread of herbicide tolerance from the modified crop to conventional crops and related weed species, decisions about the acceptability of this risk involve value judgements.

The second criticism is that the subjectivity of the decisions is compounded when the issue is not risk but uncertainty. Wynne (1992) has suggested that uncertainty comes in various forms: uncertainty about the probability of a known impact occurring, ignorance about what the possible impacts might be, and indeterminacy arising from the unpredictable nature of open systems, especially those involving human behaviour. While it may be difficult to take such uncertainties into account in the regulatory procedure, downplaying them by using the language of calculable risk undermines public trust in the regulators' precautionary efforts.

The way that ethical issues are considered can also be criticised for a number of reasons. First, the link between the regulatory procedure and the Commission's ethical advisers is weak; their opinions are not binding on the Commission. Secondly, the opinions of the professional bioethicists seem to be based on traditional anthropocentric and utilitarian ethical theory. Although some account is taken of sentient beings, little account seems to be taken of future generations, equity between developed and developing countries, and the moral considerability of ecosystems. The emerging ecocentric theories of environmental ethics are not considered, even though there are clear signs of shifting public values towards the environment, especially among environmentalists (e.g. see Grove-White and Szerszynski, 1992). Third, the main role of the Commission's ethical advisers, according to a Member of the European Parliament, is to educate the public to accept 'new mental images' (cited in Carr and Levidow, 1997, p. 148). A related point has been made before about Britain's ad-hoc national ethics committees: that they tend to look at issues in terms of what they can get the public to find acceptable, rather than what ought to be acceptable; they encourage policy makers to think 'we've referred it to them, the ethics is now sorted, now we can just get on with the business' (Harris, quoted in Vines, 1994). Fourth, the value assumptions and normative judgements underlying the risk assessment decisions are not questioned. Fifth, many of the concerns being raised are not readily separable into scientific and ethical components but are integrally linked.

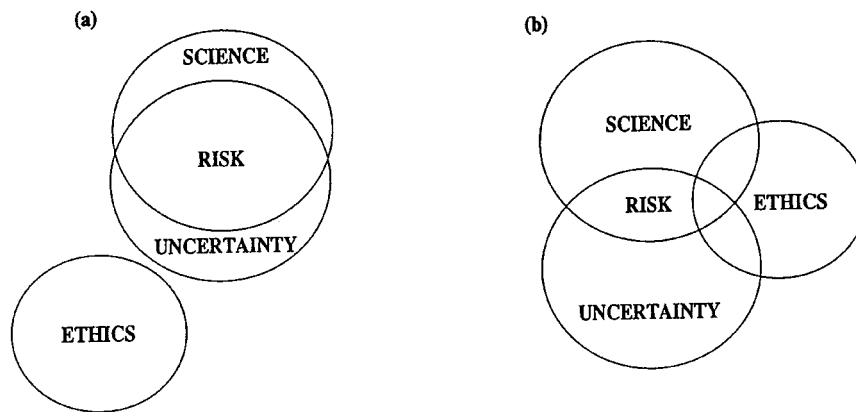


Figure 1. Conceptual maps of the links between science, risk, uncertainty and ethics.

The conceptual maps in Figure 1 show how the links between risk, science, uncertainty, and ethics seem to be viewed at present by the regulatory system (Figure 1a) and how they might be viewed in a more integrated way (Figure 1b). At present, risk is represented as if it can be assessed predominantly on the basis of scientific evidence, with relatively little uncertainty involved, while ethical judgements are treated as a separate issue (Figure 1a). A more integrated approach would view uncertainty as a larger component of the risk assessment, and ethics as integrally involved in judgements about science, risk, and uncertainty (Figure 1b).

## 2. APPLYING SYSTEMS THEORY

Soft systems theory holds that since we each have a unique background of experience and knowledge, we each bring our own perspective (based on our beliefs, assumptions, and values) to a problem, so that we may perceive the same situation differently. In taking decisions, especially those that are complex and involve uncertainty, we focus on some things and ignore others. In systems terms, we differ in where we place the boundary between the system of interest and its context, or environment. This boundary placing may be a deliberate choice, to manage and simplify complexity, or it may be unconscious, based on a taken-for-granted assumption that everyone shares the same view. It has important effects on decision outcomes, for example, by determining whose expertise is considered relevant to the decision.

Systems maps can be used to explore differences in how people perceive the boundaries of a system. For example, the boundary of the risk assessment system for the PGS herbicide-tolerant oilseed rape (see

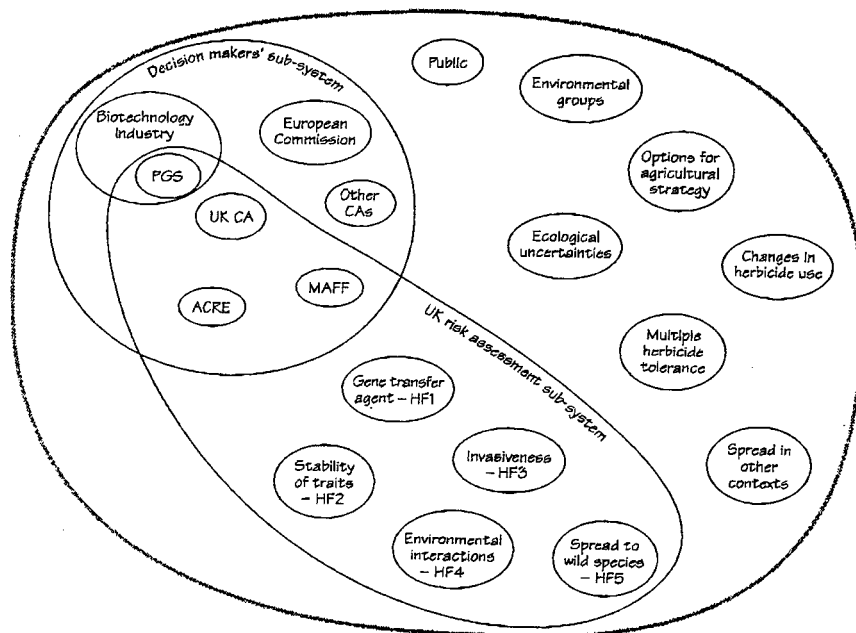


Figure 2. Systems map showing the boundary of the UK risk assessment (sub-)system for a herbicide-tolerant oilseed rape (Source: Carr, 1998).

(Key: PGS = Plant Genetic Systems, CA = Competent Authority, ACRE = Advisory Committee on Release to the Environment, MAFF = Ministry of Agriculture, Fisheries and Food, HF = hazard factor)

the first row of Table I) is shown in Figure 2 (Carr, 1998). The Government's conservation agencies argue that there should be a wider boundary to the risk assessment system. For example they believe that the remit should include assessment of the ecological effects of crop management systems associated with genetically modified crops (English Nature et al., 1998). Recently the UK Government has responded to such views by announcing that in future ACRE's remit will include secondary effects (Hansard, 05/11/98). This change is likely to mean a broader range of expertise will be needed on the advisory committee.

Challenging boundaries can be a powerful way of challenging decisions, by revealing the decision-makers' unspoken assumptions and values. Ulrich (1993, 1996) has proposed a checklist of boundary-testing questions, which can be used for this purpose. Alternatively, the checklist can be used by the decision-makers themselves to allow them to explore their own assumptions and values, or to make the basis of decisions more transparent so that they can be openly debated and, if necessary, defended or revised.

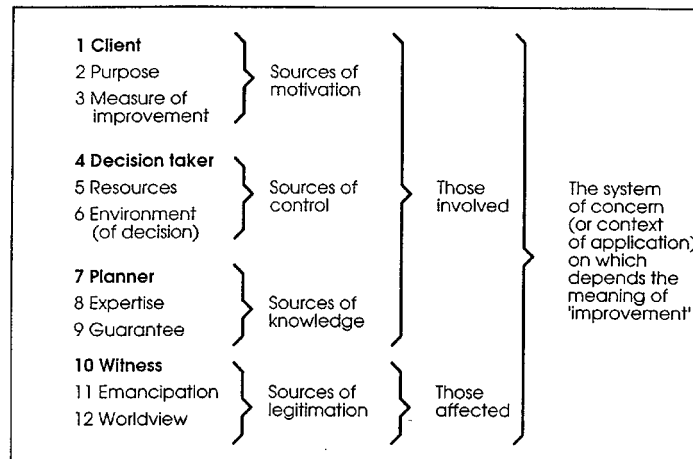


Figure 3. Ulrich's categories of boundary – testing questions (Ulrich, 1996).

Ulrichs' questions, or 'critical systems heuristics', refer both to those involved in the decision (or 'system of concern') and those affected by it (Figure 3). The questions are grouped into four sets of three: those concerning the system's sources of motivation, its sources of control, its sources of knowledge, and its sources of legitimation. Ulrich suggests the questions should be asked first in the 'ought' form, for example, for item 1 'Who ought to be the system's client? That is, whose interests ought to be served?', then in the 'is' form. Comparison of 'ought' and 'is' answers, from different viewpoints, helps make value judgements explicit.

As a preliminary test of the relevance of these boundary-testing questions to the controversies surrounding crop biotechnology, we applied them to statements in documents recently published by organisations with differing viewpoints. Here, as an example, we show statements that relate to the 'sources of motivation', Questions 1, 2, and 3 (Table II). The answers reveal some of the more fundamental differences in values that underlie the controversy and help explain the lack of trust in the regulators' safety judgements.

This test has shown us that Ulrich's checklist of boundary-setting questions *is* relevant to the controversies surrounding crop biotechnology and *can* be used to explore differences in assumptions and values. It has also indicated that the phrasing of the questions may need to be adapted to express them in terms more relevant to respondents and to the specific issues, as found by Midgley and colleagues when they used them to explore the issues surrounding the provision of housing services for elderly people (Midgley et al., 1998). A way needs to be found round the tension between allowing respondents to define their own system bound-

TABLE II

Examples of answers to Ulrich's boundary – testing questions

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*1. Who is/ought to be the system's client? That is, whose interests is/ought to be served?*

The technology holds significant benefits for farmers, food producers, consumers, and the environment (NFU et al., 1997)

[The] probability is, across Europe, industry interests are being given precedence over the interests of other groups in society, and the wider public good (SAFE, 1998)

These products are being created because those who do are hoping to make money out of them. The 'need' is to improve company bank balances (Greenpeace, 1997, p. 3).

*2. What is/ought to be the system's purpose? That is, what is/ought to be the consequences?*

Biotechnology will play a central role in maintaining growth in Europe and securing employment (Franz Fischler, EU farm commissioner, 1997).

The NFU believes that biotechnology may help improve the efficiency of production, develop new market opportunities, enhance the marketability of many existing products, and contribute to better standards of animal health and welfare. We also believe biotechnology is capable of delivering environmental benefits (NFU, 1998, p. 6).

... claims for environmental benefits resulting from these crops are not substantiated by anything other than anecdote. We would also need evidence of how real the agronomic benefits are for these [herbicide-tolerant] crops (RSPB, 1997, p. 2).

*3. What is/ought to be the underlying measure of improvement? How shall we determine that consequences constitute an improvement?*

... there should be a checklist of criteria to evaluate whether specific applications of modern biotechnology could be considered sustainable ... and a system for weighing these against an agreed definition of sustainable agriculture (de Vriend, 1997).

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aries, and pre-defining the boundaries of the system to be explored so that the answers of different respondents are sufficiently comparable to have practical relevance. For example, in the test run, some answers related specifically to the UK's risk assessment system, and some to biotechnology in general. Few 'ought' statements about biotechnology were found in the documents of some environmental groups, possibly because they oppose the technology altogether and instead support alternative systems. Midgley and colleagues resolved this boundary-setting tension by conducting their research in two phases, the first involving an open-ended exploration of the boundaries to establish where a workable outer limit might be set for the second phase of their research (Midgley et al., 1998).

We now intend to do a more thorough testing of the checklist, in which the questions, first in the 'ought' mode and then in the 'is' mode as Ulrich

suggests, are asked systematically of the regulators and other stakeholders as well as of the 'witnesses'. The research will examine if the checklist, appropriately developed and modified, or other similar approaches, might provide a framework within which the current risk assessment procedure could be embedded, to set the scientific assessment in its social and ethical context and address the broad issues that commercial releases raise.

### 3. CONCLUSIONS

In establishing the present regulatory framework for genetically modified organisms, the EC originally envisaged that its precautionary, step-by-step approach would allow earlier uncertainties gradually to be resolved as products were tested first in the laboratory and then in controlled field trials. It was assumed that if laboratory tests and field trials showed no cause for concern, it would be possible to declare the products safe for commercial use without the need for further regulatory control.

However, commercial use affects a much wider group of people than previous 'steps', and their concerns need to be addressed if genetically modified products are to gain general acceptance. The narrow, science-based, risk-assessment procedure is inadequate for this step. Much broader questions need to be satisfactorily answered and precautionary measures such as monitoring need to be intensified rather than relaxed.

New institutional arrangements, involving a broader range of expertise, better representation of consumer views, and improved transparency of decision making, have been called for by a number of individuals and organisations in the UK (e.g., see Macrory, 1997). In response, the UK Government is now considering proposals for a stakeholders forum, to work in parallel with ACRE and consider some of the broader environmental issues (Meacher, 1998). There is much that could be learnt from the changes over time that have occurred in the related procedures of environmental impact assessment, which have given gradually increasing attention to: public consultation, justification of the proposals and consideration of alternatives, monitoring and evaluation, mediation and dispute resolution, cumulative impacts, strategic assessment of policies and programmes, and compatibility with the aims of sustainable development (Sadler, 1994).

Risk assessment procedures may need to be extended in much the same way as environmental impact assessment, to take account of social issues. Boundary-testing questions, such as those proposed by Ulrich, could provide a framework to set the scientific evidence within its changing social context, in a way that examines value judgements and considers science, risk, uncertainty, and ethics as inter-related rather than separate.

While this may slow down biotechnology research and development in the short term, in the medium and long term it is likely to encourage industry to concentrate on developing the products most likely to benefit society and the environment, to find ready markets and to help achieve the European Union's sustainable development goals.

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