Contested rationality: early regulation of GMO releases in Britain

Thesis

CONTESTED RATIONALITY: EARLY REGULATION OF GMO RELEASES IN BRITAIN

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Contents

Abstract

This thesis analyses the development of safety regulation for the intentional release of genetically modified organisms (GMOs) between 1989-92, especially in Britain in its European context, and by contrast to the USA. The thesis emphasizes the practical dilemmas of GMO regulation in accommodating uncertainties about public unease and environmental harm. It serves as a case study of safety regulation as a constructed rationality, of national regulatory styles, and of environmental precaution.

In anticipating hazards prior to evidence of harm, GMO regulation had a contested 'rational' basis. Regulators encountered disputes in defining the risk problem, in establishing risk-management institutions, and in reducing scientific uncertainty about potential harm. Insofar as GMO regulation had a precautionary content, it undermined the 'rational' stereotype of risk-assessment steps.

Both the precautionary potential and its limits derived from the project of overcoming obstacles to a biotechnology market. This meant symbolically normalizing GMOs as benign products, while specifying testable ecological uncertainties rooted in some naturalistic analogy. Technical 'risk' abstracted potential harm from issues of socio-agronomic control which underlay the earlier environmental controversy.

The thesis argues for recasting theoretical models of safety regulation as a 'technical' or 'procedural' rationality. GMO regulation contained poles of tension which such theoretical models attribute to antagonistic rationalities. Broadly speaking, the regulatory system was managing an internal contradiction between social legitimacy and commercialization. The difficulties of GMO regulation arose from its implicit role in legitimizing biotechnology, by default of any democratic procedure for adjudicating a contentious technoscientific development.

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Chapter 1
INTRODUCTION

In the 1970s a public controversy arose over the hypothetical hazards of laboratory experiments which were creating genetically modified organisms (GMOs). By the mid-1980s, GMOs were being designed to survive and perform functions live in the environment; prospective products included crops, microbial pesticides, live viral vaccines and bioremediators (for pollution control). As these R&D efforts reached the stage of small-scale field release, there were renewed disputes over safety.

This thesis traces the development of Britain's approach to regulating the intentional release of GMOs between 1989-92, in the international regulatory context. The thesis analyses the contested 'rational' basis of GMO regulation, as a precautionary attempt to anticipate hazards prior to evidence of harm. This attempt provides a case study for exploring theoretical perspectives on safety regulation as a distinct type of rationality. In particular the study examines difficulties in defining the risk problem, in establishing risk-management institutions, and in reducing scientific uncertainty.

This introductory chapter sets the scene as follows:
* classifying GMOs: how the early debate disputed the status of GMOs and their regulatory implications (section 1);
* procedural rationality: theoretical perspectives on how the stereotypically 'rational' form of risk regulation becomes constructed and challeged (section 2).
* the thesis: summary argument and structure (section 3).

1.0 CLASSIFYING GMOs

The early risk debate entailed a dispute over the conceptual status of GMOs, as a leading part of the new biotechnology, for which government was providing substantial research funds. Enthusiasts celebrated the potential for biological methods to devise safer, less polluting agricultural practices. Yet popular suspicion of the genetic modification process, especially as controlled by agrochemical companies, tended to associate GMO releases with pollution, in both tangible and symbolic ways.

According to public-opinion polls, greatest unease focused on particular aspects of biotechnology, such as the prospect of food containing human genes, or of animals being

genetically modified at all. More generally, images of 'mutant' organisms potentially associated GMOs with nuclear power and pesticides (Tait, 1988, 1990).

Amidst that inchoate unease, many people conflated environmental, social and ethical aspects. For bioscience generally, 'the public is aware that traditional values are indeed at hazard in the process, despite presentation of the science as "value-free".... conflicts in this area arise from the tension between recognized social values and the unstated values embedded in scientific developments and technical possibilities' (Roy et al., 1991: 321).

Such tension was manifest in contending ways to classify GMOs, at three related levels:
* defining biotechnology (section 1.1);
* anticipating effects (section 1.2); and
* structuring safety regulation (section 1.3).

Let us consider those three levels in turn, though without assuming that the regulatory debate or policy follows such a logical sequence.

1.1 Defining biotechnology

This study concerns mainly agricultural GMOs, which form part of the new biotechnology, as variously defined. Any definition conveys some meaning about a value-free or value-laden content, about familiar or novel features, and about the natural or artificial origin of biotechnology. In this study, the term denotes the 'new biotechnology', based upon recombinant DNA techniques for transferring selected genetic material across species barriers.

In some accounts, the term 'biotechnology' encompasses the entire human history of biological intervention, including the 'old biotechnology' -- itself a retrospective new name for beer brewing, breadmaking, etc. In this way, the US Congressional Office of Technology Assessment defined biotechnology as '... any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses'; this report identified biotechnology not as an industry in itself, but as an enabling technology with diverse applications (OTA, 1984: 3). Similarly, an academic writer described biotechnology as '...knowledge and techniques involving the integrated use of biochemistry, microbiology, genetics and engineering sciences to achieve the technological application of capabilities of micro-organisms, cultured tissue cells and parts thereof'; he emphasized the greater knowledge and control over the smaller-scale 'parts' of organisms (Orsenigo, 1989: 32).

Some accounts celebrate novel features of a molecular-level control. According to an industry-funded booklet, this control offers us 'the ultimate study of mankind', perhaps 'the most dynamic of the great technological revolutions of the 20th century' (Taverne, 1990). Another such booklet, intended for school students, announces 'biotechnology -- a new

industrial revolution', defined as 'the application of organisms, and their cellular, subcellular or molecular components, in order to provide goods, services and environmental management' (Satelle, 1988). A company official speaks of 'supply-side genetics' and 'utilization-side or value-added genetics' (Lawrence, 1988: 32); such metaphors acknowledge the market priorities which are often embedded in the genetic redesign of nature.

This historical novelty has been imbued with a natural legitimacy. According to the Monsanto Company (1984), biotechnology is based upon a 'natural science', i.e., genetic engineering. With biotechnology, 'We have entered a joint venture with nature'; we have launched 'yet another industrial revolution', which offers society 'a cornucopia of new products' (Harbison, 1988). Indeed, 'We can at last find biological solutions to biological problems that mechanization and chemicals cannot solve' (Earle Harbison quoted in Krimsky, 1991: 84).

This ambitious project builds upon its 1930s origins in molecular biology: 'It is a biology built on fundamental abstractions such as the notion of a universal code, the idea of information, the metaphor of a programme controlling cellular activity.' And it redefines nature itself as constructible, reprogrammable, interchangeable (Yoxen, 1983: 34). In these ways, molecular biology de-emphasized the natural-historical, evolutionary and functional explanations which had previously characterized biology. Instead it favoured a reductionist focus on genetic structure; the latter approach proved amenable to the biotechnological project of 'capitalizing life' (Yoxen, 1981: 80).

Consequently, molecular biology has facilitated an 'industrial genetics', which applies a systems engineering model to all living things, while recasting life in its own image. In this way, biotechnology departs from Lewis Mumford's earlier vision of biotechnics, whereby improvements would 'rest upon a more organic utilization of the entire environment, in response to the needs of organisms and groups considered in their multifold relations...' (quoted in Krimsky, 1991: 9). Instead, biotechnology treats problems as genetic deficiencies; for example, it attempts to correct 'nutritionally deficient seeds' or even the undesireable outcomes of other technologies. Through this genetic 'fix', it aims to optimize ecological and economic efficiency, by industrializing environmental resources (ibid: Chapter 5; e.g. Harbison, 1988: 7).

As an industrial project, then, biotechnology extends a bioengineering vision far beyond the laboratory or factory walls. It redefines what counts as a biological problem to be solved, in terms of genetic changes; this can mean, for example, enhancing food quality as valued by market price, making crop products more interchangeable, or replacing traditional chemical inputs with genetic ones. Conversely, 'life' becomes reconceptualized in terms of computer-controlled chemicals; subcellular components become instruments

which themselves embody the 'third industrial revolution', the principles of computer programming.

In sum, given the contentious values in biotechnology, it was evaluated according to antagonistic models for conceptualizing the agricultural environment. Biotechnologists celebrated their new techniques which, paradoxically, would bring us a technological-industrial revolution by extending an evolutionary continuum of natural processes. For some critics, biotechnology transgressed and/or reconstructed nature, in ways which might preclude alternative directions for bioscience and agriculture. How, then, did they anticipate environmental effects of GMOs?

1.2 Anticipating effects

In disputing possible effects of GMO releases, protagonists evaluated biotechnology as a mode of environmental control. According to one agronomist, for example, 'As plant breeding *per se* is a wholly benign technology, any enhancement of it must be welcomed as being in the public good, no matter who does it' (quoted in Kloppenburg, 1988: 5). In this account, GMO products offered us the logical next step of a beneficent tradition.

On the contrary, according to some critics, the 'old' biotechnologies have been driven by capitalist imperatives, turning all resources into commodities and intensifying the social division of labour. Those forces have caused both socio-economic and environmental damage, the latter resulting particularly from genetically uniform seeds dependent upon chemical inputs. The seed 'becomes the nexus of control over the determination and shape of the entire crop production process' -- and now more effectively so, by 'reprogramming the genetic code' (ibid.: 201).

From that perspective, biotechnology facilitates greater genetic uniformity and commercial control. Consequently, for example, the design criteria for GMO biopesticides impose the likelihood of harm to non-target insects and selection pressure for resistant insects; the predominance of herbicide-resistant crops within biotechnology R&D carries prospects for prolonged chemical dependency and further environmental damage (ibid.: chapter 9; cf. Doyle, 1985). Herbicide-resistant crops could encourage increased herbicide spraying, which has already increased crops' vulnerability to disease and thus required additional protective chemicals (Pimentel, 1987). Such accounts warned that GMO products may aggravate types of systemic harm which have been already documented yet inadequately regulated.

Much early debate focused less upon systemic effects than upon the initial small-scale field trials, some of which met organized opposition in the USA, where R&D efforts were most advanced. According to many laboratory scientists, experience hitherto had confirmed that GMOs were analogous to other domesticated, predictable organisms;

groundless concern about hypothetical hazards was unduly restricting scientific research (e.g. Davis, 1987). At a major scientific conference in 1988, the closing address implied that the question was resolved: 'The small amounts of foreign DNA introduced by genetic engineering, however, are unlikely to increase fitness, which requires evolutionary co-adaptation of the entire, balanced genome' (in Sussman et al., 1988: 296).

For many ecologists, by contrast, it was premature to classify GMOs by analogy to organisms familiar from past experience. Indeed, some GMOs could prove analogous to non-indigenous organisms which have unexpectedly acquired a selective advantage in their new environment (e.g. Alexander, 1985; Sharples, 1987). Ecologists associated genetic novelty with greater unpredictability; some conceptualized 'ecological niches' as dependent upon genetic variation, not simply upon environment (e.g. Regal, 1985, 1990). In order to detect potential harm, they proposed extensive field tests, and more basic ecological research, before any GMO could be regarded as innocuous (e.g. Tiedje et al., 1989).

That disagreement has been analysed as a 'disciplinary fault line' between scientific paradigms. Geneticists emphasized nature's unity and stability, which warranted putting great confidence in human control over biological systems. By contrast, ecologists emphasized nature's complexity and interdependence, which left open the prospect of GMOs causing unpredicted disturbances (Krimsky, 1991: chapter 8; see further my Chapter 4, section 1.2).

Partly at issue was how to classify GMOs by analogy to previous experiences, e.g. non-indigenous organisms and/or agricultural products. Scientists disagreed on how to conceptualize unintended effects in relation to intended ones, within an overall control system. In anticipating possible effects, they brought to bear different cause-effect models of environmental harm, and different concepts of the risk-generating system, e.g. intensive monoculture. How would these differences bear upon regulating GMO releases?

1.3 Regulating GMO releases

Early GMO releases presented a difficult case for risk regulation, because there could not yet be meaningful evidence to confirm or dismiss hypothetical hazards. Regulatory measures came partly in response to public unease and protest, which lent greater weight to ecologists' proposals for safety testing. In an attempt at some international agreement, it was proposed that biotechnologists carry out a case-by-case risk assessment of GMO releases; by progressively relaxing containment, in a stepwise manner, each GMO could become better characterized and predictable (OECD, 1986: 29). This nominal agreement remained open to divergent interpretations (see Chapter 4, section 1.2).

In Britain, the government was promoting biotechnology research for its expected environmental, agricultural and economic benefits (HMG, 1990: 184; AFRC, 1992). In parallel with such R&D efforts, it co-ordinated a voluntary self-regulation of GMO releases from the mid-1980s onwards. In Britain the regulatory initiative came from biotechnologists themselves, though perhaps mindful of political protest elsewhere.

In 1985, when planning Britain's first GMO release, a research institute submitted its application to the Health & Safety Executive and consulted local environmental groups (Bishop et al., 1988: 150). Soon afterwards, the HSE set up a special subcommittee for assessing such applications (Shackley, 1988: 68); they also issued a set of wide-ranging risk-assessment criteria (ACGM/HSE, 1986; cf. OECD, 1986). According to the subcommittee chairman, 'the guidelines would have to be very general in nature to allow flexibility and to ensure that important, but presently unrecognized, aspects of risk would be considered' (Beringer, 1988: 168). Prospective releasers submitted their own risk assessments, seeking to demonstrate safety before carrying out any release (Shackley, 1988: Appendix 1).

Regulators acknowledged the unusual precautionary (or proactive) feature of their efforts. Speaking at a 1988 conference, a leading HSE official noted that 'there are few other experiences of this type of proactive regulation'. Britain had already set a precedent in the 1970s by anticipating 'conjectural hazards' from the contained use of GMOs, with flexible guidelines which could be adjusted with experience; similarly, for regulating GMO releases, 'learning by experience would be an important element' (Ager, 1990).

Such 'learning' posed new difficulties. In the 1980s, biotechnologists designed microbial GMOs not to survive outside specified conditions; soon regulators cited the absence of harm and greater predictability, to justify relaxing precautions on GMOs within contained use (Bennett et al., 1986; Wright, 1986). For agricultural products, however, regulation would have to specify the criteria for permitting GMOs to proceed from the laboratory stage, to small-scale field trials, through to commercial product approval.

Indeed, given that the live products were intended ultimately for an international market, political pressures were mounting to standardize safety rules across national borders. At the same time, governments faced political uncertainty about public responses to GMO releases. Under such pressures, governments sought appropriate safety controls which could be initially imposed and then eventually relaxed, by showing that the precautions were no longer necessary. At issue was how to formalize a statutory and scientific basis for such a regulatory procedure.

1.4 Thesis focus: research questions

This study analyses the difficulties which arose in devising and implementing a procedure for regulating GMO releases, particularly in Britain, within the international regulatory context. The research initially posed the following questions:

* How does the regulatory system define the risk problem?
* How and where do value judgements enter risk assessment?
* How do various socio-political forces interact around the regulation?
* What is the precautionary content of the regulation, and why?

In the course of this study, the regulatory regime encountered some difficulty in justifying its 'rational' status. The study gave this problem a theoretical structure, by asking: How does GMO regulation construct its own rationality? In particular:

* How does the regulatory system handle diverse accounts of the risk problem? How does this selectively treat some 'perceived risks' as if they might be real?
* How is a risk-management regime devised and justified? What is the significance of 'national regulatory styles'?
* How does the regulatory procedure attempt to reduce uncertainty about risk? (How) does this effort depoliticize scientific uncertainty?

2.0 RISK REGULATION AS PROCEDURAL RATIONALITY

Given the public dispute over a 'rational' basis for regulating GMO releases, this section will survey writings on risk regulation as a constructed and contested rationality. Social theorists of risk have analysed safety procedures as a means of providing social legitimacy for regulatory policy, even for the hazardous activity being regulated. They have variously theorized safety regulation -- as a procedural rationality, a procedural rationalism, a technical rationality, a pragmatic rationality, a scientific rationality, etc. In general this thesis will use the first term, '*procedural* rationality', partly because its adjective emphasizes a legitimation process rather than a scientific basis.

Through a series of public controversies, safety regulation has met challenges to its 'acceptable risk' judgements, its quantitative risk estimates, and even its concepts of risk. Often in dispute has been the 'rational' status of the regulatory procedure or of public protest, as if there were only one kind of rationality. Some analysts suggest that risk controversy arises from scientific uncertainty, or even from public irrationality.

Yet rationality itself is a social construct, as critical theories emphasize in various ways (e.g. Beck, 1992a: 59). As one study concludes, 'uncertainty and (ir)rationality are the outcomes of a given controversy, not its causes' (Cambrosio and Limoges, 1991: 387); that is, a policy outcome retrospectively defines the relevant scientific uncertainty and a rational manner to deal with it. Similarly, a 'pragmatic rationality' denotes a flexible procedure which can accommodate underlying disagreement on scientific evidence, even

on socio-political goals; this procedure seeks robust solutions that can withstand the pressures to which they will inevitably be exposed (Rip, 1985: 107; cf. Rip, 1986: 166).

By defining rationality as a flexible social construct, however, these theoretical models may be merely *ex-post*: any outcome can be retrospectively labelled as 'rational'. To avoid such tautology, let us consider theories of antagonistic rationalities.

According to a 'cultural theory' of risk, safety regulation exemplifies a procedural rationality; as the adjective implies, this 'is more concerned with the proprieties of who does what than with trying to evaluate the outcome', if there is one (Schwarz & Thompson, 1990: 7). A procedural rationality is one of four rationalities, or political cultures, each of which emphasizes a different structure of the relevant uncertainty, rooted in a cognitive 'myth of nature'. According to this typology (ibid.: 62-68):

* A 'hierarchist' culture imposes its authority to ensure that technological developments remain within the uncertain limits of environmental stability, within the safe bounds of 'nature perverse/tolerant'. A procedural rationality anticipates those limits, by developing an expert interdisciplinary knowledge.
* An 'individualist' (or market) culture promotes developments which can reap the cornucopian bounty of 'nature benign', through a 'trial-and-error' process. It counterposes a laissez-faire policy to any regulatory control which may threaten the functioning of the market.
* An 'egalitarian' culture often opposes technological developments as threats to a fragile 'nature ephemeral'. Through a critical rationality, it promotes democratic control over such developments, by accepting only 'trial without error', and by counterposing a holistic knowledge to any specialist expertise.
* A 'fatalist' culture passively endures the vicissitudes of 'nature capricious'; by default, such people remain excluded from the social contest among political cultures.

According to this typology, technological controversy arises from incompatible problem-definitions, each of them rooted in a distinct political culture. Each selects 'risks' which stand as proxies for technological choices, which in turn are made possible by some form of social control (ibid.: 7-8). In attempting to influence such choices, any act may be deemed as 'rational' if it promotes a preferred mode of social organization, as classified by grid-group theory (ibid.: 53, 61). However, this typology may oversimplify the subtle differences and ambivalences which arise in real-life controversies (Wynne, 1992: 291).

In particular, by distinguishing between 'regulatory hierarchies vs entrepreneurial markets', the typology may be too simplistic, for several reasons. First, when risk controversy has challenged the legitimacy of technoscientific 'progress', safety regulation has often served to overcome the threat (Beck, 1992a: 22; see further below). Second, when national regulatory differences have posed trade barriers -- to hazardous chemicals,

for example -- industry has often been willing to accept more stringent regulation and to incur higher regulatory costs, for the sake of promoting free trade (Brickman et al., 1985: 390). Third, safety standards often play the implicit economic role of co-ordinating market relations, while favouring some innovations over others (Salter, 1988: 168-71). Fourth, environmental regulation may spur innovation by altering market conditions, often as an implicit or explicit rationale for regulatory changes (e.g. Weale, 1992: 67-92). Thus a 'procedural rationality' may complement, incorporate or promote market-innovative forces.

Somewhat parallel to the 'critical versus procedural rationalities' as above, another theoretical model distinguishes between 'cultural versus technical rationalities', as a typology for theorizing conflict between public protest versus safety regulation, respectively. In the USA, for example, protest against 'mutant' organisms challenged the natural, benign status of GMOs; farmers in particular questioned wider socio-economic effects of the biotechnology R&D agenda: 'The political rhetoric of the popular culture stressed control over its environment'. Such protest expresses a cultural rationality, which 'does not separate the context from the content of risk analysis' -- in contrast to a technical rationality, which considers only measurable parameters (argue Krimsky and Plough, 1988: 107-8, 306). Yet, as their research material also indicates, the risk-assessment procedure took for granted that GMOs offer a benign control and environmental predictability (ibid.: 95); thus the technical rationality also had a cultural content.

Along similar lines, Ulrich Beck too identifies 'competing rationality claims': that is, scientific rationality emphasizes the technological manageability of accident probabilities, while social rationality locates problems in the industrial mode of production. Yet, as he also argues, the distinction is becoming less possible: scientific rationality relies upon social expectations and value judgements, while public protest depends upon scientific arguments. In these ways, 'Scientific and social rationality do indeed break apart, but they remain at the same time interwoven and interdependent' (Beck, 1992a: 30).

A related interdependence has been theorized via the concept of 'procedural rationalism'. This denotes a decision-making procedure which has promoted 'a particular model of democracy -- one that required only the expert discovery of objective facts about a narrowly defined question', e.g. the safety of particular nuclear plant (Wynne, 1982: 10, 163). A procedural rationalism can credibly claim authority only by restricting its breadth: 'To be genuinely definitive, it must eventually face the question of its own agenda-defining premises; yet, to stand a chance of being authoritative, it must pretend that no such question exists' (ibid: 172). There arises a practical dilemma: safety regulation can be authoritative only by denying the limits of its narrow problem-definition, which excludes the wider risk-generating system.

Often risk controversy revolves around assumptions about system boundaries, and thus the legitimacy of the hazardous activity. Ulrich Beck argues that current innovations generate risks which are relatively more pervasive, elusive and potentially catastrophic: 'Dealing with these consequences of modern productive and destructive forces in the normal terms of risk is a false but nevertheless effective way of legitimizing them.' At the same time, risk assessment can offer an indirect means of democratizing technological choices:

> Determinations of risk are the form in which ethics -- and with it also philosophy, culture and politics -- is resurrected *inside* the centres of modernization.... [Such determinations are] an unwanted means of democratization in the fields of industrial production and management (Beck, 1992a: 22, 28).

Thus risk regulation may have a double-edged role: legitimizing a contentious innovation and/or influencing its development.

In sum, regulatory agenda-setting entails conflicts which various theories attribute to antagonistic rationalities and/or to internal tensions, in turn arising from the implicit political role of risk regulation.

These theories also suggest ways to analyse how risk regulation constructs its 'technical' criteria. According to the official stereotype, risk assessment follows a standard sequence of steps, deploying objective science in order to guide subjective judgements or even to overcome them. Such claims have encountered political protest -- in turn interpreted by social theorists who critically analyse the putative norms of 'rational' risk regulation . The rest of this section surveys critical perspectives on regulatory claims to distinguish between objective/subjective judgements, in particular:

* real/perceived risks: identifying risks, by distinguishing real from merely perceived ones (section 2.1);
* risk assessment/management: controlling risks, by basing risk management upon a prior risk assessment (section 2.2); and
* fact/value: reducing scope for value judgements about risk, by reducing factual uncertainty (section 2.3).

2.1 Identifying risk: real versus perceived?

Risk regulation has claimed to distinguish between 'real' versus 'perceived' risks, by presuming that objective science overcomes subjective ignorance. In a major report on environmental risk assessment, for example, the authors attributed conflicting risk perceptions to inadequate information, as if better-informed people would abandon their misperceptions (Whyte and Burton, 1980: 15). In a similar vein, it has been argued that biotechnology faces public fears based partly on ignorance rather than scientific fact; real risk 'also needs to be addressed, but in ways different from unfounded risks', as if science could confidently make that distinction (in Batra and Klassen, 1987: 168).

In response to risk controversy, social science has sought to explain the gap between scientific and public perceptions of risk. Early psychometric research obscured such value conflicts by assuming them to be a function of public ignorance (Wynne, 1980). In particular, psychological studies attempted to quantify perceived risks, in terms of expected fatalities for different kinds of activity, as contrasted to the statistical record; an early survey found people more willing to tolerate voluntary risks than involuntary ones (Starr, 1969).

Later surveys found people equally influenced by such characteristics as familiarity, control and catastrophic potential of risks. Some researchers acknowledged divergent concepts of risk: although lay people may lack certain information, 'their basic conceptualization of risk is much richer than that of the experts and reflects legitimate concerns which are typically omitted from expert risk assessments' (Slovic, 1987). As a recent report acknowledged, people appear to evaluate 'characteristics of hazards, rather than some single abstract concept such as risk' (Royal Society, 1992: 89).

Even a qualitative assessment of 'real' risk involves some human interpretation, such as an implicit model of the risk-generating system, or the cognitive framework of a scientific discipline. 'In this light, what is commonly called the conflict between actual and perceived risk is better thought of as the conflict between two sets of risk perceptions: those of ranking scientists performing within their field of expertise and those of anybody else' (cited in Royal Society, 1992: 97; cf. Schwarz & Thompson, 1990: 21, 139). Similarly,

> ...if all risk is defined in accordance with the categories of a particular scientific or modeling theory, then there is no actual hazard apart from some particular theoretical account of it. Hence there is no uncontroversial way to distinguish 'actual' from 'perceived' risk (Shrader-Frechette, 1991: 82).

Indeed, any such distinction has remained controversial in the realm of 'modernization risks': here cause-effect pathways of harm become more pervasive yet less accessible to sensory perception, even to scientific disciplines. At the same time, lay protest has catalysed interdisciplinary research, which often turns out to validate some 'perceived risks' as real. Contrary to the official stereotype, public perception and experience has helped to overcome specialist scientific ignorance. Thus, 'The distinction between (rational) determination of risks and (irrational) perception of them also inverts the role of scientific and social rationality in the origin of a civilizational risk consciousness.' Moreover, 'The monopoly of rationality enjoyed by scientific hazard definition stands or falls with this distinction' between real/perceived risks (Beck, 1992a: 57-58, 160).

That official distinction often attributes 'risk' to inadequate control, yet 'risk' often denotes a fear that institutions will impose an ominous control. New technological developments generate 'rational anxieties about loss of control and vulnerability' -- feelings which do not

have 'an inevitable physical, environmental focus'. Yet risk regulation displaces these tensions rather than address their substance (Grove-White, 1991: 439).

In particular, environmental biotechnology points to previously unthinkable ways of controlling the environment, and so calls into question our environmental values: 'In some ways, the public is more worried about biotechnology's succeeding than its failing' (Wachbroit, 1991: 370); that is, people may associate risk with efficacious biotechnological control. More generally, risk perception is about 'acceptance of the totality of whatever activity causes the risk', i.e., about the entire risk-generating system; to consider only quantitative risk, therefore, 'would be truly irrational' (Otway, 1992: 224).

These issues of control resonate with theories of how people evaluate technological developments as modes of social organization (see section 2.0 above). Drawing upon 'cultural theory' in particular, commentators have analysed the diverse risk perceptions which inform political protest. In general, 'different kinds of environmentalism' can stem from each of the four political cultures (Johnson, 1987: 160).

Protest against GMO releases could take a NIMBY form, i.e. 'not in my backyard', or even NIABY, i.e. 'not in anybody's backyard' (Tait, 1988). Early US protests expressed both local and global concerns (Krimsky and Plough, 1988: 96, 104); they can be interpreted as merging NIMBY and NIABY aspects. NIMBY protests may start by opposing some local, negotiable nuisance, but they often develop into a NIABY stance, even into an egalitarian culture which resists negotiation (Schwarz & Thompson, 1990: 21; Rayner, 1992: 92).

From these perspectives, we may examine how GMO regulation constructs a boundary between real/perceived risk; the boundary can be analysed as favouring a specific problem-definition, cognitive framework and mode of institutional control.

2.2 Controlling risk: assessment before managment?

Officially, safety regulation manages hazardous activities in order to ascertain the objective risks and keep them within acceptable limits. This procedure has been codified as a standard sequence of three main steps: from risk identification, to risk estimation, and then risk evaluation, i.e., judging the acceptability of the estimated risk and setting preventive measures (e.g. Whyte and Burton, 1980: 10). In elaborating on this standard sequence, risk analysts tend to acknowledge that value judgements arise in the third step, though not in earlier steps (e.g. Lowrance, 1976). As regulators have come under political pressure to justify the type of preventive measures, especially in the USA, they have used the term 'risk management' to distinguish the third step from earlier ones.

According to the above-cited report, risk-management procedures allow safety regulation to achieve rationality, though this ideal requires acknowledging scientific uncertainties and any judgements which go beyond the available scientific evidence (Whyte and Burton, 1980: xvi, 16); the authors imply that values begin where facts end. Yet this fact/value distinction often becomes blurred or disputed. According to other experts, 'the selection of which [dose-response] model to use has as large an influence on the [risk] estimate as the experimental data'; yet somehow regulation must distinguish clearly 'between fact, assumption and science policy' (quotes from contributors to Hoel et al., 1985: 182, 309).

Moreover, at issue is not only the putative boundary between risk assessment and management but also the logical sequence -- i.e. how control methods may frame the risk problem. For example, in the more socially transparent case of crowd control, engineering-based methods may lead practitioners to manage crowds as if they were inherently dangerous objects which warrant strict external control (Royal Society, 1992: 175). Conversely, 'it is said that risks which are not yet technically manageable do not exist -- at least not in scientific calculation or jurisdictional judgement' (Beck, 1992a: 29). Thus risk-management methods and capacities may influence risk assessment, depending upon which variables can be credibly controlled.

As another example of cognitive framing, hazardous substances are often declared 'safe if used as directed'; this presumes that industrial workplace practices can be controlled as carefully as a laboratory safety test. Critics argue that realistic conditions of chemical usage are not reflected in safety testing; its over-confident assumptions entail a 'naive sociology': 'These [assumptions] are not extra aspects distorting objective risk perceptions -- they are judgements of factors that determine the objective risks' (Wynne, 1989: 35; cf. Salter, 1988: 177).

As this problem illustrates, 'risk assessment' depends upon constructing and measuring artificial microworlds, where variations are restricted or ignored. For predictive purposes, reality becomes standardized according to some cognitive framework which informs an organizational culture (Jasanoff, 1993). In this vein, 'cultural theory' makes a stronger claim: that cognitive differences render policymaking possible (Schwarz & Thompson, 1990: 68). Such theoretical perspectives challenge the putative or idealized neutrality of 'science-based regulation', as expressed in a recent report which lamented that 'rational' risk-management institutions have been difficult to design, supposedly because risk debate 'has become heavily politicized around different cosmologies or worldviews' (Royal Society, 1992: 153).

For analysing links between risk assessment and management, national regulatory styles are also relevant (e.g. Vogel, 1985; Jasanoff, 1986); although also called political cultures,

they can be seen as national variants on a procedural rationality. These theoretical models identify recurring patterns by which a nation-state handles regulatory conflict. In particular, the USA has been characterized as an adversarial culture, where the regulatory authority enforces compliance with pre-set rules, which are publicly justified in clear scientific terms. As the US government has a constitutional separation of powers, this offers outsiders many entry points for influencing or undermining regulatory policy, e.g. through court cases and Congressional oversight. By contrast, Britain has been characterized as a consensual political culture, where the regulatory authority flexibly applies its broad powers, exercising much discretion in guiding self-regulation by industry; conflicts are mediated by incorporating selected representatives into confidential procedures (O'Riordan & Wynne, 1987: 398-402).

More specifically, in the early 1980s, US regulatory agencies were accused of pro-industry bias, thus undermining their claims to base policy upon neutral expertise. Subsequently, in regulating chemicals, the US government attempted to demarcate risk assessment from risk management, and so to demonstrate the objective status of the former (e.g. NRC, 1983: 7). In order to fill an apparent gap between ambiguous scientific findings and public policy, regulatory agencies devised clear administrative rules, known as 'science policy'; yet these rules in turn came into political dispute, thus undermining the executive's attempt to depoliticize regulatory science (Jasanoff, 1986: 10, 26-27, 72).

More generally, the US government has tried to substitute detailed technical criteria for overtly political ones. Yet 'the role allotted to science in American policymaking is one which it simply cannot fulfil' (Collingridge and Reeve, 1986: 158). Despite those difficulties, 'what matters most in risk management is the process, not the outcome' (Jasanoff, 1986: 81); in the USA, the open participatory process can lend legitimacy to the formal regulatory outcome.

Recently such access has become more exclusive in practice, as US regulatory agencies have attempted to enhance their own authority through scientific advisory committees. In this way, diverse experts could negotiate a more resilient version of 'good science', capable of resisting external political attack. In some cases this procedure has helped to stabilize a 'science policy', i.e. a risk-assessment policy which can protect risk-management measures from transient political pressures. In so doing, the policymaking venue has been moved from high-profile administrative hearings to routine meetings; in effect, such a terrain has favoured industry specialists over public-interest organizations. Thus a more resilient 'science policy' may restrict the substantive access which formerly lent legitimacy to regulatory decisions (Jasanoff, 1990).

In contrast to the USA, Britain's regulatory procedures have not attempted to demarcate between stages of risk assessment and management. Rather than claim expertise,

regulators claim 'competence' in obtaining and applying appropriate scientific advice. By integrating science and policy in advisory committees or Royal Commissions, the British government has generally avoided public disputes over the scientific basis of policy, e.g. in regulating hazardous chemicals (Jasanoff, 1986: 73-75, 58-59). Britain has developed a strategy of 'responsible co-optation', incorporating relevant interest groups into confidential procedures; this serves to protect the neutral image of regulatory science, while gaining public deference to expert committees (Vogel, 1986: 51-52; Brickman et al., 1985: 310; Jasanoff, 1986: 66). More recently, however, British regulation has undergone pressure to formalize its scientific rationale by adopting clear statutory rules (O'Riordan & Wynne, 1987: 409).

From these theoretical perspectives, we may examine how GMO regulation justifies its risk-management measures, as linked to risk assessment. We may also examine how GMO regulation reproduces or alters national regulatory styles (also known as political cultures).

2.3 Reducing uncertainty: facts before values?

It is often assumed that scientific uncertainty causes policy conflict, which therefore can be overcome by obtaining additional scientific knowledge. However, new data has often intensified methodological controversy among experts (e.g. Collingridge and Reeve, 1986: 51-60; Salter, 1988: 166, 199-201). This difficulty has been explained by theorizing how facts are value-laden, though theoretical models do so in different ways.

According to some models, technical uncertainty sets the context for risk controversy. For example, such uncertainty provides greater opportunity for conflicting interpretations of science for policy, even though such conflicts may be irreducible to facts (e.g. Majone, 1989: 40; Nelkin, 1979: 16). Technical uncertainty lends greater importance to value conflicts over 'risk', though the term may really denote a problem of moral responsibility (Nelkin, 1985: 18-21). Similarly, it is argued, the fact/value distinction breaks down in a context of high uncertainty, though our scientific knowledge always arises from some vision for framing the social and natural order (Jasanoff, 1993: 125).

In contrast, other theoretical models deny that 'uncertainty' explains conflict. In the controversy around a proposed oil pipeline in Canada, for example, experts variously expressed confidence or caution about managing uncertainty, partly according to how they evaluated its potential consequences. Here 'uncertainty' served as a strategic argument among experts, rather than as the source of their disagreement. That is, 'the problem of adequate knowledge becomes related to what is reasonable to know for practical purposes' (Campbell, 1985).

Moreover, actors draw upon divergent cognitive frameworks for disputing the range of uncertainty deemed relevant for policy; yet often an administrative procedure treats this structural uncertainty as if it were merely a technical uncertainty (Schwarz and Thompson, 1990: 159-62). Values arise in generating facts, not simply in interpreting them: new scientific knowledge 'is *formed* politically'. Each problem-definition generates its own 'structural interdependence of facts and values'; thus any putative fact/value boundary is a social construct which warrants analysis (ibid.: 22, 27). A procedural rationality treats a particular range of uncertainty as the most relevant to policy, defines this range as the 'technical' issues, and thus depoliticizes its own problem-definition (ibid.: 139) -- at least potentially.

Yet safety regulation can also do the opposite -- i.e. inadvertently politicize the attempt to reduce scientific uncertainty. Under critical examination, argues Beck, scientific facts 'are nothing but answers to questions that could have been asked differently'; they are products of rules for gathering and omitting aspects of reality. Given the competing assumptions of different scientific disciplines, science 'offers an image of the self-relativizing pluralism of interpretations', which 'virtually force the practitioner to make his own cognitive decisions'. Thus the mobilization of belief becomes a central means for the social enforcement of validity claims (Beck, 1992a: 166-68). That is, the policy relevance of any factual evidence requires a cognitive argument, which may undermine its apparent neutrality.

What would it mean, then, to reduce uncertainty about risk? Even the initial step of 'risk identification' presupposes some causal theory, 'an epistemic value judgement' which guides actors in generating and interpreting scientific facts. Likewise for risk estimation, where for example toxicity estimates depend upon some dose-response model. Moreover, when attempting to confirm such a predictive model, any test presupposes some methodological value judgement (Shrader-Frechette, 1991: 58-59, 42).

Nevertheless it remains tempting to presume a single account of the risk problem. This was implied by the above author in prescribing 'democratic proceduralism', an attempt at 'increasing the analytic precision of hazards assessment and the democratic control of environmental risks' (ibid.: 29, 171). Would such an attempt be a contradiction in terms?

Moreover, in cases where evidence of harm is absent or disputed, how can uncertainty be reduced? When a Royal Society report (1992: 155) discussed the precautionary principle, it asked 'how far public policy should run ahead of clear scientific findings'. Such language presumes an ordinal scale of safety, operating within a consensual range of scientific uncertainty.

More generally it is assumed that a precautionary approach intervenes mainly at the third step of risk assessment -- risk evaluation -- by lowering the burden of evidence for risk: 'This conventional view appears to hold that the body of scientific knowledge remains qualitatively the same, whilst the threshhold of acceptable risk is simply moved across the body of knowledge to a different position within that knowledge' (Wynne, 1993).

However, in regulating North Sea pollution, a prime case for a precautionary approach, there arises a fundamental conflict between two bodies of knowledge; their respective 'natural' facts derive from two competing methodologies for marine epidemiology. Many toxicologists perceive the environment as an 'assimilative capacity' for waste; they simply cannot perceive the indirect cause-effect inferences and circumstantial evidence which are studied by other scientists. In dispute are the criteria for evidence of harm; the technical aspects 'merge with epistemic questions as to why we are constructing such knowledge anyway' (ibid.).

Given these theoretical perspectives, what would it mean to reduce uncertainty about GMO releases? In the North Sea pollution case, ecologists could at least cite some evidence of harm, as grounds for investigating its causes, even for relaxing the burden of evidence for harm. In the case of GMO releases, however, there was little common ground for how to define the relevant uncertainty, so as to enhance predictability.

According to an early report on GMO releases, a complex ecosystem dynamics allows at best an 'embryonic' predictive capability; little would be resolved merely by identifying possible outcomes (Fiksel and Covello, 1986: 26-27). A subsequent report asserted that new genetic tools, along with a study of organisms introduced into the environment, offer useful knowledge which 'can provide a rational base to the establishment of prudent procedures for future applications' (Mooney and Berardi, 1990: 6).

Yet that 'rational base' lacked criteria for meaningful evidence; it depended upon posing hypothetical analogies, e.g. between GMOs and non-indigenous organisms. For example, argued a risk analyst, 'the distinction between domesticated and weedy or feral varieties of an organism is far from absolute'. And, in seeking evidence, 'the absence of positive evidence [for risk] is not at all the same as the presence of negative evidence [for safety]'. An anticipatory approach should 'strike a reasonable balance, always improving in the light of experience, between technical progress and environmental safety' (Ravetz, 1989: 72). How, then, would such progress and safety be 'balanced'? We should 'examine the structure of our uncertainties': that is, 'a natural ordering of relevant questions can be accomplished so that enquiry and debate can have some coherent structure' (ibid.: 78).

At issue, however, was the relevant structure of uncertainty: any 'natural ordering' presumed some model for how to convert a fundamental ignorance into mere uncertainty

about identifiable cause-effect relationships. For the hypothetical hazards of GMO releases, at issue was not simply uncertainty, but how to prioritize among different uncertainties, and how to test them by producing new facts. Yet new facts would not necessarily bridge the disciplinary divide between geneticists and ecologists, who embed facts in a different model of causality (Krimsky, 1991: 151).

More fundamentally, what was the problem-object, the risk-generating system? Safety regulation could variously define the problem as the genetic modification techniques, particular GMOs, their 'natural' properties, their agronomic design, intensive monoculture, etc. From these theoretical perspectives, we may examine how GMO regulation defined the relevant 'uncertainty' to be reduced.

3.0 THE THESIS

This thesis builds upon earlier critical studies which have analysed the contested 'rational' basis of safety regulation. The thesis argues for moving beyond theoretical models of antagonistic *a priori* 'rationalities', e.g. beyond technical-procedural, socio-critical, and/or individualist-market rationalities. Such models emphasize external conflicts which, in GMO regulation, arose also as internal poles of tension within the regulatory procedure.

Broadly speaking, the regulatory system mediated tensions between social legitimacy and commercialization. These tensions arose from the implicit role of the safety procedure in symbolically normalizing agricultural biotechnology. This role can be seen by elaborating the theoretical concept of a 'procedural rationality', at many levels: how safety regulation defines the risk problem; how its risk-management rules frame risk assessment; and how it reduces scientific uncertainty.

In the late 1980s biotechnologists faced political challenges to their R&D agenda of further industrializing agriculture, of investing nature with computer and market metaphors. For enthusiasts, society was at risk of failing to reap the indispensible benefits of biotechnology. For some critics, society was at risk from a sinister biotechnological control.

In response to public controversy, safety regulation fragmented issues of biotechnological control into distinct benefits and 'risks'. It emphasized the hypothetical prospect that GMOs might escape from an otherwise benign control; in this way, GMO regulation selectively incorporated some accounts of the risk problem, while marginalizing others. As a procedural rationality, safety regulation translated risk as cultural danger into risk as a technical uncertainty, amenable to expert management.

Regulators had difficulty in justifying their risk-management rules in terms of a prior risk-identification method for hypothetical hazards. As a scientific rationale for their rules, regulatory authorities cited naturalistic biological analogies, such as exotic introduced organisms (EC & Britain) or plant pests (USDA). In each case, the risk-management regime embodied a cognitive framework; although this framework made a regulatory commitment possible, it also generated disputes, thus politicizing the official account of scientific uncertainty.

In particular, the US 'product-based' system provided little regulatory scope beyond preventing hazards already regulated. Rigid executive-level rules provoked environmentalist challenge and constrained agency-level efforts at building a scientific consensus. While invoking 'risk-based regulation', the government inadvertently extended the US 'adversarial' style to GMO regulation from other regulatory regimes.

The EC 'process-based' framework arose partly from the political imperative of overcoming national regulatory differences. The EC Directive, with its precautionary features, came under industry attack as 'irrational'; there were related pressures to narrow the risk-assessment criteria, especially for market approval of GMO products. At least in Britain, however, industry participated in developing the process-based regulatory framework, which served to legitimize small-scale field trials.

As the EC framework pushed Britain to go beyond the HSE's voluntary controls, the DoE took the opportunity to devise a 'precautionary' rationale for process-based legislation. For its new advisory committee, the DoE strengthened the ecologists' role and incorporated an implicit public-interest representation. By subjecting all GMO releases to scrutiny, the regulatory authorities could discreetly negotiate risk-management judgements, case by case. This broadly-based, confidential procedure extended Britain's consultative regulatory style to GMO releases.

The step-by-step principle provided a means for Britain's regulators to postpone distinguishing between 'real versus perceived risks', and thus to legitimize early releases. Regulatory advisors were informed by pollution analogies in perceiving and anticipating hypothetical hazards; by keeping trial releases under safe control, initial precautions accommodated the perceived abnormality of GMOs. Nevertheless, some GMOs evoked anxiety about a sinister biotechnological control -- concerns which the formal procedure displaced.

In effect, value conflicts over potential consequences made scientific uncertainty more important, rather than vice versa. Starting from divergent accounts of the risk problem, each actor emphasized particular types of uncertainty. This meant favouring some inner link between science and policy, not simply filling an *a priori* 'gap' between them. As

regulatory advisors acknowledged, the acceptability judgements on hypothetical effects would influence the effort to ascertain whether such effects were plausible; environmental values guided proposals for fact-finding. Nevertheless a naturalistic framework provided a means for eventually routinizing safety criteria through a 'technical' form, thus depoliticizing uncertainty.

The regulatory procedure translated some 'perceived risks' into testable characteristics of GMOs, while marginalizing complexities which might defy such testing. Monitoring results were cited to justify relaxing or even abandoning some regulatory controls. Safety sceptics emphasized further ecological and/or agronomic uncertainties, thus implicitly challenging the prevalent R&D priorities. Yet the political context offered little potential for democratizing risk assessment, much less for influencing biotechnological innovation.

Insofar as GMO regulation had a precautionary content, both its potential and limits derived from the project of overcoming obstacles to a biotechnology market. This task meant symbolically normalizing GMOs as benign products, while specifying testable ecological uncertainties rooted in some naturalistic analogy; technical risk was abstracted from issues of socio-agronomic control, thus displacing wider environmental issues. The regulation was less about applying some *a priori* 'precautionary principle', than about defining both safety and innovation.

In effect, the regulatory procedure was managing internal contradictions between social legitimacy and commercialization. These tensions arose from the implicit regulatory task of legitimizing biotechnology, by default of any democratic procedure for adjudicating a contentious technoscientific development. In this case study, the theoretical concept of a 'procedural rationality' is elaborated to encompass poles of tension which some theories attribute to distinct rationalities, e.g. to a socio-cultural rationality or an individualist-market rationality.

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The thesis has the following structure:
Chapter 1 surveyed early debates over how to classify GMOs; discussed theories of risk regulation as contested rationality; and summarized the thesis argument, which Chapters 3-9 elaborate in detail.
Chapter 2 discusses methods for researching GMO regulation as a case study, for investigating the aims which guide social actors, and for depicting their strategies via cognitive maps.
Chapter 3 describes how political forces portrayed GMOs as an environmental issue, and how public-interest groups defined the 'risk' problem, which the regulatory system might accommodate or marginalize.

Chapters 4-6 describes how risk-management institutions were established in the USA, EC, and Britain, with their difficulties in justifying a scientific basis. Chapter 4 contrasts the US product-based and the EC's process-based regulatory frameworks, the latter mandating a precautionary approach. Chapter 5 describes how Britain's new legislation formulated a broad technical-legal language for a precautionary approach to GMO releases, yet narrowly defined the 'risk' system and legal liability. Chapter 6 describes how Britain's advisory committee was constituted so as to negotiate diverse values and interests within confidential procedures, thus maintaining the neutral image of regulatory science.

Chapters 7-9 describe how Britain's regulatory procedures handled diverse accounts of uncertainty. Chapter 7 describes how initial safety measures deferred the stereotypical boundary between real/perceived risks, though not always so readily. Chapter 8 describes attempts at 'reducing uncertainty' and so relaxing controls, amidst value conflicts over which uncertainties warranted scientific fact-finding. Chapter 9 describes disputes over rules for market approval, as a terrain for attempts at limiting the precautionary content and symbolically normalizing GMO products.

Chapter 10 sets out the overall thesis argument on 'procedural rationality', by drawing on earlier chapters and by referring back to theoretical issues raised in the literature survey (Chapter 1, section 2).

A terminological note: Rather than 'the UK', the text often refers to 'Britain', for several reasons: because the statutory controls initially excluded Northern Ireland; because no GMO releases were requested there; and because the 'consensual' regulatory style hardly applies there.

Chapter 2
RESEARCH METHODS

This chapter relates the research methods to the aims of the study. The chapter discusses:
* theoretical aims (section 1);
* case-study methods (section 2);
* publicly available materials (section 3);
* interviews (section 4); and
* cognitive mapping (section 5)

1.0 THEORETICAL AIMS OF STUDY

In this thesis, the main object of study is Britain's system for regulating GMO releases, during its shift from a voluntary to a statutory basis between 1989-1992, seen in its international context. The initial research questions emphasized the role of value judgements and the interactions among institutional actors (see Chapter 1, section 1.4). The research results could have general relevance for technological-environmental controversies, in particular for precautionary regulation, and for national regulatory styles.

The initial plan was to analyse GMO regulation by juxtaposing it with a quasi-official procedure for selecting the Best Practicable Environmental Option (BPEO). The RCEP (1988) had recommended the BPEO procedure for integrated pollution control, as part of its more general argument for precautionary regulation. The RCEP intended the BPEO to make value judgements more publicly transparent and accessible, while deferring such judgements until after an investigative phase -- in effect, maintaining the fact/value distinction. So the BPEO procedure seemed a useful reference point for studying how value judgements arise in GMO regulation (see Chapter 5, section 1.1).

Eventually the BPEO procedure seemed less important than originally expected, for both contingent and theoretical reasons. As it turned out, the RCEP did not mention the BPEO procedure in its proposals for precautionary regulation of GMO releases (RCEP, 1989), nor in its subsequent proposals for a risk-identification method, Genhaz (RCEP, 1991). Nevertheless, the latter proposal did include a type of public transparency, similar to the BPEO procedure (see Chapter 8, section 2.2).

While the BPEO procedure can open up issues of technology assessment, GMO regulation tended to convert such issues into risk assessment (see Chapter 3). In Britain's GMO legislation, the duty of care cited the BATNEEC criterion, which would form part of any BPEO procedure; for GMO releases, however, BATNEEC had an ambiguous meaning, with little apparent bearing upon technological choices. More fundamentally, the BPEO procedure is a variant of 'rational' decision-making models, which have become a collective target of critical social scientists.

Their theoretical critiques of safety regulation seemed particularly relevant to my research questions, in overlapping ways (see Chapter 1, section 2). For analysing value judgements, the official fact/value boundary has been theorized as a social construct, embedded in a procedural rationalism or procedural rationality (e.g. Wynne, 1982; Schwarz & Thompson, 1990). For analysing the interactions among social actors, the regulatory procedure has been theorized as a distinctive national form of regulatory style or political culture (e.g. Vogel, 1985; Brickman et al., 1985; Jasanoff, 1986; O'Riordan & Wynne, 1987). For analysing the attempt to reduce scientific uncertainty, 'uncertainty' itself has been theorized as both a cause and outcome of controversy (see Chapter 1, section 2.3); some have analysed the dynamics of 'policy-relevant science', also called 'mandated' science (e.g. Jasanoff, 1986, 1990; Salter, 1988).

All those theories can help illuminate recurrent patterns through which actors seek social legitimacy for a decision-making procedure. This chapter will describe the research methods and sources which I used to study these features of GMO regulation.

2.0 CASE-STUDY METHODS

This section elaborates upon the research methods which bear upon the validity and wider relevance of this case study -- for example, to precautionary regulation, procedural rationality, and political cultures. Although there exists no definitive 'case-study method', there are well-documented methods for investigating qualitative patterns of social dynamics. The following sub-sections discuss: testing theories; interpreting actions; and decoding 'risk'.

2.1 Testing theories

Extending arguments of early social anthropologists, a sociologist has noted that a case study does not consider each case as a representative sample, unlike a quantitive study. Rather, from each set of events, certain social processes are abstracted for analysis. In implying some relevance to other cases, 'the extrapolation is in fact based on the validity of the analysis rather than the representativeness of the events.... A case study is essentially heuristic; it

reflects, in the events portrayed, features which may be construed as a manifestation of some general abstract theoretical principle' (Mitchell, 1983: 190-92). Because a system is always responding to external forces, predictions from studying it tend to be theoretical rather than empirical; the case becomes a way to study those influences, which by definition have wider implications of some kind (ibid.: 205).

According to a commentary on Mitchell's argument, 'It is clear that the case is an event which exemplifies because it is taken for granted that the real focus of interest is the underlying social structures which generate the event; note, however, that these structures might to other writers constitute the "case"' (Platt, 1988: 5). In that sense, no case can be entirely typical or atyptical, though its wider relevance depends upon how one defines the crucial features.

Exactly how does a case demonstrate the social structures behind events or institutions? It is suggested that the case serves as 'a social barium meal, whose progress through the system illuminates it' (ibid.: 10). This medical analogy presupposes a ready-made meter to detect the social equivalent of radiation signals emanating from a discrete social body, now made transparent. For a research method, however, partly at issue is how to define the boundary of the system, and how to interpret its signals, especially the symbolic meanings which may inform or even motivate actions (see later subsections).

Regarding its wider analytical relevance, the case of GMO regulation might be considered a special, 'atypical' one. After all, it was Britain's first attempt to provide a statutory basis for precautionary risk regulation, for a new technology whose status as 'progress' came under political challenge from the very start. The wider relevance of this case may depend partly upon how those features recur in other regulatory efforts. Equally, those combined features of GMO regulation might well serve to highlight difficulties which arise subtly (though less obviously so) in risk regulation more generally.

How might this case hold some wider theoretical relevance? For example, one can test a theory by choosing a case most likely to confirm it; if the case results show the opposite, then the theory itself requires modification, according to the *a fortiori* principle (ibid.: 17). Although this study was not designed to disprove a theory by counter-example, it is worth considering the *a fortiori* principle here, from several angles:

* Given the precautionary character of GMO regulation, one might expect this case in particular to defy any BPEO-type 'rational' procedure, which is supposed to defer value judgements until after a preliminary stage of fact-finding. GMO regulation did indeed undermine that stereotypical sequence. Such a result would come as no surprise to social-science researchers who investigate how the official stereotype of risk assessment always

conceals its constitutive values. As a precautionary case, GMO regulation may have wider significance for the following features: the flexibility of the fact/value boundary, regulators' vulnerability to industry attack, the potential for democratic participation, and the apparent political neutrality of regulatory decisions.

* Given the early public disputes over how to conceptualize GMOs, and the subsequent industry attacks upon the regulatory system as 'irrational', one might expect this case to provide ideal material for confirming a theoretical model of antagonistic rationalities (e.g. Schwarz & Thompson, 1990). Insofar as my conclusions contradict models of a distinct technical-procedural rationality, this case casts doubt upon the general relevance of such theoretical models, though it also suggests recasting them.

* Given that GMO regulation imposed an unprecedented statutory basis for precautionary regulation and for information disclosure, one might expect this case to transform Britain's regulatory political culture, i.e., its consultative procedure for reaching an apparent consensus among selected insiders. Yet GMO regulation was anticipating and even pre-empting protest, prior to any high-profile controversy in Britain. If the familiar British pattern is extended, as in this study, then the wider theoretical significance remains open to interpretation. At the very least, this case should lead us to doubt whether the characteristic national style ever depended fundamentally upon voluntary regulation and confidentiality.

2.2 Interpreting actions

In a world pre-interpreted by its human producers, the meanings developed by active subjects enter into the constitution of that world (Giddens, 1976: 146). This thesis analyses the symbolic meanings which inform the strategic action. By studying the actors' own language and stated aims, this study sought to avoid common pitfalls in social-science research.

In particular, some research has been criticized for conflating a 'meaningful act' with an 'intended outcome', and neglecting 'the origins of the purposes that actors endeavour to realize' (Giddens, 1976: 156). In this regard, it is essential to understand 'the varying definitions of the situation held by the actors', and their hierarchy of aims (Silverman, 1970: 222, 47). Otherwise, by default, one might attribute actions to some pre-defined interest, to their intended outcome, and/or to the needs of a system, in turn reified as a thing (ibid: 221).

By investigating the actors' diverse aims, research can more readily identify conflicting aims, and thus analyse conflicts as contradictions, rather than as a dysfunction or a functional incompatibility (Giddens, 1976: 128). In a superficial sense, the term 'contradiction' denotes opposed interests. In a more complex sense, as emphasized here, it denotes a double-bind or

self-constraint of a system, whereby pursuing one course of action generates a countervailing or inhibitory course of action (Bottomore, 1983: 93).

In the latter sense of internal contradiction, this thesis often describes the actors' dilemmas in reconciling various aims. Such dilemmas may be more complex than the dictionary definition -- i.e., making a stark choice between two equally unwelcome alternatives. For example, by downplaying ecological uncertainties which defy meaningful testing, the regulatory system may make itself vulnerable to environmentalist criticism; yet by highlighting such uncertainties, it may strengthen arguments for greater public participation (see Chapter 9).

Some actors and analysts have articulated these practical dilemmas in functionalist terms. For example, they assume that the regulatory system must 'balance' competing priorities -- such as ensuring safety versus encouraging innovation. By diagnosing a potential 'imbalance', their language obscures conflicts over how to *define* safety and innovative progress. Their diagnosis, and implied cure, also presumes that a finely 'balanced' regulatory system could function smoothly on behalf of society's common interest.

In response, this thesis analyses a dynamic of internal contradiction, rooted in a legitimation crisis of technoscientific 'progress'. My analysis eschews the pretended political neutrality of a functionalist framework, which tends to flatten contradictions into correctible dysfunctions. If my thesis has any political utility, then it may illuminate how the internal contradictions of the regulatory system can be better managed -- or, alternatively, better exploited by biotechnology critics.

2.3 Decoding 'risk'

In this case study, the 'risk' concept warrants a content analysis of its diverse labels and meanings. In the standard administrative sense, 'hazard' denotes a qualitative potential for harm; 'risk' denotes a calculated 'probability x magnitude' of such harm, though risk can also mean simply a hazard (e.g. Whyte & Burton, 1980: 1). Alongside such meanings, the same term 'risk' may also connote social illegitimacy. As 'risk' carries diverse meanings, this thesis analyses how the regulatory system symbolically converts unknown dangers into a manageable, acceptable form.

Some earlier studies provide evocative examples of such analysis. Through divergent 'languages of risk', protagonists have conveyed images of disorder versus precision control; key terms can portray an issue as a problem or as routine. Language can define the risk problem as inadequate scientific information or as a moral choice -- even to the extent that

'the discourse frames the policy agenda' (Nelkin, 1985: 20-21). In a similar vein, the term 'risk' may articulate protest against an abuse of power, while lending an aura of science and predictable calculation, unlike the term 'danger' (Douglas, 1990: 3-4). These perspectives can be helpful for analysing languages of environmental risk, and its management, which portray GMOs as a problem of control in various ways.

From such perspectives, there arises a methodological question: whether or how to attribute special significance to actors' choice of term -- e.g. risk, hazard, conjectural hazard, potential hazard (surely a tautology, given that any 'hazard' is a potential, by definition). In this study, such terminological analysis did not seem to be warranted by any systematic patterns of intended meaning. Nor were such patterns evident in linguistic variants, such as 'planned introduction' and 'intentional release' of GMOs. Rather, the thesis analyses how multiple meanings of the 'risk' concept are linked to the euphemistic renaming of 'GMOs' (see Chapters 3 and 4).

In that regard, actors disputed whether regulatory controls would associate GMOs with pollution, and even whether they should do so. Like risk, the concept of pollution connotes an action which violates some accepted value system; such values are expressed in the ways a society classifies things (argues Mary Douglas, 1975: 50-51). It would be illusory to expect that a society can base its pollution fears entirely upon science, devoid of social or moral persuasion; indeed, any form of knowledge depends upon principles of classification, arising from social values and experience (ibid.: 242-45).

However, Douglas further argues that the symbolic meanings serve an integrative or stabilizing function. For example, 'pollution ideas are adaptive and protective' for a society's values (ibid.: 245). Contrary to that functionalist perspective, this study investigated how the conceptual status of GMOs provided a symbolic terrain for accommodating and/or imposing antagonistic social values.

All these cultural perspectives provide methods for decoding 'risk', for analysing how its symbolic meanings inform social actors. They help illuminate regulatory dilemmas regarding, for example, how to classify GMOs, how to overcome their stigma as suspected pollutants, how to exercise appropriate control, how to specify the relevant uncertainties, etc. Most striking was the perceived importance of legitimizing one's action or policy, and of devising a procedure which could allow a favoured meaning to prevail, e.g. to portray GMOs as normal and/or benign.

3.0 PUBLICLY AVAILABLE MATERIALS

For studying the regulatory system for GMO releases, the period 1989-92 generated much publicly available material, both written documents and conferences. Throughout the period, a clippings file was compiled from the popular and scientific press.

Initially studied was Britain, in particular, the shaping of the Environmental Protection Act Part VI (EPA, 1990). Relevant documents included the Royal Commission on Environmental Pollution 13th report (RCEP, 1989), the Department of Environment consultation paper (DoE, 1989), and the numerous written submissions to both bodies. Prior to publishing its 13th Report, the RCEP received forty written submissions, ten of which were possible to obtain. Almost simultaneously the Department of the Environment (DoE, 1989) published its consultation paper and solicited replies, which were filed at the DoE library, so it was possible to obtain copies of them all. Many of the submissions to the DoE also commented on the RCEP report. By collating and comparing comments from those submissions, the study was able to clarify the range of issues and concerns, as well as to compare later positions with earlier ones.

Some of those issues came to a head as the British government finalized the Environmental Protection Bill Part VI, whose Parliamentary debate received some press coverage. Key documents were Hansard reports of Parliamentary proceedings, including proposed amendments from MPs. Their amendments could be traced to lobbying documents, which I was able to obtain from industry and public-interest groups; also, the latter groups held a briefing meeting before the House of Lords debate on Part VI. This material is discussed mainly in my thesis Chapters 5 and 6.

This study did not extend to a detailed analysis of the Regulations, i.e. the secondary legislation for implementing the Environmental Protection Act Part VI. The Regulations underwent two major redrafts (DoE/HSC, 1991, 1992) before being finalized and taking effect in February 1993 (DoE/MAFF, 1992). Until that time, the regulatory authority remained the HSE, under the Department of Employment, which provided little information on GMO releases.

Other documents pertained more to risk-assessment methods and research. These included official guidelines (ACGM/HSE, 1986, 1990), an additional report by the Royal Commission on their proposed risk-assessment scheme, Genhaz (RCEP, 1991), unpublished briefs for risk-assessment research (DoE, 1991; Prosamo, 1989), and reports of research findings. A series of international conferences was held in order to share results of biosafety research and to

discuss common standards (e.g. MacKenzie and Henry, eds, 1990; Casper and Landsmann, eds, 1992). These documents are discussed mainly in Chapter 8.

Several conferences in Britain provided occasions for hearing and querying regulatory actors. These included the following:
* April 1990, London, HSE/DoE/BIA conference on biotechnology regulation (CBC, 1990);
* June 1990, London, Society of the Chemical Industry conference on risk assessment for GMOs; and
* August 1991, Nottingham, Regem 2 conference on risk- assessment research for microbial GMOs, following up Regem 1 (Sussman et al., 1988; Stewart-Tull and Sussman, 1992; Levidow, 1992a).

For links between Britain and the European Community, the EC Deliberate Release Directive (CEC, 1988; EEC, 1990) set parameters for Britain's legislation long before both were finalized and enacted. Industry lobbyists published glossy brochures (e.g. GIBiP, 1989, 1990; SAGB, 1990), intended to influence the Directive or its implementation, particularly how it would be superseded by product legislation, e.g. the pesticides directive (EEC, 1991). These efforts are discussed mainly in Chapters 4 and 9.

My attendance at three additional conferences provided an international perspective:
* November 1990, Montreal, 'Biotechnology and the Environment: Managing the Risks';
* May 1992, Brussels, DGXI information seminar on implementation of EC directives 90/220 and 90/221;
* June 1992, The Hague, 'The First Biotechnology Europe Conference: Products, Regulators, and Politics' (see my combined report in Levidow, 1992b).

The USA's regulatory system became a frequent reference point in the EC debate, though this debate glossed over the USA's difficulties. For my study of the USA, relevant documents were available from the US executive office (OSTP, 1986, 1990, 1991, 1992; BWG/Quayle, 1991), from regulatory agencies (e.g USDA/APHIS, 1987; USDA, 1991; BSAC/EPA, 1990), and from regulators justifying their policy. Also instructive was my attendance at two conferences there:
* November 1990, Washington, D.C., 'Biotechnology: Agriculture and Environment', a large quasi-public meeting of activists; and
* June 1991, Sacramento, 'Biotechnology at the Crossroads', a conference of the US biotechnology academic-industrial complex (as reported in Levidow, 1991b).
The US material is discussed mainly in Chapter 4, and somewhat in Chapter 7, section 1.

OECD reports were relevant for documenting differences in national regulatory approaches (OECD, 1990a), and in attempting to overcome them. The initial 'blue book' (OECD, 1986) was followed by detailed risk-assessment guidelines (OECD, 1990b), ultimately published as an expanded blue book (OECD, 1992), and supplemented by a survey of transgenic plant releases (OECD, 1993).

In a category of semi-public documents, I obtained copies of several applications to release GMOs; these came from ICI Seeds, as well as from government-funded research institutions (AFRC at Rothamstead, IVEM-NERC at Oxford, and John Innes Institute at Norwich, formerly Cambridge). Unfortunately, in no case did I request an application prior to a relevant interview. I hesitated to press for these documents early on, lest I jeopardize the interviewees' trust, at a time when industry was criticizing proposals for broad information disclosure as a threat to commercial confidentiality. In retrospect, my hesitation was probably over-cautious, unnecessarily losing the opportunity to discuss these applications in interviews. Nevertheless it was instructive to read the applications, especially regarding how they accommodated requests for evidence of safety.

Near the formal end of the study, I requested the IVEM (1991a, 1991b) application for their proposed release of a viral insecticide, after learning this had encountered difficulty within ACRE. I chose this proposal for more detailed study, mainly by telephone mini-interviews, even though the particular GMO set it quite apart from other GMO releases in Britain. For similar reasons, I focused upon a trial release of a herbicide-resistant crop after learning that it had provoked some public protest, unusually in Britain. As discussed in Chapter 7, the two episodes illustrate the tensions managed by the regulatory system.

4.0 INTERVIEWS

During 1990-91 I conducted sixty interviews with key individuals involved in shaping the risk regulation for GMO releases, particularly in its transition from a voluntary to statutory basis. Some interviews were conducted jointly with Joanna Chataway, as part of her research project on 'Strategic R&D Decision-Making in Biotechnology', and/or with Joyce Tait, who supervised both projects. For reasons described earlier (section 2), the interviews sought to clarify the aims of regulatory actors, as a way of investigating their interactions and the role of value judgements.

4.1 Selection of interviewees

Interviewees were selected according to their key roles, especially their responsibility to develop and promote an organization's policy. They included civil servants, their scientific

advisors, other scientists responsible for risk-assessment research, industry officials, Parliamentary lobbyists, and public-interest groups.

The British interviewees came from the following categories:
* civil servants: DoE, HSE, DTI, MAFF;
* members of their advisory committees: ACGM, IISC, ACRE;
* industrialists from biotechnology companies: ICI Seeds, Unilever, Nickerson Seeds International, Agricultural Genetics Company, Shell (some individuals overlapping with the previous category);
* industry-wide regulatory officers: Confederation of British Industry (CBI), Chemical Industries Association (CIA), British Society of Plant Breeders (BSPB), Bio-Industry Association (BIA);
* scientists involved in risk research: Prosamo, Genhaz (of the RCEP);
* dual members of the RCEP and House of Lords;
* public-interest groups which attempted to influence the regulation: the Green Alliance, Genetics Forum, Trades Union Congress (TUC), and Association of Metropolitan Authorities (AMA); and other such groups which attempted to generate wider public debate on GMO releases: Norfolk Education and Action for Development (NEAD), and Greenpeace.

For the EC context, interviewees included officers from the European Commission's DGXI (Environment) and DGXII (Science, Research and Development), the European Parliament's Environment Committee, and the OECD's Environment Directorate. EC-level industry lobbyists included the Senior Advisory Group on Biotechnology (SAGB), which arose from the chemical industry; and Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (GIFAP), which represents pesticides companies. For comparing the EC and UK with the USA, interviewees included officials from the EPA and USDA.

When this research project was designed, it was uncertain how many prospective interviewees would accept my request and what information they would divulge. Particularly important were members and departmental assessors on Britain's advisory committees (ACGM, its subcommittee IISC, succeeded by ACRE). Formally they were bound by the Official Secrets Act, as well as commercial confidentiality; yet, as it turned out, some committee members were so forthcoming that it seemed worthwhile to interview more than twenty of them. Of all my requests for interviews, the few refusals came from front-bench Parliamentarians, who were understandably busy, and from two IISC members who were retiring from both the committee and from their full-time employment.

Much later I learned that the ACRE Secretariat had asked all members to redirect our requests back to those government officers, for reasons of confidentiality. Fortunately for this study, most members ignored the Secretariat's advice. It was almost as if the members were selected for, and were already acting upon, an ethos of public access -- even at this early stage, before the regulatory system had established rules for information disclosure, which were not implemented until 1993. As one ACRE member commented after an interview, 'I am glad that someone is recording these events for posterity.'

I undertook to cite interviewees' comments on a non-attributable basis, unless otherwise agreed later (e.g. by Julie Hill of the Green Alliance). Many interviewees were women, so I generally maintain their anonymity by using the male gender, 'he'. Of course, some individuals might be identifiable by comparing their interview comments here with their public statements.
In Chapters 6-9, interviewees in Britain are identified by a category code, as follows:
* ACRE members: C1-C4 (CBI nominees), T1-T2 (TUC nominees), S1-S12 (other specialist members), D1-D7 (departmental assessors);
* Royal Commission on Environmental Pollution members: R1-R2;
* Officers of companies, industry-wide organizations or DTI: I1-I8.

4.2 Interview method and analysis

This study investigated how the actors conceptualized their actions within their own means-ends (cause-effect) models of how the world works. In particular, my questions asked how they could best influence the regulatory system and thus biotechnology more generally. In this way, the study could connect regulatory procedures and outcomes to actors' diverse intentions, which could be depicted in cognitive maps (see section 5). The documents mentioned earlier (in section 4.1) provided a useful basis for formulating interview questions and for interpreting the interviewees' comments.

I designed a standard set of questions for each interviewee category, such as regulatory advisors, industry lobbyists, public-interest groups. In some cases, such as biosafety researchers, the interview questions were specially designed for each individual. Interviews were semi-structured; the planned order of questions had an internal logic, though sometimes I adjusted them to each interviewee's responses.

The questions were designed for interviewees to give meaningful replies without necessarily divulging details of particular GMO releases or committee discussions. Nevertheless, sometimes the interviewee volunteered such details, and sometimes my follow-up questions

elicited more. In retrospect, my interview approach may have been over-cautious, as was my delay in requesting copies of GMO release applications.

Generally I requested a two-hour interview as a reasonable time period for replying to my standard questions; most interviewees vaguely and/or reluctantly agreed in advance to that request, though most turned out to give me at least that much time. Aware of the time constraints, I was constantly having to decide whether to pursue a point or move on to other ones. When a question elicited an awkward or cryptic reply, it might have been more tactful to move on; however, sometimes pursuing the point yielded striking results, which otherwise might have been foregone. Even in retrospect it is difficult to know which approach would have been best.

Most interviews were tape-recorded and then transcribed; only two interviewees objected to being tape-recorded (IVEM-NERC and DGXI). Transcripts were then analysed by two different means: by collating different interviewees' comments on the same issue, and/or by constructing cognitive maps for some of them, particularly for regulators, their advisors and industry officials (see following section). Then, from individual maps of the advisory committee members, I constructed composite maps on particular aspects, which relate to Chapters 6-9.

5.0 COGNITIVE MAPPING

The term 'cognitive mapping' can refer to various diagrams for depicting cause-effect relationships. These include, for example, influence diagrams with feedback loops, which present the researcher's models of institutional dynamics. In this study the term refers to a different type, known as a 'causal reasoning' map, which describes actors' own understanding of how the world is organized. These relatively simple maps facilitate comparing different actors' views, though that same feature does not lend itself very well to visualising perceived points of uncertainty and contradictory forces (Huff, 1990: 28-31).

5.1 Individual maps

Cognitive mapping was originally developed in operations research, by consultants involved in helping an organization to explore the problems that it faces; the resulting maps attempt to clarify the 'messiness' of those problems (Eden et al., 1983). Such maps indicate how an organization's managers conceptualize their role: 'The manager is taken to be involved in the psychological *construction* of the world rather than the perception of an objective world'; in that sense, 'action arises out of the meaning of situations', which may vary for different individuals. By taking 'language as the common currency of organizational life', cognitive

mapping can help clarify different languages or different meanings of similar language (Eden, 1989: 23, 25).

Paid consultancy has used cognitive mapping as an integral part of an interview, so that the map can be developed interactively between interviewer and interviewee. That time-consuming process has been feasible where the client organization is seeking a counselor's advice on how to handle its problems.

In our different context, using cognitive mapping for social-science research, a two-hour interview was barely enough time to explore the planned interview questions. To construct a map simultaneously, I would have required much more interview time and/or a two-person team. Therefore I decided to concentrate on listening, taking notes and asking follow-up questions during the interviews.

Also unlike a consultancy context, my interviews were directed more at the research questions, especially concerning interactions among socio-political forces. The research context is reflected in the cognitive maps, where often a cause-effect relationship spans different institutions. The maps cannot help but oversimplify complex views but do help to make instructive comparisons.

The cognitive map identifies and arranges 'concepts' from the interview, so as to indicate how each actor locates their his/her purposeful action within a model of cause-effect relationships. As indicated in the simplified mini-example provided below: ideas (or 'concepts') are arranged in a hierarchical format, leading from lower-level options to higher-level outcomes; arrows link the options to the goals (dotted lines indicate implicit links between concepts); when warranted by the interview, the negative pole of a concept is indicated after three dots (...), meaning 'rather than'; a negative sign attached to an arrow indicates that the lower-level option links to the negative pole of the higher-level concept.

The previous paragraphs are illustrated by a simple three-concept map:

obtain material
for broad-
ranging map

cover essential
points within
limited time

do map afterwards
... during interview

Usually each map was done first with paper-and-pencil, in order to see how best it could fit as sub-sections into the COPE computer software. I had access only to the early software, whose grid was limited to eight columns of concepts (Eden, 1988; Eden et al., 1985). I found the software helpful more for printing out the map than for deciding its structure. This was because the software did not allow the user to save or revise the map structure; it saved only the list of concepts.

From all those standpoints, I later found the MacDraw program more helpful. Most maps in this thesis were done or redone on that program (except Map 6.9, composite map on public access). The thesis includes only a few of the individual maps, and only an excerpt from each one, mainly for reasons of the space needed to explain an entire map.

Each map was sent for checking to the respective interviewees. Some returned it with minor corrections, and none of them objected to the dotted lines, indicating presumed links. However, most did not reply at all; one interviewee mentioned, in person, some difficulty in understanding the map of his own interview.

It should be acknowledged that the researcher has some discretion in converting the interviewee's comments into a cognitive map, i.e. into an action strategy as s/he perceives it (Eden, 1989: 29). This is true especially if constructing the map after the interview. For example, when an interviewee described some aspect of the regulatory process with implicit approval, I often took the liberty of representing that description as a prescription. In some cases the interviewee expressed ambivalence -- 'on the one hand and on the other' -- which does not lend itself very well to the map's logical cause-effect format.

The final set of interviews were mainly with ACRE members who had not served on its predecessor committee. At this stage, I did not construct a new map for each individual; rather, I scanned the transcripts for points to collate with the earlier interviews, more than for points to map. Perhaps as a result, ambivalent or ironic comments became more noticeable than in the earlier transcripts.

5.2 Composite maps

When the researcher inter-relates the individual cognitive maps, there potentially arises another difference between operations research and social-science research. In the former case, the consultant looks for overlaps among the concepts in different individuals' maps, so as to link them (e.g. Eden, 1989: 35). This procedure can identify intersecting problem-definitions and avoid misunderstandings, thus helping to improve the organization's internal coherence.

In a similar vein, social-science research has used cognitive mapping to draw out the shared, implicit assumptions of an organization, whose internal differences concerned minor nuances (Hamwee et al., 1990). As in paid consultancy, here the composite map can clarify the internal coherence of an organization.

My study, however, featured different problem-definitions among social actors, and different meanings of similar language. When I was attempting to merge the individual maps into composite maps, it was essential to depict divergences as well as convergences. As a result, the form of composite map depends upon the particular aspect at issue.

In the simplest case, the composite map indicates complementary options which lead to shared goals -- for example, as ACRE members seek to keep all GMO releases publicly acceptable (Map 6.8). Another map depicts apparent agreement on information access, but this entails somewhat different aims for whether or how the access should influence R&D priorities (see Map 6.9).

In a more complex map, the same concept has quite divergent rationales but which are somehow accommodated within a consensual regulatory procedure; in particular, initial precautions 'contain perceived risks' (see Map 7.1). Further maps depict more divergent views, e.g. regarding whether or how additional scientific knowledge can minimize the need for value judgements (see Map 8.1). Moreover, the same map depicts scientific uncertainties in stereotypical 'rational' sequence, if only to emphasize that the value judgements may run in the reverse sequence as well; the map should be read from the bottom up, but then also from the top down (and juxtaposed with Table 8.1).

Another kind of composite map depicts interviewees using similar language whose practical meanings become incompatible, as shown in distinct sectors of the map. A common regulatory slogan, 'regulate the product, not the process', has divergent meanings for how to obtain market approval (see Map 9.1).

In these ways, the composite maps can clarify different aims or meanings which might otherwise remain hidden within a common language. Variant structures for a composite map become appropriate, depending upon the shape of convergent and divergent views. Such interpretations are possible, provided the analysis becomes freed from the consultant's task of merging or reconciling different problem-definitions.

The maps are also included in the list of Figures on page v. Each map is discussed in the corresponding chapter.

Chapter 3
BIOTECHNOLOGY AS ENVIRONMENTAL POLITICS

GMO regulation was being formalized in Britain and the EC in the late 1980s, a period of heightened environmental controversy. How would biotechnology intersect with the 'greening' of politics? How was the risk problem defined? Which uncertainties were emphasized? How were value conflicts expressed? What kinds of previous experiences were cited as most relevant for anticipating the effects of GMO releases?

This chapter analyses how GMOs were portrayed as an environmental promise or threat. Although referring to an international context, the survey emphasizes protagonists mainly in Britain. Whenever appropriate, the analysis relates symbolic language to modes of control and social organization (see Chapter 1, section 2.0). In particular the chapter analyses:

* the rhetorical greening of biotechnology, via contentious metaphors of control (section 1);
* strategic perspectives and dilemmas of public-interest groups (section 2); and
* the issues of control which underlay the 'risk' debate (section 3).

1.0 THE GREENING OF BIOTECHNOLOGY?

On the surface, the environmental debate concerned whether and/or how to permit GMO releases. More fundamentally, it concerned whether the biotechnological project should be accepted as progress, whose effects would be divisible into distinct risks and benefits. Scenarios of potential harm went beyond physically measurable effects, to encompass features which some proponents regarded as beneficial. (For more detailed references to this section, see Levidow and Tait, 1991; Levidow, 1991a.)

Biotechnologists sought to 'industrialize agriculture' (GIBiP, 1990), while critics attacked them for aiming 'to convert agriculture into a branch of industry' (Haerlin, 1990) -- in reality, a conversion long since underway. Put more starkly, enthusiasts emphasized the 'risks', even the immorality, of *failing* to adopt biotechnological solutions essential for humanity's welfare (e.g. Taverne, 1990: 42), while some critics attributed 'risks' to biotechnology as such.

In particular, GMOs were cast as a violation of nature, which may then run out of control. Environmentalists warned against opening a Pandora's Box of GMOs (Wheale and McNally,

1990) -- a suitable analogy for putative gifts which wreak disorder; similarly GMO releases would plant an 'ecological time bomb', by analogy to some non-indigenous organisms (Hatchwell, 1989). Amidst these fears of nature running out of control, moreover, GMOs also symbolized invisible institutional forces controlling our lives, as in other technological controversies (cf. Wynne, 1980: 285).

Biotechnologists counterposed a language of precision control. Their molecular-level intervention would make GMOs' behaviour even more predictable than the products of earlier techniques, such as cross-breeding, which improved strains of useful organisms by directed selection from natural variation. By comparison to those techniques, genetic modification offered even greater improvements: GMOs embodied a precision control, while retaining proximity to natural processes and domesticated organisms (e.g. Sussman et al., 1988: 290, 296; AoA, 1989: 2).

On this basis, industry promised 'environment-friendly' products, reliably kept under benign control, yielding up nature's cornucopia for society's benefit. GMOs offered us precisely programmed, evolutionary extensions of naturally efficient organisms which would reduce the need for harmful chemical inputs in agriculture. These metaphors of control -- software, evolution and efficiency -- are not merely rhetorical; they express the biotechnological reconstruction of nature as a mode of control. They also provide an entry point for analysing different accounts of the risk problem.

1.1 GMOs as reprogrammed software

In a survey on the public understanding of science, less than half the respondents associated DNA with living things, and seven per cent associated it with computers (Durant et al., 1989). Although technically 'incorrect', such ideas may derive from industry's reduction of organic matter to programmable, interchangeable chemicals. Through a computer metaphor, life becomes reducible to a universal genetic 'code' which can be read, copied and edited (Yoxen, 1981: 69; Yoxen, 1983: 32-37).

Biotechnology enhances control by isolating and manipulating molecular-level components, as industrial chemists had already done with chemical 'building-blocks'. Molecular intervention reprograms life, in a manner analogous to running software on a computer. To ensure that a gene is expressed only where intended, biotechnologists construct and then insert genetic 'cassettes', a term which has entered common parlance (e.g. BBC, 1990: 5).

This project encourages a fantasy of technological omnipotence, blurring the distinction between science fiction and science. As one biotechnology publicist claimed, '... if we have

the imagination and resources, there is almost no biological problem we cannot solve' (Taverne, 1990: 4). This self-confidence derives from the prospect of selectively transferring genes which 'encode life's processes' (ibid.), as if nature were reducible to coded information.

However, the computer metaphor for DNA has been contentious, especially where genetic engineering crosses species barriers. Some critics portrayed DNA as sacred, as an 'essence of life', whose molecular recombination transgresses the unity of living things and thus threatens disaster (F&FS, 1989). Similarly, the World Council of Churches (WCC, 1989) regarded 'the integrity of creation' as threatened by the mechanistic worldview of biotechnology .

The biotechnological claim to precision control also encountered scientific sceptics. A leading ecologist argued that precise genetic changes do not guarantee precise prediction of ecological characters, for several reasons: genes have pleiotropic effects; a particular gene may turn out to interact with others, altering characters of ecological importance (Williamson, 1988). Moreover, 'the distinction between a crop and a weed is very narrow'; it depends upon poorly understood genetic and environmental differences. Indeed, a slight change in its environment can turn an innocuous organism into a pest (Williamson et al., 1990).

In early scientific debates, ecologists suggested that the products of traditional breeding techniques are less relevant precedents for GMOs than the introduction of 'exotic' (non-native) species, some of which have displaced native species (see Chapter 1, section 1.2). This analogy was taken up by Britain's Royal Commission on Environmental Pollution. Even where a GMO is derived from an organism already well characterized in a particular environment, some genetic change might warrant calling it a 'non-native' organism, argued the Commission (RCEP, 1989: 21).

Thus critics challenged the software metaphor by emphasizing complex interactions within living systems vulnerable to ecological disturbance. While some overtly denounced biotechnology as unethical, ecologists' warnings also provided an implicit ethical stance. And these warnings provided some opportunity for promoting holistic concepts of the risk problem, either within scientific ecology or beyond it.

1.2 GMOs as accelerated evolution

In the 1970s, when new biotechnology firms were seeking large injections of venture capital, enthusiasts proclaimed that this new technology would transform our way of life; they drew analogies to both the industrial and information revolutions (examples cited in Tait et al., 1990). By the late 1980s some enthusiasts were still issuing revolutionary proclamations (e.g.

Taverne, 1990). However, such language became more characteristic of science journalists, in the form of futuristic phrases like 'brave new botany' (Buck, 1989).

Generally promoters of biotechnology came to reserve the language of total novelty for more selective occasions, e.g. in arguments for extending patent rights to GMOs, or in appeals for government funds. According to a leading science advisor, for example, 'the biological revolution' presents opportunities and challenges for Britain 'to survive in a hostile competitive society [world]'; therefore funding priorities must ensure that Britain's agricultural research strengthens its base in molecular biology (Stewart, 1989: 4-7).

In public discourse, the promoters' language largely shifted from biological revolution to evolution. Biotechnology was presented as a modest extension of traditional methods: 'For centuries biotechnology has been used in the development of products -- the conversion of barley to beer for instance' (ICI, 1989: 3), Thus the term 'biotechnology' was stripped of the novelty associated with the term 'genetic engineering'.

In a similar vein, the genetic alteration itself was renamed. Until 1989, official documents and regulatory bodies in Britain generally referred to genetic 'manipulation', sometimes used interchangeably with 'engineering' (e.g. DoE, 1989). Given the sinister nuance of those terms, they were replaced by 'modification', which presents GMOs as a modest evolutionary step. The official term changed when draft legislation was published by European Community and then by Britain (CEC, 1988; HC Bill 14, 1989).

This terminological shift can be understood partly as a response to public fears -- about novel organisms degrading the environment or about industry controlling human destiny. The shift formed part of an attempt to overcome doubts over whether the effects of GMO releases would be adequately controlled -- that is, reliably predictable and socially beneficial. Complementing the software metaphor for GMOs, the 'evolution' metaphor now classified them as a familiar, benign control of nature.

Such evolutionary language has relevant antecedents in earlier ideas of nature, which was anthropomorphized as a 'selective breeder'. In the late eighteenth-century concept of evolution, such personification of Nature implied that nature 'could do something as conscious as select'. Moreover, as the Enclosures transformed the social meaning of agricultural land, 'any positive conception of a just society... was replaced by new and ratifying concepts of a mechanism and market' (Williams, 1980: 73, 79).

In a similar vein, biotechnologists have literally invested nature with metaphors of computer programs and industrial efficiency, while presenting their reconstruction as a discovery of genetic properties. Not merely rhetorical, evolutionary language both expressed and naturalized the values by which biotechnology reconstructs living matter. This language eternalized 'biotechnology' as an accelerated selection of 'natural' qualities. Nevertheless its project came under attack, e.g. for violating 'natural' boundaries, or for imposing the wrong social values.

1.3 GMOs as enhanced efficiency

In claiming to enhance agricultural efficiency, biotechnologists often took for granted a market definition of wealth. As expressed in the metaphor, 'value-added genetics' (Lawrence, 1988: 38), the term 'efficiency' tended to denote the maximum short-term extraction of a particular raw material. Such a meaning was implied when ICI (1989) described its biotechnology programme as 'giving nature a nudge towards greater efficiency' (cf. Derek Burke in NEAD, 1989a: 33). In this account, a commercial criterion of 'efficiency' was attributed to natural selection and/or selective breeding; this efficiency is then enhanced through a careful molecular-level control, gently accelerating the evolutionary process.

Some critics counterposed a different concept of wealth -- in particular, traditional plant varieties, which have come under threat from agricultural practices favouring genetically uniform strains. From this perspective, efficiency should mean optimizing the use of biodiversity for fulfilling people's needs, as well as maintaining farmers' access to this diversity for the future, so that they can adjust to crop failures with indigenous solutions (NEAD, 1989b: 10). Critics foresaw commercial biotechnology weakening that capacity by making farmers more dependent upon selling cash crops and buying laboratory-based inputs; indeed, the latter were directed at solving the wrong problem.

In these antagonistic accounts of agricultural wealth, at issue was the social form of food production as well as its 'efficiency'. Predicting worse food shortages in the future, ICI Seeds declared biotechnology to be essential for feeding the world: 'New varieties of wheat were the key to India's successful green revolution, and improved varieties of all crops will be the most reliable and environmentally acceptable way to secure the world's future food supplies' (Pike, 1989).

On the contrary, others argued that the Green Revolution made farmers more dependent upon expensive inputs and even dispossessed them, as they became less able to buy the revolutionary products. Such critics foresaw biotechnology causing yet more dispossession (NEAD, 1989b: 33). From this perspective, socio-economic forces are not merely external

conditions which affect the distribution of benefits; more profoundly, these forces become embedded in a particular choice of research strategy amenable to empowering multinational corporations.

In the industrial model of agricultural efficiency, also at issue were systemic hazards, such as the scenario of pests and diseases adapting to the single-gene defence of biotechnology products. Critics warned that the familiar 'chemical treadmill' would be replaced or supplemented by a 'genetic treadmill' (e.g. Genetics Forum, 1989). They criticized a short-term view of efficiency, whereby genetic designers solve problems by intensifying the sorts of interventions that created the problems in the first place. For some biotechnologists, this scenario was not hazard but rather a challenge for subsequent progress; for example, a leading research manager expressed confidence that biotechnology would always find 'technical solutions to the technical problems of homogeneous monoculture' (interview, 8 August 1990).

1.4 Environment-friendly products?

So far this chapter has analysed three contentious metaphors for GMOs -- as a reprogrammed genome, as a modest evolutionary extension, and as an enhanced natural efficiency. By conceptually grounding biotechnology in natural or familiar processes, these metaphors supported industry's claim to be developing 'environment-friendly' products. Such language also provided a natural, even ethical legitimacy for industry's stated aim of industrializing agriculture, a tendency epitomized by herbicide-resistant crops.

As Britain's largest seeds merchant, ICI Seeds defended herbicide-resistant crops as 'environment-friendly', on behalf of the entire biotechnology industry. It argued 'that even such a simple effect... has much to offer.... The general concept of herbicide tolerance... is not new.... Such natural variation within species has always existed.' Biotechnology now offered the opportunity to extend that variation to more plants, by designing selective tolerance into the crop species, rather needing to find selective herbicides. Moreover, they argued, 'By encouraging the development of more efficient systems of integrated weed control, the cost of food production will be contained at the present low levels', while reducing dependence upon herbicides (Bartle, 1991). This scenario appealed to the key metaphors discussed earlier: a precise genetic reprogramming of a modest, single-gene evolutionary modification, offering enhanced efficiency.

In opposing this R&D priority, critics emphasized risks which arise from ecological and agronomic uncertainties of herbicide-resistant crops. These scenarios included, for example, the spread of herbicide-resistance genes to weedy relatives of the crop, or more widespread use of a particular herbicide, in turn intensifying selection pressure for resistant weeds. The

World Council of Churches described the prospect of increased herbicide usage as an ominous example of 'intended effects' (WCC, 1989: 25).

Thus the concept of 'risk' went beyond mere accidental effects. For critics, herbicide-resistant crops highlighted the potential of biotechnology to aggravate familiar hazards of intensive monoculture. Such solutions would also preclude alternative methods of crop protection (ibid.; Genetics Forum, 1989). Moreover, the crop-gene link would provide 'the ideal form of total market control', i.e. an ominous control (Lees, 1990: 136).

As this example illustrates, the 'risk' debate linked physically measurable harm to issues of socio-economic control and dependency. More generally, languages of risk associated GMOs with a stigma of abnormality, implying special hazards, but also associating them with familiar hazards of intensive monoculture. As biotechnologists explicitly sought to industrialize agriculture, at issue was their reconstruction of nature, with its implicit model of social organization. In questioning safety claims, critics also challenged the prevalent R&D agendas, and so questioned whether potential effects could be divided into distinct risks and benefits.

How, then, did various public-interest groups attempt to generate wider debate and to influence biotechnology?

2.0 PUBLIC-INTEREST GROUPS: strategic difficulties

During the course of this study, Britain had scant public controversy on the safety of GMO releases. Sporadic mass-media reports raised questions about particular GMOs and about information disclosure on them generally (e.g. Erlichman, 1990; Chapter 5, section 2.6 ; Chapter 7, section 3.0). A few television programmes questioned the R&D priorities of biotechnology (e.g. BBC, 1990; BBC, 1991).

By surveying the public-interest groups which intervened in some way, this section analyses their strategic difficulties. Many organizations in Britain expressed concerns about environmental effects of GMO releases, but few raised these issues publicly. Friends of the Earth made critical comments in 1988 (Lees, 1990) but proved unable to include biotechnology among its campaigning priorities. In 1989 Greenpeace called for a total moratorium on GMO releases but did not actively campaign for this proposal. The organization Compassion in World Farming, with its magazine *AgScene*, campaigned against genetically modifying animals and injecting bovine somatotropin into dairy cattle, but did so mainly as an issue of animal welfare, not environment.

A key actor offstage was the World Wildlife Fund, more recently called the World Wide Fund for Nature; its new name indicates a conceptual shift from protecting identifiable species, symbolized by its familiar panda logo, to protecting entire habitats. Although the WWF did not make an issue of GMOs, it funded interventions by the Green Alliance and Genetics Forum; together those two groups lobbied Parliament on the Environmental Protection Bill, Part VI (see Chapter 5). Government eventually accommodated their proposed amendments to guarantee specified information disclosure and to make the advisory committee statutory, though not their other proposals, such as to establish a Public Biotechnology Commission for assessing all implications of prospective products.

Also the Genetics Forum and Greenpeace, along with some other groups, formed a coalition to oppose the patenting of 'life forms'. Their campaign against 'the ownership of life' emphasized the commercial criteria guiding biotechnology (Patent Concern, 1991; Greenpeace, 1991a). The coalition was responding to proposals, from the GATT negotiations and the European Commission, which would clarify and extend patent rights on GMOs. Meanwhile Greenpeace formally challenged a company application to patent a herbicide-resistance gene; the challenge cited, among other grounds, the European Patent Office rule forbidding a patent on any product which contravenes 'public order or morality' (Greenpeace 1991b). Thus, for uniting diverse public-interest groups, patent rights seemd to provide a clearer target than the safety issues.

Some groups regarded herbicide-resistant crops as a likely campaign target for highlighting undesirable directions of biotechnology R&D (e.g. Pesticides Trust/Greenpeace, 1991; also interview with Greenpeace, 31 July 1991). Such a campaign did emerge in the USA (Goldburg et al., 1990), where herbicide-resistant crops comprised half of all plant GMOs being released in the late 1980s. When similar releases began in 1990 in Britain, on a more modest scale, no protest campaign materialized (but see chapter 7, section 3.2).

For challenging the industry overall, it was even more difficult to find an effective strategy. As the relevant groups were well aware, public opinion showed some ambivalence towards biotechnology; many people both expected environmental benefits and feared potential risks, partly depending upon the particular application (Connor, 1989; Highfield, 1990; Marlier, 1992). The campaign against patent rights encountered such ambivalence towards the promised benefits of medical biotechnology, which provided early test cases of patent rights on genes. Also, the existence of credible regulatory procedures may have also limited the possibilities for campaigning on safety issues.

Lastly, the biotechnology industry's green rhetoric found some resonance within an entrepreneurial strand of environmentalism in Britain. A business consultancy, SustainAbility, promoted the environmental benefits of biotechnology, as part of its mission to encourage 'green capitalism' (Elkington and Burke, 1989). In particular it advised the Danish firm Novo Nordisk, though mainly on traditional types of biotechnology; this firm intended to conduct no GMO releases in Europe (but see Chapter 9, section 1.2). SustainAbility's involvement was an apparent exception which perhaps proves the rule about the stigmatized image of the new biotechnology.

By 1991 only a few public-interest groups had attempted to influence GMO releases and/or their regulation; these included Greenpeace, Green Alliance, Genetics Forum and NEAD. The rest of this section analyses each group in turn. The following material is drawn largely from interviews conducted in 1991 with officers or leading members; in some places I have condensed quotations, which the interviewees subsequently approved.

2.1 *Greenpeace*

Greenpeace UK, funded mainly by individual membership subscriptions, was the only real campaigning organization to make an issue of biotechnology in Britain. In its submission to the DoE in 1989, Greenpeace UK called for a total moratorium on GMO releases, but it did not campaign for that demand or intervene further in the regulatory debate. Meanwhile the Science Director devoted some time to keeping up with developments in biotechnology.

In 1990 Greenpeace International decided to appoint a full-time staff member to prepare campaigns against biotechnology; this appointee took up the post in late 1991, based in San Francisco. Greenpeace thereby strengthened wider efforts to raise the patenting and biodiversity issues. However, by 1992 it had still done no campaigning against GMO releases, even though European industry was leaving itself more vulnerable to environmentalist attack by undermining process-based, precautionary regulation (see Chapter 9, section 1).

Greenpeace conceptualized GMOs virtually as pollution -- as antagonistic to natural evolution and threatening a vulnerable environment, including agriculture itself. As the Science Director explained,

> In any species, evolutionary changes have involved several parallel genetic changes on a long timescale. Biotechnology creates single-gene changes, which are not dependent upon an ecological balance. GMOs could reduce biodiversity and increase reliance upon high-tech inputs; we already know that genetic uniformity has reduced plants' resistance to disease. GMO products will be constantly pressurizing the ecosystem. They may not only raise new hazards, but also intensify harmful processes in

> agriculture, which has been concentrated in fewer and fewer hands. GMOs divert resources from solving the fundamental problems.... Irrespective of a precautionary approach, GMOs fundamentally change how our society deals with nature: the risks simply should not be taken (interview, 31 July 1991).

Greenpeace doubted that the regulatory procedure could prevent hazards: it criticized even precautionary regulation for presuming safety and excluding wider complexities.

> Science doesn't ask the right questions; it cites 'no proven damage' instead of proving 'no damage'. The present regulatory procedures cannot consider the wider effects on agriculture. Small-scale field trials cannot answer all the important questions for risk assessment... For regulation of GMO biopesticides, for example, relevant expertise is unlikely to be available under existing product legislation (ibid.). [This would soon supplant GMO legislation; see Chapter 9, section 1.2].

For Greenpeace, their diagnosis warranted attacking the entire industry:

> We will highlight the agrichemical industry's intentions and the implications of GMOs, particularly herbicide-resistant crops, arguing that it's better to stop such developments now, before GMOs do harm at a later stage. We will challenge the industry across international borders. By raising the public profile of biotechnology, we can take advantage of companies' intrinsic worry about public perception, and thus slow down the investment and technology (ibid.).

In their view, GMOs inherently transgress evolutionary processes, and so threaten a fragile ecological balance, including the agricultural environment. Greenpeace saw no grounds for incurring these risks, which would mean intensifying harmful tendencies in agriculture. Only 'trial without error' was acceptable; regardless of precautionary regulation, no scientific evidence could provide meaningful safety reassurances about self-reproducing pollutants. Yet Greenpeace did not attempt to mobilize public unease into active opposition.

2.2 *Green Alliance*

According to the Green Alliance, it 'aims to raise the prominence of the environment on the agendas of public and private institutions', particularly through Parliamentary lobbying. It has been funded by diverse sources which include private foundations, industry subscriptions and the DoE, for which the Green Alliance often prepares consultancy reports (Green Alliance, 1991; Dixon, 1993).

The Green Alliance organized Jeremy Rifkin's 1987 speaking tour, which it had hoped would lead other organizations to make an issue of biotechnology, though none did so. When the Environmental Protection Bill was published in late 1989, the Green Alliance co-ordinated efforts to propose amendments strengthening the Bill (see Chapter 5, section 2). It obtained funds from WWF to organize both the Rifkin tour and the Parliamentary lobbying. In April 1990 its Parliamentary officer was appointed to ACRE, the government's advisory committee (see chapter 6, section 3.3).

The Green Alliance regarded GMOs as inherently suspect, warranting special regulation. Stated its Parliamentary officer, 'I feel that the fact that something has been through the process of recombinant DNA technology distinguishes it qualitatively from almost anything else you could call it' (CBC, 1990: 48). She later described GMO releases as a potentially reckless activity, though adequate safety regulation could keep them safe and allow for beneficial products:

> I wish that people didn't feel the need to alter the genetic make-up of organisms and throw them around in the environment. It's not a good idea. There is a lack of knowledge about ecological interactions...
> But I (and other environmentalists) see potential environmental benefits, as well as potential pollution. We don't oppose GMO releases as such; we would never win such a demand. And we would have no credibility if we called for a moratorium on GMO releases and then demanded information disclosure (interview, 30 October 1991).

In developing precautionary regulation, the Green Alliance was carrying out its perceived duty: 'We have always argued that environmental groups must take the responsibility to be part of the decision-making process, for example, my role on ACRE.' At least provisionally, this meant a commitment to the regulatory system: 'The Green Alliance would take a more radical position against GMO releases only if the present regulatory caution became compromised by political pressure; if something disastrous happens, then we'll have to admit the weakness of our precautionary approach' (ibid.).

The Green Alliance regarded hazards as a problem of technical uncertainties, which might be resolved by better scientific information, particularly through ecological research:

> Genetic modification is not precise overall, for knowing what a GMO will do in the environment; a small genetic change can cause a large phenotypic change.... My intuition about GMOs translates into extreme caution. I wish that we didn't have to take regulatory decisions on the basis of inadequate knowledge. There should be more funding of pure ecological research, underpinning the risk assessment (ibid.).

By taking part in the regulatory system, the Green Alliance was committed to translating environmentalist suspicions into technical criteria. This willingness applied even to the most controversial case, herbicide-resistant crops:

> It is not invalid for environmental groups to oppose herbicide-resistant crops for running counter to sustainable agriculture. But I won't say that, because we are looking for more evidence about what would actually happen in practice; it's not reducible to technical considerations before you have experience in agronomic practice (ibid.).

The Green Alliance saw its insider role as assisting wider political forces:

> In lobbying on the Environmental Protection Bill Part VI, we engaged in the workman-like task of getting the regulations through, with [an amendment for] maximum information disclosure. That will help promote public debate about how biotechnology fits into broader agricultural policy....

> We try to stimulate other, big groups to take on GMOs as an issue. Other groups are more interested in the strategic agricultural questions; none seem very stimulated by the risks of release per se, except perhaps Greenpeace (ibid.).

By 1992 these wider forces had hardly materialized; and neither had the information disclosure (which was delayed until 1993). Yet some credible threat was needed in order for industry to discuss its R&D priorities in relation to sustainable agriculture; indeed, the mere mention of 'Greenpeace' provoked anxious responses:

> Direct discussion with the industry will be practically more productive than discussion with other public-interest groups, but you need the chimera of an opposition movement in order for industry to feel any pressure to discuss it [sustainable agriculture] (ibid.).

In summary, the Green Alliance regarded GMOs as potential pollutants but treated their conceptual status as an empirical matter. It welcomed the challenge of developing precautionary regulation, which would seek technical evidence to resolve uncertainties; this empirical treatment could extend even to herbicide-resistant crops, which many other environmentalists opposed on principle. The Green Alliance accepted the constraints of operating within the terms of the regulatory system, while sharing other groups' concerns about agronomic issues which lay beyond it.

2.3 *Genetics Forum*

The Genetics Forum forged a less distinctive identity of its own, as it acted as an umbrella for several organizations and took up all aspects of biotechnology. Founded in 1988 without any paid worker, it eventually obtained funding from the WWF to employ a part-time director in 1990, though that funding remained precarious.

The Genetics Forum (1989) located GMOs within a 'socio-economic revolution', ominous because of the technology's power and 'continuing pressure on agriculture to become more intensified and industrialized'. The group also saw GMOs as carrying 'inherent risks' due to the genetic modification process itself, as well as due to ecological complexities.

Two years later, the director emphasized complex effects of genetic novelty rather than the genetic modification process:

> Classical breeding was 'dirtier' [less precise] but recombined genes only from the same species. Genes can interact in unpredictable ways and have multiple effects; when we combine genes from different species, even precisely, the element of genetic novelty carries an additional set of risks. Ecosystem complexity makes prediction difficult; a predictive science of ecology certainly doesn't exist at the moment (interview, 20 September 1991).

For environmental risk assessment, the Director wanted the advisory committee to be both more scientific and more self-conscious about its constituent value judgements: 'I have reasonable confidence in ACRE to deal with technical risk assessment, though it should have more representatives of environmental organizations' (ibid.). He favoured wider participation -- so that the assessment is properly scientific, takes into account a broader range of scientific opinion, and learns from the experience of other environmental problems.

Moreover, he argued,

> Conventional risk assessment treats nature as a resource to be used and exploited for humans' benefit; this value judgement, however, is presented as the norm of objectivity .... Regulatory science should consider the purposes for which we use nature' (ibid.).

He regarded such ethical considerations as essential for making risk assessment truly scientific, though he acknowledged that most scientists would regard his proposal as a contradiction in terms.

In effect, the Genetics Forum sought some middle ground between the Green Alliance and Greenpeace, as regards the proper basis for permitting GMO releases:

> Most trial releases have been testing prospective products from GMOs. Our position remains that there should be a partial moratorium, allowing releases only for scientific purposes -- to learn more about potential hazards, not efficacy; but we are not actively campaigning for it [a partial moratorium].

Here the Genetics Forum was attempting to define a cautious, scientifically reasonable basis for advancing the ecological knowledge relevant to risk assessment -- learning more about nature's vulnerability, short of commercial testing. Yet the partial moratorium remained a notional compromise on paper; it had no means to resist the efficacy testing which drove the regulatory system.

Earlier the Genetics Forum (1989) had warned that the 'chemical treadmill' may be replaced or supplemented by a 'genetic treadmill' of GMOs, e.g. of pests developing resistance to successive biopesticides. This critique was developed further:

> Biotechnology is being used to pursue chemical-intensive agriculture, rather than LISA (low-input sustainable agriculture). Even apart from herbicide-resistant crops, there is the risk of [generating] resistance due to overuse of a particular set of genes. We need to be careful even about those aspects of genetic modification which seem to point towards organic agriculture. Biotech will create new [plant] varieties but with a narrow set of inserted genes, so reducing biodiversity overall... There needs to be more research by ecologists and agronomists on sustainable agriculture, to know what it is or isn't; certainly it is not herbicide-resistant crops (interview, 20 September 1991).

In summary, the Genetics Forum attributed hazards of GMOs to their genetic novelty, to ecological complexities, and to features of intensive monoculture. Its risk-assessment proposals went far beyond integrating diverse scientific disciplines, towards ethically evaluating the treatment of nature. This self-reflexive version of science potentially facilitated

greater public participation, but it did not generate wider debate, much less a mass political constituency.

2.4 Norfolk Education for Action and Development (NEAD)

As indicated by its magazine's title, *Farmers' Link*, NEAD developed a network of relevant groups, including its local base of farmers and agronomists, and others in Third World countries. NEAD promoted public debate on agricultural biotechnology, especially on biodiversity and farmers' control, through its publications and public conferences (e.g. NEAD, 1989a, 1989b). NEAD funded that work mainly with a grant from the European Commission's DGXII, which was promoting biotechnology R&D and 'information' campaigns which emphasized the benefits of biotechnology. As an organization, NEAD issued no policy statements and largely ignored safety regulation (unlike the three groups previously discussed).

Echoing some other groups, NEAD foresaw hazards arising from the genetic novelty of GMOs, though more so from the economic forces driving innovation:

> One objective of the current biotechnology is speed, which is rarely compatible with safety. Pushed by the profit motive, biotech speeds up breeding and substitutes biological for chemical processes. In terms of safety, double haploids are no problem; there are no extra ecological risks as a result. However, for GMOs, the analogy to natural toxins is valid. Environmentalists must answer the challenge of ecological uncertainty if we are going to live on the same planet as those who work for out-of-control institutions (interview, 26 June 1991).

In this account, it was agribusiness rather than GMOs which might run out of control. That is, NEAD located any hazards in the prevalent agricultural strategies:

> Molecular biology is swapping [or adding] tool boxes in order to solve past problems arising from intensive monoculture. Genetic modification speeds up the process of genetic loss that has been brought by conventional breeding. Any hazards from GMOs derive from the farming system into which they are put; the value or effect of genetic modification depends on the context. There is no evidence that current developments will produce something ecologically harmful; we don't want to make an issue of GMOs as such (interview, 4 November 1991).

As NEAD recognized, the political system 'attempts to detach the environment from political-development issues'; NEAD reconnected these issues, particularly by emphasizing farmers' knowledge and control of biodiversity. It criticized industry's definition of biodiversity -- as a negotiable proportion of genetic diversity controlled in seed banks, or a few selected genes inserted into different plant varieties. In this vein, NEAD would flexibly evaluate biotechnology according to its R&D agenda:

> Our earlier view of biotechnology and sustainable agriculture has shifted from a contradictory to a complementary view; they can be complementary, if we start from

> the [agronomic] problem, not from a set of techniques that we must apply. ICI wants to use all these techniques to make a lot of products (interview, 26 June 1991).

Overall, NEAD saw GMOs less as a problem than as a false solution. The organization sought to raise public debate on industry's R&D priorities, rather than to campaign against GMOs:

> We take an educational approach, rather than a campaigning approach; that way, we can continue dialogue with industry and generate a wider debate... When other organizations (such as Greenpeace) go in hard against the industry, it opens up space for NEAD as reasonable, nice guys who can talk to ICI (ibid.).

In this vein, the organization promoted dialogue directly with industry, through such encounters as 'A Day at ICI' (NEAD, 1990). It sought 'a more participatory approach, so that we can have a real debate on technological choices before the horse has bolted' -- again, a metaphor of agribusiness running out of control.

In summary, NEAD regarded GMO products as a potential threat to farmers' security and independence, more than to the environment generally. This agricultural focus left NEAD with little basis for gaining an environmentalist constituency or for intervening in GMO risk regulation. NEAD remained ideologically distant from those environmentalists who advise industry on green products, but found itself by default seeking regular dialogue with industry; it was attempting to influence R&D agendas by mediating between agricultural suppliers and their farmer-consumers. In this effort, NEAD regarded its political effectiveness as dependent upon an anti-biotechnology campaign that did not materialize (e.g. from Greenpeace); meanwhile, paradoxically, its critical approach was funded by biotechnology promoters, the EC's DGXII.

3.0 CONCLUSIONS: 'RISK' AS CONTROL

Agricultural biotechnology was stigmatized as abnormal, portrayed as a cultural danger, and thus turned into an environmental issue. GMOs were debated through languages of risk which fundamentally concerned control -- i.e. GMOs as nature under a benign control, as nature out of control, and/or as nature under a sinister control.

Each account of the problem had its own inner link between risk and benefit. On one side, society was 'at risk' from biotechnology, which imposed a sinister control, transgressed natural boundaries, created new pollutants, perpetuated intensive monoculture, and/or excluded beneficial alternatives. On the other side, society was at risk from failing to reap the indispensible benefits of biotechnology, whose environment-friendly products offered a benign mode of controlling environmental threats to agriculture.

To some extent, biotechnological risk became a proxy for disputing concepts of sustainable agriculture. Biotechnologists promised to overcome the problems of chemical-intensive agriculture by further industrializing it; critics warned against the prospect of aggravating familiar agronomic hazards and possibly generating new ones. Partly at issue was the source of agricultural vulnerability, which was attributed to intensive monoculture or to correctible genetic defects. In this way, the debate concerned how to diagnose 'the injuries of the industrially exhausted ex-nature', and how to claim legitimacy for an effective remedy, as in risk debates more generally (Beck, 1992a: 81).

Languages of risk conveyed an implicit ethics: GMOs would enhance or degrade the environment, even reorder or disorder nature (cf. Nelkin, 1985: 20). To some extent, these accounts illustrate recurrent 'myths of nature' which morally justify a stance in technological controversies (Schwarz and Thompson, 1990: 9-10, 59-61). Moreover, each environmental model served as a rhetorical weapon for disputing the conceptual status of GMOs.

For enthusiasts, GMOs provided an environment-friendly means to yield up nature's cornucopian potential, while overcoming environmental threats to agricultural security. Through a set of metaphors, GMOs were cast as precisely reprogrammed organisms which simulate and modestly enhance nature's efficiency. As a benign form of control, GMOs warranted undertaking a trial-and-error improvement on previous agricultural progress.

For some opponents, especially Greenpeace, GMOs were virtually self-reproducing pollutants. In this account, GMOs threatened an inherently fragile environment; new products would weaken crops, thus necessitating yet more corrective high-tech intervention. Any error had a potential for severe consequences, so only 'trial without error' was acceptable; this absolute stance allowed little scope for intervening in safety regulation.

Other public-interest groups also criticized the industry's R&D priorities, though differently linked to risk. One group advocated that safety regulators consider the environmental values implicit in the R&D priorities, and that they restrict GMO releases to risk research; yet this stance had no effective means to challenge the commercial forces which drove trial releases. Another group made direct attempts at influencing the R&D priorities, while regarding safety regulation as irrelevant.

Of all the groups which took some interest in GMO releases, only one regarded the environmental issues as reducible to technical evidence, at least in principle. Partly funded by government and industry, the Green Alliance made a commitment to develop precautionary

regulation. This anticipatory effort would, in effect, ascertain the limits of perturbing nature's stability.

With its expert-based risk as a problem of expert-based control, the safety regulation analytically fragmented the wider control issues into risks and benefits; it largely accepted biotechnological control as benign. The regulatory procedure developed and favoured a specialist interdisciplinary expertise; for early trial releases in particular, hazards lay beyond short-term sensory perception, so only science could provide the means for making potential harm visible and interpretable (cf. Beck, 1992a: 162-63). In this way, safety regulation marginalized concerned public-interest groups, which variously regarded GMOs as an ethical violation, as a sinister control and/or as a socio-agronomic threat.

In their strategic thinking, these groups sought ways to make biotechnology R&D responsive to environmentalist and farmer pressure, towards promoting sustainable agriculture. Yet they found it difficult to generate such debate at this early stage, long before commercial products. They saw little prospect of influencing products unless industry faced a credible threat from overt opponents (e.g. Greenpeace), yet GMO releases met no active opposition in Britain.

How, then, did safety regulation incorporate some accounts of the risk problem, while marginalizing others? How did it define the hypothetical harm which warranted risk-management measures? Which 'perceived risks' did it treat as potentially real? How did safety regulation respond to the symbolic meanings associated with GMOs, e.g. their perceived abnormality?

Chapter 4
PRECAUTIONARY OR PREVENTIVE REGULATION?

In many areas of environmental protection, there have been proposals to avoid the need for remedial measures by adopting preventive ones, such as by reducing waste production at source. There have also been calls to go beyond mere prevention, to precaution, by anticipating hazards. Broadly speaking, the latter means taking protective measures before obtaining persuasive evidence of harm.

Given the disputed conceptual status of GMOs, how were these organisms classified for regulatory purposes? How were regulatory measures justified by some account of the risk problem? How were environmental issues translated into regulatory terms? What might precaution mean for GMO releases?

This chapter will juxtapose the preventive/precautionary distinction with frameworks devised for regulating GMO releases, mainly in the USA and European Community. The chapter will discuss in particular:

* some precedents for precautionary regulation (sections 1.1);
* the 'product vs process' debate over regulating GMO releases (section 1.2);
* the US product-based regulatory framework (section 2);
* the EC's process-based regulatory framework (section 3);
* common dilemmas arising in these different frameworks (section 4).

1.0 FROM PREVENTION TO PRECAUTION

The shift from prevention to precaution can be schematically summarized as follows: Preventive measures respond to harm already documented, e.g. by screening new products for hazards similar to those documented for earlier generations of products; such regulatory decisions are taken in relation to the relevant benefits and costs. By contrast, precaution attempts to avoid hazards prior to accepted scientific evidence for their existence, or even in advance of new products; thus safety issues can become an integral part of product development (Tait and Levidow, 1992: 221-22).

This section will survey proposals for moving from preventive to precautionary approaches, mainly in Europe; then it will discuss their relevance to disputes over regulating GMO releases.

1.1 Precautionary meanings

The precautionary principle has had diverse, controversial meanings: e.g. reducing waste emissions at source, valuing the environment in its own right, relaxing the burden of evidence for harm, and/or anticipating hazards not already documented. These meanings have proven difficult to justify incorporating into policy. After all, even an inferential 'risk identification' presumes some evidence of harm or grounds for expecting harm -- if only by analogy to some other experience (Lowrance, 1976: 56-69).

As advocated by environmental scientists, a precautionary approach 'shifts the burden of proof so as to give the environment the benefit of the doubt... [This approach] actually increases the rigour of the scientific process because it is based on an understanding of the real limitations of science' (Johnston and Simmonds, 1991).

However, even if the burden of evidence is shifted from harm to safety, there remain awkward questions: If the aim is to prevent serious and irreversible harm, then which activities warrant imposing precautionary measures? In the case of disputed evidence, one commentator has asked, 'How much evidence of environmental harm is necessary to warrant precautionary action?' As those questions receive such different answers, 'it is difficult to speak of a single precautionary principle at all' (Bodansky, 1991). A brief survey will illustrate ambiguous meanings of both 'preventive' and 'precautionary'.

The 'precautionary principle' found its classic statement in the *Vorsorgeprinzip*, formally adopted by the Federal Republic of Germany in 1976. Beyond remedying damage and preventing imminent hazards, the principle required 'that natural resources are protected and demands upon them are made with care'. According to a leading advocate, precaution requires prevention as an end in itself; it initially accepts no economic criteria, though 'they tend to reappear in practice'. Moreover, at least in Germany, the Vorsorgeprinzip became cited for urging safety measures 'before damage occurs and beyond the current state of knowledge', even for 'acting against risks which are not (yet) identifiable' (von Moltke, 1988: 58-61).

A prime site for precaution was the North Sea. As a large, complex ecosystem, it posed an inherent difficulty for linking pollution sources with identifiable environmental effects (ibid.; cf. Wynne, 1993). That case received a special mention in the EC's Third Environmental

Action Programme, which advocated 'preventive measures' for ensuring 'the continued existence of the North Sea as an important and immensely valuable ecological unit' (EEC, 1983). Here its economic value was left ambiguous, though Britain officially valued the North Sea for its 'waste-absorbing capacity' (Holdgate, 1983: 12-13).

Like the EC's Third Environmental Action Programme, the Fourth one used the term 'preventive' and often mentioned economic criteria for safety measures. Yet it went further, by welcoming 'the challenge to make a definitive move away from reacting to environmental problems after they have arisen, towards a general preventive approach...', which would 'encourage the free market to operate in an environmentally rational way' (EEC, 1987: 40). Thus the EC gave the term 'prevention' a precautionary nuance; it also appropriated the term 'rationality' for stronger environmental standards which could force technological improvements. The Fourth EAP signalled a policy move towards 'ecological modernisation', as one analyst has called it; this advocates using environmental protection as a spur to technological innovation and economic growth (Weale, 1992: 75-79; Weale and Williams, 1992: 51-52).

In the case of acid rain, for example, the environmental damage became undeniable but the precise source remained in dispute among EC countries and scientists. Amidst these disputes, the German government imposed vehicle-emission standards so stringent as to favour the catalytic converter, which German industry developed with state assistance. Following moves to extend these environmental standards, German manufacturers gained new export opportunities. In contrast, Britain has generally treated regulatory costs as lost income rather than as industrial investment (Boehmer-Christiansen, 1990).

Regardless of whether these examples are called 'preventive' or 'precautionary', they suggest how some economic or market rationale may overcome disagreements over adequate evidence of environmental harm. Thus non-environmental factors may facilitate or even guide environmental protection.

1.2 GMOs: product- vs process-based regulation

As in the previous examples, environmental safety measures have generally restricted the use or disposal of substances deemed harmful. For GMO releases, however, their conceptual status was in dispute. Not only were they designed to persist in the environment, but they were also suspected pollutants, in several senses of the word.

Early on, international meetings had apparently agreed upon 'progressively decreasing physical containment' of a GMO; this 'allows a logical, incremental step-wise process whereby

safety and performance data are collected' (OECD, 1986: 29). This 'step-by-step' principle left open the way for sharp disagreements on the following questions: What would be the scientific criteria for applying precautions in the first place, and then for relaxing them? What would be the proper scientific and legal basis for the state's role? And, less explicitly, how would safety regulation affect the stigmatized image of GMOs?

Regulatory proposals included the following: to use only the existing product-based regulation, also called 'vertical' regulation; or to establish a 'process-based' regulatory system specially for GMOs, also called 'horizontal'; and/or to strengthen all product regulation, so that it could encompass a broader range of environmental problems. In arguments over the proper basis for regulating GMO releases, actors cited different scientific accounts of the genetic novelty which may arise from the genetic modification process. This section briefly surveys such accounts, in turn (see also my Chapter 3, section 1; Tait and Levidow, 1992; Krimsky, 1991, Chapter 8).

According to an early key document, 'the means for assessing rDNA organisms can be approached by analogy with the existing data base gained from the extensive use of traditionally modified organisms in agriculture and the environment generally' (OECD, 1986: 29). This account both accepted and reinforced a prevalent view among laboratory scientists; they portrayed GMOs as modest, precise extensions of the familiar domesticated organisms which were undergoing the recombinant DNA process. Indeed, the inserted gene would enhance behavioural predictability, or even reduce the GMO's fitness, according to the 'excess baggage' hypothesis (e.g. Davis, 1987; Sussman et al., 1988: 296). According to prestigious reports, genetic modification could not make a crop more weed-like (NAS, 1987: 14; NRC, 1989: 37-53; OECD, 1990b: 16-17; OECD, 1992: 36).

With their counter-polemics, ecologists warned that the genetic novelty could inadvertently enhance a GMO's competitive advantage, by analogy to some non-indigenous organisms or to some crops which had become weeds (e.g. Regal, 1985, 1990; Williamson, 1988; Fitter et al., 1990). Leading ecologists foresaw GMOs causing unpredictable ecological effects, due to their genetic novelty. That is, 'because many novel combinations of properties can be achieved only by molecular and cellular techniques, products of these techniques may often be subject to greater scrutiny than the products of traditional techniques' (Tiedje et al., 1989: 302).

Moreover, various biologists anticipated direct or indirect harm arising from the agronomic context of GMOs. For example, GMO biopesticides might harm non-target organisms and/or generate resistant pests (e.g. Pimentel et al., 1989). Others argued that weed-crop hybrids had

already disrupted agriculture, in ways which some GMOs could intensify (Ellstrand and Hoffman, 1990). Although not unique to GMOs, these hazards went beyond scenarios anticipated by existing product regulation.

Such arguments were selectively appropriated for justifying quite different statutory frameworks in the USA and European Community. In brief, the USA adapted existing product legislation, classifying GMOs according to their product category. The EC enacted new legislation specifically for GMOs, which were classified together, according to the recombinant DNA process which produced them. These were widely labelled as the 'US product-based' versus the 'EC process-based' frameworks.

However, the 'product vs process' labels were misleading, for several reasons:
* The genetic modification process as such was already subject to regulations for GMOs in contained use; the new debate concerned how such organisms would be identified and classified for the purpose of regulating their intentional release (Tait and Levidow, 1992: 224).
* In many cases a GMO release was already subject to some regulation, for example, because it was a pesticide or contained parts of a plant pathogen. The new issue was its 'additional' regulation as a GMO. Indeed, with this term 'additional', regulators could deny imposing 'special regulation' (as in interviews with DoE, 10 August 1990; USDA, 8 November 1990).
* The regulatory procedure considered risk-assessment criteria relating to both the product and process: the issue was *how* they are considered, not whether.

In the 'product versus process' debate around GMO regulation, neither the US nor the EC authorities cited the precautionary principle as relevant (though the British authorities did so; see Chapter 5, section 2). Nevertheless, as will be argued later, the EC process-based system encouraged a precautionary approach, unlike the US product-based system. Precaution has been implicitly at stake in disputes over the following issues: what 'perceived risks' should be investigated as potentially real, what warranted the effort of identifying and preventing such risks, how they could be identified scientifically, what administrative system was most appropriate for doing so, as well as for protecting biotechnology R&D from political disruption.

The subsequent two sections will outline how all these issues arose in developing the US and EC regulatory frameworks.

2.0 USA: 'Risk-based regulation'

The US government took its existing product legislation as an adequate basis for regulating GMO releases, starting with small-scale field trials. It justified that basis as 'rational' and 'scientifically sound', by specifying 'product characteristics' which could warrant subjecting an organism to 'additional' regulation.

This section on the US regulatory system will sketch some difficulties encountered in implementing those formal principles, particularly during 1989-92, the period of this study. (The interviews cited below were all conducted in the same month, November 1990, but the interview material is cited where relevant to policy changes over time.)

2.1 Co-ordinated Framework

After sporadic local protest over GMO releases in the mid-1980s, both the US government and industry recognized the need for a comprehensive regulatory policy. Firms wanted clear regulatory procedures and agency responsibility; they regarded 'national consistency and international harmonization' as essential for the US industry's competitiveness (Krimsky, 1991: 193-94). According to the Industrial Biotechnology Association, industry feared the prospect of 'local restrictive regimes coupled with Federal indecisiveness'; on the other hand, it suspected the Federal agencies of excessive regulatory ambitions (Mackler, 1987: 331-32).

In response to these pressures, the US government established a Biotechnology Science Coordinating Committee (BSCC); this recommended a 'Co-ordinated Framework for Regulation of Biotechnology', in turn promoted by the President's Office of Science and Technology Policy (OSTP, 1986). In administrative terms, the Framework assigned regulatory responsibility to named Federal agencies according to a GMO's product use, and within existing statutory powers. The three agencies were: the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA); each would operate its own scientific advisory committee. Of these three agencies, the USDA and FDA also had a remit to promote products, while the EPA did not.

In the Co-ordinated Framework, 'product-based' regulation had several meanings: not only the product use, but also the biological characteristics of a GMO. The OSTP proposed two main criteria which a Federal agency could invoke for subjecting a particular GMO to additional regulatory oversight. The first was 'intergeneric organisms', that is, those containing DNA from species of different taxonomic genera, which by definition could not naturally interbreed; it was suggested that any resulting hazards could be identified and ranked, roughly

according to the taxonomic distance between the donor and recipient of DNA in an 'intergeneric' (transgenic) organism. The second main criterion was organisms which belong to a pathogenic species or which contain genetic material from a pathogenic organism (OSTP, 1986).

The BSCC's chairman retrospectively celebrated the Co-ordinated Framework as follows: 'The [BSCC/OSTP] policy guidelines are based on widely accepted scientific principles and provide a stringent, yet rational, basis for regulation.' The guidelines would help Federal agencies answer the central question of 'what [rDNA] products constitute a potential hazard, based on a sound analysis of their genetic makeup'. On this scientific basis, 'the potential hazards posed by recombinant-DNA technology may be identified with little difficulty and may be managed easily at the early research stage' (Kingsbury, 1990).

However, Federal agencies encountered more than a 'little difficulty' in justifying the nominally initial step of risk identification. A closer look at the USDA and EPA will illustrate their problems in implementing 'rational' regulation as defined by the OSTP. (The following account omits the FDA because it had no regulatory authority for any live GMOs being released during this period, 1989-92.)

2.1.1 US Department of Agriculture (USDA): screening plant pests

The OSTP criterion of 'plant pathogen' had particular relevance to USDA regulation of plant pests under the Federal Plant Pest Act (FPPA) and Plant Quarantine Act (PQA). The USDA applied the Co-ordinated Framework to those laws by issuing new rules. As the USDA defensively argued, these were not 'process' based, and so were not subjecting GMOs as such to different treatment. Rather, these new regulations were needed in order to define a 'regulated article', e.g. a potential plant pest, based on objective scientific standards. The new rules defined a plant pest as any infectious agent which can damage a plant; the USDA provided a long taxonomic list of micro-organisms, potentially subject to 'additional' regulation (USDA/APHIS, 1987).

Already a narrow basis for regulating GMO releases, this was further constrained by scientific and economic assumptions. The USDA denied that novel traits could result from inserting DNA from a 'well-characterized, non-coding regulatory region', given 'the absolute understanding of the underlying molecular genetic mechanisms...'. With such language it claimed an omniscient rationale for exempting such organisms. USDA also argued that its new rules would have no significant economic effect on prices, competition, employment,

etc.; thus the rules would comply with the cost-benefit criteria of a 1981 Executive Order (ibid.; cf. Jasanoff 1990: 190).

Although the 1987 USDA rules were formally product-based, their substantive content derived from the recombinant DNA process, which generally used plasmids from plant pests as vectors for inserting genes; only in the late 1980s were other processes developed for constructing GMOs. According to the USDA, 'When the plasmid is from a known pathogen, such as the Ti plasmid of *Agrobacterium tumefaciens*, we must be able to certify that the plasmid has been effectively disarmed' (interview, 8 November 1990). USDA officials saw their role mainly as preventing the spread of any plant pest 'which constitutes a threat to agriculture'. That preventive task required verifying that 'the pathogenic potential... [from vector material] has been removed or will be contained' (McCammon and Medley, 1990a). In that sense, the USDA described its regulations as 'risk based and process specific' (Medley, 1989: 4), by analogy to known hazards of plant pests, though no GMO had manifest such hazards.

In applying the criterion of 'plant pathogen', the USDA emphasized predictability:

> From our data in the literature search, if well-characterized, non-coding regulatory DNA was inserted into a microorganism, it was not going to produce a new protein, so there wasn't a [safety] problem. For plants, however, the most common inserted promoter [regulatory DNA] is the S35 from cauliflower mosaic virus -- a plant pathogen -- so we would exercise oversight on that.... More generally, if the inserted DNA regulates expression of a protein which in itself is not a dangerous substance, then it's not a problem (interview, 8 November 1990).

In this way, the USDA was accepting geneticists' claims that genetic precision enhances phenotypic predictability; it was also endorsing the OSTP proposal to exempt GMOs with 'well-characterized, non-coding regulatory DNA'. Thus it ignored warnings, from ecologists and environmentalists, that pleiotropic effects could change an organism's behaviour (e.g. Tiedje et al., 1989; Krimsky, 1991: 198-99).

For hazards other than plant pathogens, USDA officials confidently cited first principles and the absence of alarming evidence. In particular, they appealed to the 'excess baggage' hypothesis, for reassurance that an inserted gene could not inadvertantly give a competitive advantage to a GMO:

> I haven't seen anywhere in the scientific literature that the addition of one gene or one trait is going to totally alter a receiving organism... With biotechnology the real problem is not creating a superplant that's going to over-express; by adding genetic material, you actually make the plant weaker... (interview 8 November 1990). If you tinker [genetically] with bacteria, they somehow lose their competitive ability (interview 15 November 1990).

For the risk factor of unintended gene transfer from plants, safety assurances or precautions could reduce the need for regulatory oversight and monitoring, according to the USDA:

> If one can demonstrate safety in terms of male sterility or reproductive isolation, your monitoring might be as simplistic as visual inspection of the phenotypic changes that might occur in the plant. The local safety committee might feel that built-in limitations like that would lessen the oversight that they would need to do on the researcher's experiment (interview 8 November 1990).

USDA stated that its trial-release permits require 'standard conditions to be met, one of which involves the collection and submission of test data... to build a data base upon which to make future assessments' (McCammon and Medley, 1990a). However, by 1990 there was little sign of such anticipation. According to an academic study, the USDA generally accepted whatever safety arguments, safety precautions and monitoring was proposed by the applicant. Of all the ecological risk factors mentioned by applicants, they offered empirical data for only one factor -- to rule out the potential for unintended dissemination of the inserted gene -- and virtually all such data came from already published literature. Most applicants did not propose, nor did the USDA suggest, monitoring the trial releases for gene flow, much less for other ecological risk factors (Wrubel et al., 1992).

Of course, containment measures might have rendered these risk factors negligible in small-scale trial releases. Yet the releases were not designed to test the efficacy of the containment measures. Much less were they designed 'to build a database upon which to make future assessments', as the USDA had claimed. The agency hardly acknowledged less identifiable hazards -- such as gene transfer, much less pleiotropic effects and wider ecological interactions -- which concerned many ecologists (e.g. Regal, 1985; Alexander, 1985; Tiedje et al., 1989).

Thus the USDA initially regulated GMOs according to an aspect of the genetic modification process which just happened to fall under existing legislation. USDA saw its task mainly as preventing 'plant pest' hazards to agriculture, though no GMO was known to have manifest such hazards. In that sense, the Co-ordinated Framework might have proven adequate for the USDA's self-perceived role, though not for satisfying wider environmental concerns.

2.1.2 Environmental Protection Agency (EPA): screening genetic novelty

Like the USDA, the EPA could find some authority in existing legislation for regulating GMO releases. In particular, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) placed upon the applicant the burden of demonstrating that the benefits of product use outweigh the risks. The Toxic Substances Control Act (TSCA) authorized the EPA to require safety information on 'chemical substances' and new combinations thereof, so that the agency could identify potentially harmful ones before commercial use; 'new' substances may undergo a special approval procedure (Milewski, 1988).

Applying the 1986 OSTP guidelines, the EPA announced that the 'intergeneric' criterion provided a definition of 'new' under TSCA and could be applied under FIFRA to describe a category of microbial pesticides. Also under TSCA, the EPA would classify GMOs as containing new chemicals, i.e. recombinant DNA (Milewski, 1990: 327). Under TSCA the EPA had usually permitted a regulatory exemption for 'small-scale' tests of new substances; however, the EPA argued that living micro-organisms did not meet the 'small-scale' criterion, given their capacity to reproduce and disseminate (EPA interview, 8 November 1990; cf. Dull et al., 1987: 312). Similarly, the EPA regarded the 'small-scale' exemption as inappropriate for microbial pesticides and non-indigenous organisms (Betz et al., 1987: 316).

Unlike the USDA, the EPA included ecologists in its advisory committee and generally attempted to accommodate environmentalists' concerns in its procedures. As a leading official explained, 'Without such involvement, public fear of the unknown could derail the whole process and delay the testing through extensive administrative and judicial manoeuvres' (Milewski, 1990: 335).

According to an academic survey of the EPA's own risk assessments on proposed GMO releases between 1984-88, the agency emphasized broad ecological considerations, such as dispersal, competitive advantage and genetic transfer. However, the EPA's data requirements related mainly to toxicity and pathogenicity; this was partly because the requirements derived from existing legislation, intended for regulating chemicals and naturally occurring microbial pesticides (Akcakaya and Ginzburg, 1991).

The earlier risk-assessment criteria allowed the EPA only a limited authority to request additional information from applicants for GMO releases. According to the academic researchers, this gap between GMO risk assessment and regulation arose because the latter was lagging behind ecological science and new technological hazards (ibid.: 286). However, this gap arose for more fundamental reasons: it was difficult for regulators to justify data requirements for hypothetical hazards, i.e. prior to evidence of harm from the GMO or from the unmodified organism.

As a related problem, the EPA encountered difficulty in implementing the OSTP criterion of 'intergeneric' organisms. The criterion could not straightforwardly apply to micro-organisms, given that taxonomic genera remained imprecise in microbiology -- a problem which the President's Office later acknowledged (OSTP, 1990: 31119). Instead the EPA drafted regulations based upon other criteria: first, inserted DNA which imparts the ability to express characteristics outside the normal phenotypic range of that organism; and second, the potential

for an organism to transfer genetic material, e.g. through the use of vectors not naturally present in the organism (EPA interview, 8 November 1990).

In this way, the EPA attempted to base its regulatory scope upon 'product characteristics', though for different reasons than did the USDA or OSTP:

> We have already seen an example of an organism where it had an ecological behaviour that we did not predict for it, probably as a result of its [genetic] modification.... Particularly in microbial ecology, our information bases are rather thin. We need a system that can respond to novel organisms and to new processes which can perform even better movements of genetic material. That has always been one of the problems with a process-based approach [i.e. based upon pre-specified techniques]. So we try to make regulations which are flexible (EPA interview, 8 November 1990).

Thus the EPA emphasized inadequate knowledge for predicting GMOs' behaviour. The EPA attributed greater ecological uncertainty to genetic novelty, regardless of the specific genetic change within the 'product', and regardless of the techniques used to create it.

2.2 Disputed 'Scope'

According to proponents of the Co-ordinated Framework, its scientific basis lay in the uniform criteria for identifying any risks, i.e. 'intergeneric' and 'pathogenic' organisms (OSTP, 1986; Kingsbury, 1990). Yet these criteria were turning out to delay agency regulations and to intensify conflicts, within and outside government. Each agency was developing biotechnology regulation under laws not designed for that purpose, and hardly amenable to a uniform set of scientific definitions (Krimsky, 1991: 199).

As part of the original Co-ordinated Framework, the EPA had published a list of scientific criteria for assessing proposed GMO releases (OSTP, 1986), but it did not yet publish additional regulations. The USDA did so, but mainly in order to regulate 'plant pests' (as discussed earlier, USDA/APHIS, 1987). By early 1990, neither the EPA nor USDA had clarified what additional safety testing they might require. The third relevant agency, the FDA, had no responsibility for preventing environmental hazards, but the FDA's overt disputes with the USDA and EPA further undermined any rational image of a harmonious 'Co-ordinated Framework' (e.g. Miller et al., 1990). Meanwhile, industry was urging the Federal government to adopt comprehensive regulations, partly because state governments were beginning to fill the breach (Crawford, 1990).

Finally the OSTP proposed to replace its 1986 guidelines with a new 'Scope' document in July 1990. The OSTP acknowledged that 'Federal agencies experienced unanticipated difficulty developing operational definitions for regulatory purposes'. It now proposed different criteria for specifying the 'scope' of organisms which Federal agencies could subject to additional regulation. The document linguistically abolished GMOs by coining a new phrase, 'organisms

with modified hereditary traits'. The OSTP substituted that new term in order 'to avoid the incorrect implication that the use of any particular genetic modification process *per se* makes a modified organism of greater risk than its unmodified parent' (OSTP, 1990).

When defining the regulatory scope as 'organisms with modified hereditary traits', regardless of how they were modified, the document specified broad categories of exclusion. These invoked the principle of sufficient 'familiarity' which permits assessing the introduction as 'similar to previous safe introductions'. Moreover, the OSTP proposed that organisms shall not be subject to regulatory oversight 'unless information concerning the risk posed by the introduction indicates that oversight is necessary' (ibid.).

This 'information' requirement weakened agencies' authority to request safety data. Indeed, its circular logic reinforced the general presumption of GMOs' predictability. By proclaiming 'the risk-based approach', the OSTP was echoing recent scientific reports which suggested that any risks of GMO releases could be readily identified according to their 'product' characteristics (NAS, 1987; NRC, 1989), though that claim had been disputed by ecologists (e.g. Tiedje et al., 1989).

Given the difficulties around the OSTP's 1986 criteria, its 1990 'Scope' document met a guardedly positive response from environmentalists. For example, it was welcomed by the National Wildlife Fund 'because it casts a wide regulatory net with exclusions based on experience'. However, the NWF opposed some of the exclusions. In the case of micro-organisms altered by traditional laboratory techniques, the OSTP had assumed that the same genetic combinations also occur in nature, such that the laboratory could create no genetic novelty. In another proposed exclusion, the wording had no practical basis in the experience of GMOs: 'organisms with a new phenotypic trait(s) conferring no greater risk to the target environment than the parental strain, which is considered to be safe'. Moreover, as the NWF sardonically commented, some OSTP exclusions cited familiar processes, such as traditional breeding techniques, rather than familiar 'product characteristics' (NWF, 1990; OSTP, 1990).

Such criticisms highlighted the confident assumptions underlying this putatively 'risk-based' approach, which accepted first principles as a substitute for case-by-case environmental testing. Also at issue was the significance of genetic novelty: Which past or future experience would warrant classifying GMOs as similar to familiar organisms? Some regulators claimed to go beyond the the 'product vs process' debate (e.g. Medley, 1990), yet the earlier dispute now found a new venue: instead of specifying GMOs, they were specifying exclusions. Metaphorically speaking, the issues shifted from the type of regulatory 'net' to the type of holes in a broad net (cf. Regal, 1989).

2.2.1 US Department of Agriculture: 'sound scientific' euphemisms

The broad-net approach also had a symbolic importance. One USDA official acknowledged the perceptual shift implicit in the new OSTP phrase, 'organisms with modified heritable traits':

> It didn't change the organisms that you're talking about; scientifically, it was not very different. But I think the drafters were trying to get away from a pejorative label [GMO], from misconceptions that people might have (interview, 8 November 1990).

In that same period, the USDA adopted the OSTP 'risk-based' language, denoting predictability. The USDA sought 'to maintain a regulatory structure based on risk, not process' (Medley, 1990; cf. McCammon and Medley, 1990b: 108).

Citing the 'familiarity' principle from recent documents (NRC, 1989; OSTP, 1990), a USDA official explained that the principle meant assessing the organism in terms of past familiar releases, and thus categorizing it in terms of a qualitative risk type. The priority for regulatory oversight was 'to look at unfamiliar organisms, where you don't have enough information to judge the safety or risk'. The USDA felt it could use this risk-assessment system 'to make a very rational decision' about the initial trial-release introduction into the environment. A plant genetically modified for enhanced virus resistance, or for endogenous Bt (an insect toxin), for example, is 'similar to previous safe introductions'; accordingly, its behaviour would lie within a familiar range of impacts. Only such a risk-based approach would be 'scientifically defensible' (interview 8 November 1990).

That basis often meant presuming adequate information and/or accepting first principles for anticipating any hazards. As a further example, although the USDA had included *Rhizobium* in its long list of potential plant pathogens (USDA/APHIS, 1987), it now routinely exempted genetically modified *Rhizobium* from regulatory oversight:

> We do not do full-scale environmental assessment at all on it [*Rhizobium*]. We write letters back to the applicant, saying that we won't regulate it because we know the safe history of introduction of conventional *Rhizobium* (interview 15 November 1990).

Confident safety assumptions became more explicit for unintended gene transfer. At a November 1990 conference, USDA speakers acknowledged that published data on isolation distance were developed to assure seed purity, not to avoid gene flow *from* the crop, and that the standard isolation distances in agriculture presume some unintended interbreeding. To prevent outward gene flow, then, 'supporting data is recommended and normally twice the recommended distance is used in field testing'. The speakers also suggested that, for larger-scale trials, 'the emphasis would shift for certain issues': the potential for weediness and other

biosafety factors would become more important criteria (McCammon and Medley, 1990b: 112-13). Thus they compensated for uncertainty with a rule-of-thumb, while hardly using the trial releases themselves to reduce that uncertainty for the future.

For moving beyond small-scale tests, 'the inserted genes and their resulting phenotype [will] begin to dominate the analysis of these plants' (USDA/APHIS, 1990). Accordingly, in February 1991 the USDA finally applied the 1990 OSTP scope principles to wider ecological concerns, as follows: The new guidelines suggested procedures for classifying any proposed release into a 'level of safety concern', which would warrant a corresponding 'confinement level'. Invoking 'sound scientific judgement', the procedure emphasized familiar characteristics of the unmodified parental organism, as well as the precise genetic modification, which would allow better predictability of the modified organism's behaviour (USDA, 1991). This document extended earlier euphemisms: rather than 'risk regulation' of 'GMO releases', the USDA now offered voluntary guidelines for 'safety concerns' about 'organisms with deliberately modified hereditary traits', with no USDA oversight.

In summary, then, the 1990 OSTP guidelines served to justify the USDA policy of applying 'additional' regulation only in cases of suspected plant pest risks or 'lack of familiarity', in turn defined narrowly. Thus the USDA 'risk-based' slogan made more explicit the assumptions of the earlier 'product-based' slogan, by treating safety as a readily knowable property of a GMO 'product'.

2.2.2 Environmental Protection Agency*: stretching the scope*

By contrast to the USDA, the EPA's regulatory role and perspective conflicted with the 'risk-based' assumptions. Particularly difficult was the OSTP criterion -- 'unless information... indicates that oversight is necessary'. In effect, this criterion placed the burden of evidence for risk upon any agency which imposed 'additional' regulation.

Even some industrialists regarded that basis as inadequate for legitimizing their trial releases as safe. Having sought EPA regulation, one company argued that the OSTP criterion ('unless information...') was tautological, because even a review of risk information would constitute 'oversight' if done by a regulatory agency. Moreover, warned the company, the OSTP criterion might allow only 'self-regulation', which would not be viewed favourably by the public. Rather, industry needed a routine notification system for all GMO releases, so that each agency could then decide whether further review was necessary (BTI, 1990).

When the EPA's advisory committee discussed how to incorporate the OSTP guidelines, the committee interpreted the risk 'information' requirement in a broad way. It proposed screening all organisms with 'new' behaviours under TSCA, and all organisms with 'intentionally modified pesticidal properties' under FIFRA. Although naming some possible exclusions, the committee implied that any type of genetic novelty would constitute the relevant 'information' which warranted initial oversight. Moreover, EPA's committee posed awkward questions about 'the most scientifically sound way' to interpret the criteria found in the OSTP document; thus members cast doubt upon whether such criteria could guide 'objectively determinable, rather than subjective, concepts and terms' (BSAC/EPA, 1990).

In describing its own 'objective review process', the EPA emphasized uncertainty rather than familiarity: 'As uncertainty or the potential for adverse effects increases, monitoring intensity should also increase to asssure that adverse effects are identified and limited.' The EPA sometimes requested laboratory tests as a precondition for small-scale trial releases, whose monitoring in turn should detect whether the GMO differs from the unmodified organism -- for example, regarding its competitive advantage or dissemination (Anderson and Betz, 1990).

Also by contrast to the USDA, the EPA generally did not regard the experience of conventional organisms as an adequate basis for classifying a GMO as familiar. Some testing was necessary before routinizing small-scale releases: 'Once we have done three or four field tests of this [genetically modified] organism, we may feel that it is sufficiently familiar, to exempt it [from extra oversight] for small-scale releases' (EPA interview, 15 November 1990).

For the EPA, then, precise genetic changes in a GMO did not guarantee predictable behaviour. Rather, the EPA regarded genetic novelty itself as 'information' which warranted notifying GMO releases to the agency, and which warranted requesting still more data in order to assess risk. In making such proposals, it was stretching the terms of the 1990 OSTP document. However, further OSTP moves would precluded this precautionary version of a 'sound scientific basis', with its subtle negotiations in the EPA's advisory committee.

2.2.3 Scope revised: GMOs 'innocent until proven guilty'

Disagreement persisted over how the 1990 OSTP proposal would be finalized and implemented by Federal agencies. In February 1991 the President's Council on Competitiveness, chaired by Vice-President Dan Quayle, issued a report reiterating the need for 'risk-based regulation', in order to 'avoid excessive restrictions that would curtail the benefits of biotechnology to society'. It urged government to finalize the 1990 OSTP

proposal, so that Federal agencies could clarify which field tests require prior regulatory scrutiny (BWG/Quayle, 1991).

In May 1991 the OSTP circulated for comment a revised 'Scope' proposal, which further strengthened the burden of evidence upon Federal agencies for demonstrating risk. Agencies could not exercise additional regulatory oversight without 'substantial evidence that a significant and unreasonable risk may be posed by the introduction and is not addressed by other risk-management mechanisms' (OSTP, 1991: 20-21). Although describing this approach as 'scientifically sound', the 1991 proposal said little about its scientific rationale.

Objections to the 1991 OSTP proposal came from many quarters. As the Environmental Defense Fund sarcastically paraphrased it, 'Only organisms we already know to be dangerous should receive any oversight' (EDF, 1991). ICI Americas warned that the new formulation would further delay agreement and would risk 'regulatory chaos'. The EPA expressed suspicions that the Council on Competitiveness was seeking to block the draft regulations that the agency had been developing under the 1990 OSTP document, as those would have required initial notification of all GMO releases (Charles, 1991).

Two years after its first 'Scope' document, in February 1992 the OSTP issued a final version. It allowed for varying degrees of oversight, which

> '... will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed.... Any information requests should be designed to maximize their benefits and minimize their costs by soliciting only the most useful information in the least costly manner' (OSTP, 1992).

Alvin Young, directory of the USDA Office of Biotechnology, noted approvingly that biotechnology products were now considered 'innocent until proven guilty' (Anon, 1992).

On the one hand, the finalized OSTP rule could permit agencies to require advance notification, or even to exercise some initial oversight, without strong evidence of risk. Permitting flexible degrees of oversight, the wording accommodated some concerns of environmentalist groups and industry (e.g. Fox, 1992). Yet the rule required an agency to justify any such measure as quantifiably reducing risk, in a context where safety sceptics denied that GMOs could be classified according to qualitative hazards, much less according to quantifiable risk. Thus the new rule limited agencies' capacity to identify any hazards not yet documented for GMOs or for the unmodified organism.

Such constraints on Federal agencies had been foresaged a month earlier (January 1992), when President Bush announced a 90-day moratorium on all new safety regulations. By then, biotechnology regulations had been finalized only for the Federal Plant Pest Act in 1987; none

of the other promised regulations had been issued, not even in draft. Given that they were moving ahead so slowly, the President's further blockage was hardly 'deregulation'. Nevertheless, the moratorium reinforced the rhetorical imperative of economic competitiveness, by implying that the USA's prolonged recession was due to excessive regulation.

Throughout this episode, the OSTP sought 'scientifically sound' criteria for identifying in advance which GMOs warranted 'additional' regulation, without stigmatizing the recombinant DNA process. In effect, this meant that Federal agencies held the burden of evidence for citing adequate 'risk information' prior to 'risk identification'. By imposing this requirement, the OSTP favoured a presumption of ecological predictability over uncertainty, and so constrained any precautionary approach, especially by the EPA. Moreover, even the USDA's modest role came under challenge: citing the 1992 OSTP principles, industry soon argued that a 'scientifically sound' risk-based approach justified relaxing USDA oversight, given that no plant GMO had ever exhibited 'plant pest' behaviour associated with the plasmid vector (Huttner et al., 1992).

In summary: As its official slogan shifted from 'product-based' to 'risk-based' regulation, the OSTP guidelines brought Federal agencies no closer to a consensual basis for specifying which organisms warrant additional regulation. Even when the OSTP dissolved GMOs conceptually into a wider category -- 'organisms with modified hereditary traits' -- the earlier regulatory issues remained no less contentious. Both industry and environmentalists, in different ways, disputed the scientific rationale for the Federal agencies' approaches. Nevertheless a 'rational', idealized image of the USA's product-based regulatory system was being deployed to attack the EC's process-based framework (as described in the following section and Chapter 9, section 1).

3.0 EUROPEAN COMMUNITY: 'Uncertainty-based' regulation

In contrast to the USA, the European Community adopted new legislation: the 1990 Deliberate Release Directive. The Directive regulated all GMO releases, i.e. all products of the genetic modification process. Also unlike the 'risk-based' language of USA, the Directive was informally called 'uncertainty-based regulation' (e.g. DGXII official, interview 18 July 1991; Dutch Environment Ministry official, at Biotechnology Europe conference, 24 June 1992). Nevertheless this ambiguous phrase did not accommodate divergent views on whether a process-based Directive was necessary.

In the ensuing disputes over the Directive, implicitly at stake was its precautionary content. This section will outline its precautionary features, trace its origins, and analyse related conflicts within the European Commission. (Wider EC conflicts, especially over the terms of market approval for GMOs, are described in Chapter 9, section 1.)

3.1 EC Directive: precautionary features

The EC Deliberate Release Directive was consistently described as a 'preventive' measure, rather than as 'precautionary'. It cited the Treaty of Rome, which had asserted the principle of 'preventive action'. Quoting its legal base, Treaty article 100a, the Directive emphasized that completion of the internal market must be based on 'a high level of [environmental] protection' (EEC, 1990: 15). The lead agency (*chef de file*) for the Directive was the Environment Directorate, DGXI, whose officials located the Directive within 'a preventive approach that the Community is taking on environmental and other issues' (CBC, 1990: 18).

However, in substance the Directive was more than merely 'preventive'. It had the following precautionary features (EEC, 1990):

* The preamble justified the mandatory measures by warning that living organisms may reproduce, cross national frontiers, and cause 'irreversible' effects. Thus, unable to cite harmful effects from GMO releases, the preamble implicitly drew an analogy to non-indigenous organisms.

* The regulatory scope encompassed all GMOs -- that is, 'all organisms in which the genetic material has been altered in a way that does not occur naturally by mating and/or by natural recombination'. These were specified as products of named techniques, as listed in Annex I (ibid.: 22); accordingly, GMOs included all products of recombinant DNA, and even some products of traditional techniques, such as cell fusion. In effect the genetic modification 'process' denoted a presumption of, and screening for, artificial genetic novelty.

* Prior to GMO release, the applicant had to carry out an environmental risk assessment, applying specified criteria, as listed in Annex II (ibid.: 23-27). These included, for example, 'likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits', 'likelihood of post-release shifts in biological interactions', etc. Unlike the USA's OSTP rules, then, the EC Directive subjected all GMO releases to wide-ranging risk-assessment criteria. These were drawn from the 'blue book' (OECD, 1986: 48-49), though both documents implied some discretion in whether or how to apply the criteria to each proposed release.

* The Directive imposed upon member states the responsibility 'to avoid adverse effects on human health and the environment' from all GMO releases, and to certify their safety. Each release required a prior consent from the designated 'competent authority' of the country in which it takes place; this requirement encouraged each 'authority' to accumulate experience of GMO releases in general.

* At the stage of market approval of a GMO product, an EC-wide procedure allowed for objections from any member state. However, final approval would then apply to all member states. This procedure fulfilled the Directive's legal base, Article 100a, on completing the internal market.

* A GMO product could not obtain market approval unless it had undergone safety tests according to the risk-assessment criteria of the Directive. Products could be exempted only on procedural grounds, not substantive grounds: the Directive would 'not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive' (ibid.: 18).

3.2 Shaping the Directive

Having achieved a process-based framework, DGXI attempted to downplay any substantive difference between the Directive and US regulation. According to a DGXI official, the Directive was 'largely based on the 1986 OECD report' and therefore 'based firmly on the international consensus of how this area should be regulated' (CBC, 1990: 19). However, the report had clearly asserted that 'There is no scientific basis for specific legislation for the implementation of rDNA techniques and applications' (OECD, 1986: 41). The report had recommended a case-by-case, step-by-step procedure, but only as the basis of a notification and monitoring system. The EC went far beyond that limited intent by adopting process-based legislation. How did the EC's divergence come about?

Advocates of the EC Directive had been able to cite the imperative of harmonizing disparate regulatory regimes. These regimes were arising partly in response to organized protest; in various ways, some member states were subjecting GMO releases to process-based restrictions, potentially jeopardizing any EC internal market for GMO products. As early as 1986, public opposition led the Danish Parliament to enact the Environment & Gene Technology Act, which imposed stringent limits on GMO releases there (Shackley and Hodgson, 1991).

The same year in Germany, public concern about GMO releases was articulated in a Commission of Inquiry, initiated by the Greens and Social Democrats; the Commission

ultimately recommended a five-year moratorium on releasing GMOs (Bundestag, 1986), though the Parliament did not accept that proposal. Industry portrayed GMOs as modest, precise, benign extensions of natural processes, but that account was ideologically deconstructed by German critics; they portrayed genetic modification as fundamentally interfering with nature, and so bearing potentially disastrous, unpredictable consequences (Gottweis, 1995). A subsequent court case there ruled in the protestors' favour; it interpreted the country's Basic Law as forbidding GMO releases unless specifically permitted by some supplementary legislation, which was eventually provided by the 1990 Gene Technology Act (Fritsch and Haverkamp, 1991).

Amidst considerable public unease over biotechnology, not just in Germany and Denmark, some EC countries were developing less stringent regulation, while some had no regulatory policy at all (RCEP, 1989: 65-66; OECD, 1990a: 15-29). A DGXI official later reiterated the market rationale in the Directive's preamble: that is, a situation of divergent regulatory regimes 'was not going to help the harmonious development of biotechnology in Europe and would hamper access, in fact, to the entire Community market of 1992' (CBC, 1990: 18; cf. EEC, 1990: 15). Partly for that reason, industry reluctantly accepted the need for an EC Directive, despite the extra regulatory burden (Lake, 1991; see also Chapter 9, section 1). How, then, would new legislation define the risk problem?

An early DGXI-commissioned report had suggested a scientific rationale for new legislation: the author attributed ecological uncertainties to the novel genetic combinations generated by the recombinant DNA process. He regarded 'agriculture and other human-created systems' as particularly vulnerable to disruption; this was partly by analogy to introduced exotic organisms, and partly by analogy to past agricultural problems associated with reduced biodiversity, pathogen invasions, pest resistance, herbicide resistance, etc. The report proposed a case-by-case environmental risk assessment before releasing any 'new or exotic micro-organisms'; it also proposed further ecological research on the safety of novel organisms more generally (Mantegazzini, 1986).

Similarly the EC's Fourth Environmental Action Programme acknowledged possible environmental risks from 'genetically altered or exotic organisms'. It argued that 'no fundamental distinction can be made between the type of risks' which arise from various organisms according to how they are produced, i.e. whether by laboratory techniques or selective breeding. The great variety and quantity of new uses being developed for GMOs, however, 'could increase the scale of risks from these uses unless their development takes place in a well-defined regulatory environment'. Such regulation was necessary also 'to protect the common market against unilateral national regulations' (EEC, 1987: 26-28). Thus

the EAP advocated additional legislation in order to prevent familiar hazards from novel organisms and to avoid regulatory disharmony.

In the European Commission, regulatory responsibility was taken on by DGXI, the Environment Directorate, by agreement with DGIII, Directorate for Internal Trade. Initial deliberations considered regulating not only GMOs but also a wide range of biological agents. However, DGVI (the Agriculture Directorate) opposed any additional environmental regulation of 'naturally occurring organisms', such as exotic organisms and traditional breeding, for which it wanted to keep responsibility. Thus DGIII and DGVI supported DGXI in drafting new legislation only for GMOs, defined as organisms produced by novel techniques (Shackley et al., 1992). In effect this focus upon GMOs downplayed the systemic agricultural hazards which were cited in the DGXI-funded report (i.e. Mantegazzini, 1986: 76-80, cited above).

The European Commission published the first draft of the Deliberate Release Directive in 1988. Its Part B on trial releases covered all GMOs. Part C, on market approval, exempted a named list of product categories, such as pesticides, if they were 'covered by Community legislation which includes a specific risk assessment' (CEC, 1988: 7-8). However, two years later the final version made no specific exemptions; instead it permitted exempting any GMO product which was subject to a 'similar' risk assessment in another product directive (EEC, 1990: 18). Thus the Directive potentially extended the precautionary criteria to the market approval stage of all GMOs. How, then, was Part C strengthened?

The more stringent process-based version resulted partly from public unease and environmentalist lobbying, expressed through the European Parliament. Indeed, its Environment Committee initially opposed derogating any GMO products from the Deliberate Release Directive; the Committee insisted that market approval of every GMO should remain subject to the Directive, regardless of any separate product legislation. The Parliament's second reading gave that proposal a simple majority of those MEPs voting, though not an absolute majority of the members, which would have strengthened the Parliament's bargaining position in EC consultation procedures (Lake, 1991). The anti-derogation proposal initially received support even from the Christian Democratic Group of MEPs, mainly because its German members were responding to public and environmental concerns; ultimately, however, 'their fears about overly strict regulation overcame their fears about dangers to the environment', according to one Parliament official (Environment Cttee interview, 17 July 1991).

The Parliament communicated its anti-derogation stance to the European Commission in May, one month before Green parties significantly increased their vote in the 1989 European Parliament elections. Industry backed DGXII in supporting the original version, which mandated derogating GMO products (e.g. GIBiP, 1990: 56); yet that version was opposed by Denmark, DGXI and the Parliament (Lake, 1991). In November the European Commission successfully put a compromise proposal before the Council of Ministers: Part C would allow derogating a GMO product to separate legislation, provided that the relevant product directive had a 'similar' risk assessment (EC: The Council, 1989). In effect the final wording was a compromise -- between either prohibiting derogation, or mandating it for entire product categories.

In summary, organized protest became translated into process-based regulation of GMOs, initially in some EC countries and ultimately for an EC-wide framework, even for the stage of market approval. Nominally 'preventive', the Directive had many precautionary features. This framework was intended to accommodate both public unease and ecological uncertainties, while establishing rules for an internal market.

3.3 An efficient Directive?

Before and after the Deliberate Release Directive was finalized, its process-based framework was opposed by DGXII, the Directorate-General for Science, Research and Development. DGXII repeatedly questioned the 'rational' basis for any safety rules specific to recombinant DNA techniques per se (e.g. Cantley, 1992: 23-25). It preferred simply a notification and monitoring scheme, as proposed by the 1986 OECD report. Although accepting that some EC-wide regulation was necessary, DGXII advocated new legislation only for GMOs which did not come under existing product regulation, e.g. nitrogen-fixing bacteria (DGXII interview, 18 July 1991). DGXII had lost the argument by the time the Commission published its 1988 draft Directive, though it later succeeded in rallying industry lobbyists and isolating DGXI (see Chapter 9, section 1).

The conflict within the Commission, particularly between DGXII and DGXI, arose partly from those Directorates' different roles. The relevant section of DGXII, the Concertation Unit on Biotechnology in Europe (CUBE), funded biotechnology promotion and research (Vassarotti and Magnien, 1990; Cantley, 1992). Not simply serving industry's perceived interests, DGXII redefined them by arguing that product-based regulation of biotechnology would best serve the cause of enhancing the EC's industrial innovation and thus socio-economic progress. CUBE's chief, Mark Cantley, regularly gave public talks celebrating biotechnology as the vanguard of 'molecularisation, informatisation and globalisation' (e.g. at the May 1992 Citizens' Audit on Biotechnology).

DGXI is the lead agency (*chef de file*) for environmental regulation. It holds responsibility for devising and monitoring directives acceptable to both the European Parliament and Council of Ministers, and capable of harmonizing regulation among the EC-member countries. Within that dual constraint and opportunity, DGXI formulated a distinctive rationale for process-based regulation of GMO releases; unlike DGXII, it put forward no grand vision for what biotechnology should be, notwithstanding the EC commitment to 'ecological modernisation' (see this chapter, section 1.1).

In this conflict, DGXII and DGXI each defended their respective regulatory stance as the truly rational, efficient one. Perhaps not merely rhetorical, a distinct rationality can be inferred from each DG's views, at three related levels: the type of hazard, the regulatory role of science, and regulatory effects. (See Shackley et al., 1992, for a more detailed account, starting from the mid-1980s. The following quotations are from my interviews of 18 July 1991, unless otherwise noted.)

** *Type of hazard*

Regarding the type and predictability of any hazard, DGXII regarded biotechnological safety as having been already vindicated by the laboratory experience of genetic modification. An official emphasized 'the absence of specific adverse effects attributable to the [rDNA] techniques'; in fact, these techniques make GMOs' behaviour even more predictable. DGXII described itself as 'funding risk-assessment research to establish whether there are any risks associated specifically with these techniques', i.e., rDNA. In this regard, for example, 'there is ongoing research on the management of the Bt gene' [the toxin gene from a microbial pesticide]. Regarding the environmental safety of agricultural GMOs, DGXII also cited 'our understanding of the robustness and interactions in nature' -- unlike 'highly artificial crops stripped of their capacity to survive without the continued efforts of the farmer'.

For DGXI, by contrast, genetic novelty presents an inherent ecological uncertainty, even a risk of 'ecological imbalances' (exemplifying the 'irreversible effects' cited in the Directive). 'Genetic modification technology creates the real novelty, so process-based regulation focuses on the area of most potential concern, as well as avoiding unnecessary concern.' For example, 'There is more in common among herbicide-resistance genes in different plants; we are looking for specific aspects resulting from the genetic novelty.' For DGXI, then, process-based regulation helps scientific research to learn what kinds of hazards might materialize and what additional expertise would be needed to avert them.

** *Science-based regulation*

DGXII felt that regulators should resist the external political pressures which had led to a process-based Directive, and which were now obstructing the environmental potential of biotechnology:

> Biotechnology was crossing the road from the lab to the marketplace when this bus of environmental enthusiasm was coming along. And instead of being on board the bus, where it belongs, biotechnology has been hit by it and is now in the hospital of public opinion. This is an unfortunate accident which we are trying to repair.

Formulation of the Directive had involved a clear choice 'between political opportunism and scientific advice', where DGXI had chosen the former option. DXII resented the symbolic effect: 'Some sectors of industry have taken a beating, and scientists in Europe have seen safe techniques with a 100% track record being stigmatized' (cited in Balter, 1990). Given the proven safety record of biotechnology, process-based regulation was 'not rational or necessary'. Argued DGXII, 'We can learn faster from making mistakes, where we lack the foresight to prevent them'; thus any unexpected damage would help indicate whatever hazards warrant taking precautions.

By contrast, DGXI regarded public unease as partly justified by ecologists' concerns about GMO releases. Those concerns presented an opportunity to go beyond the existing knowledge of product categories, to develop a new interdisciplinary expertise. For DGXI, process-based (horizontal) regulation offered a sensible use of resources: 'with a horizontal system, each risk assessment can benefit from the experience of different GMOs, considered by the same group of experts'. For DGXI, 'It is more efficient to have the same experts assessing all releases of the organism, [from trial release] through to product approval; there are logical, rational advantages of horizontal regulation... And there is not yet any general scientific basis for making the transition to vertical [product-based] regulation; it can only be done case by case'.

** *Regulatory effects*

Regarding the wider effects of safety regulation, DGXII foresaw the Directive putting European biotechnology at a competitive disadvantage. It questioned whether hypothetical hazards warranted 'a rational allocation of resources, given the existence of other known problems'. Society's resources were needed to reap the expected benefits of biotechnology and to avert familiar hazards of traditional products, such as naturally occurring carcinogens in food. After all, faced with continued famine in the Third World, 'We are in a race against time in which we [Western societies] are handicapping the most relevant technologies.'

By contrast, DGXI regarded the Directive as providing a uniform, stable framework for European industry. Safety regulation could not be blamed for holding back the biotechnology industry, 'provided that regulation is predictable, broadly reasonable and stable', argued the DGXI Director General (quoted in Dickson, 1990b).

** *Reconcilable differences?*

Superficially, the two DGs were disputing the most 'efficient' means of regulating GMO releases and of facilitating innovation. Yet they did so from incompatible cognitive frameworks; each Directorate justified its stance by citing different structural uncertainties. For example, they portrayed the environment either as threatening agriculture, or as potentially threatened by agricultural products; they regarded public unease either as a problem, or as an opportunity. To some extent, the two Directorates exemplified the 'individualist-market' versus 'hierarchist' political cultures (as theorized by Schwarz and Thompson, 1990). Their standpoints can be summarized as follows:

DGXII advocated classifying GMOs within existing product regulation. Its arguments conflated process and product safety, by citing the safe experience of GMOs in contained use; it presumed a precise genetic-level control over product characteristics and thus over environmental effects. DGXII posited a robust environment which not only endures perturbations but also threatens agricultural yield and thus food security. If GMOs did cause any damage, presumably minimal or reversible, then this would facilitate efficient learning by trial-and-error. Faster innovation, towards a genetically reprogrammed nature, would yield up nature's cornucopia for the common good.

By contrast, DGXI advocated classifying all GMOs together for regulatory purposes. Its arguments drew selectively upon scientists' warnings that some cases of genetic novelty might cause ecological instability. This unacceptable consequence, which presumed an environmental vulnerability, warranted imposing a case-by-case scrutiny upon all GMOs, and developing an interdisciplinary expertise for assessing their safety. Only such efforts could test the hypothetical hazards cited in public debate.

How could the EC accommodate these different stances? Faced with sharp disagreements over the safety and ethics of biotechnology at a 1988 conference, DGXII's Mark Cantley had commented, 'I think that reconciling apparently irreconcilable differences is our daily business in Brussels' (Wheale and McNally, 1990: 265). Rather than reconcile them, the Deliberate Release Directive decisively favoured a process-based regulatory system.

Politically, however, process-based regulation depended upon the claim that it was essential for completing the EC's internal market and thus facilitating innovation. This market imperative left the Directive vulnerable to further political pressure, especially towards narrowing the range of ecological uncertainty deemed relevant (as described in Chapter 9).

4.0 CONCLUSIONS: 'RATIONAL' DILEMMAS

In conclusion, when state authorities formalized risk-management procedures for GMO releases, they were responding to political threats: i.e., actual or potential protest, the stigmatized image of GMOs, and political obstacles to an eventual biotechnology market. With the administrative term 'additional regulation', regulators denied they were treating GMOs as a special problem. Moreover, the safety measures marginalized the systemic 'risk' which had featured in public debate, such as issues of environmental control and intensive monoculture (see Chapter 3). Safety measures were designed to anticipate any direct, physically measurable harm from GMOs or from their inserted genes. Within this account of the risk problem, the 'product versus process' debate concerned how to classify GMOs for regulatory purposes.

The US government adopted a product-based regulatory system, which gave several meanings to the term 'product'. Under the 1986 Co-ordinated Framework, new administrative rules classified GMOs according to their ultimate product use and assigned them to Federal agencies under existing product legislation. The rules specified 'product characteristics' which would warrant a Federal agency in imposing 'additional' regulation, beyond that which otherwise applied to the unmodified organism. This policy took for granted a benign analogy between GMOs and familiar products.

This product-based regulation was also called 'risk-based'. With such language, rulemakers largely presumed that existing knowledge was adequate to predict the significance of any genetic novelty and thus to identify any risks. However, by the late 1980s, Federal agencies had encountered political and scientific difficulties in implementing the original criteria for risk identification.

In response, the government linguistically abolished 'GMOs', by dissolving them into a broader regulatory net -- 'organisms with modified hereditary traits' -- while specifying exclusions, e.g. on grounds of 'familiarity' from past experience. Further rules specified cost-benefit criteria for any 'additional regulation', thus imposing a greater burden of evidence upon regulators. With these constraints, the US 'product-based' system allowed Federal

agencies to do little more than prevent some hazards already documented; it pre-empted issues of risk assessment and risk evaluation, especially the consequences of any hypothetical harm.

Earlier the 'product versus process' debate had disputed risk-identification criteria; the same issues were now shifted to a dispute over which organisms to exclude from the a broad regulatory net. In the name of 'rational' regulation, the US government had attempted to standardize a scientific basis for imposing risk-management procedures upon GMO releases; yet, paradoxically, this attempt made regulatory science appear even more political (as had happened earlier in regulating hazardous chemicals, e.g. Jasanoff, 1986: 26-27, 72). The OSTP's rules intensified public controversy, highlighted conceptual differences among the Federal agencies, and constrained the Environmental Protection Agency in particular. Executive-level pressures were disrupting EPA moves towards a stable, expert-based 'science policy', of the sort which characterized other regulatory areas in the late 1980s (cf. Jasanoff, 1990).

In contrast to the USA, the EC adopted a process-based regulatory system, covering all products of the genetic modification process. Although the 1990 EC Deliberate Release Directive was called 'preventive', it had several precautionary features. It subjected all GMO releases to risk-management procedures, which required a prior consent and risk assessment, applying broad ecological criteria. In effect, this framework deferred the issues of risk identification until the regulatory procedures could develop some method from experience; in the meantime, applicants held the burden of evidence for demonstrating safety.

Regulators justified this broad regulatory scope by citing the potential for 'irreversible' environmental damage, i.e. the unacceptability of hypothetical harm. They attributed greater uncertainty to the genetic novelty of GMOs, partly by analogy to some non-indigenous organisms which had caused environmental damage. Informally, some officials called this 'uncertainty-based' regulation, thus acknowledging indeterminate cause-effect models of potential harm.

The opportunity for this legislation arose from several sources: a regulatory division of labour within the European Commission, an environmentalist unease over biotechnology, the process-based regulation adopted by some EC member states, and the EC's commitment harmonized regulation. These somewhat contradictory sources were manifest in formulating the Directive, particularly in extending process-based regulation to the market approval stage of GMO products.

Moreover the EC Directive came under political attack on several grounds: for stigmatizing the genetic modification process, for encouraging public unease over unreal risks, and for hampering a benign innovation. In this conflict, arising initially within the European Commission, DGXI and DGXII invoked incompatible accounts of the relevant scientific uncertainty and of environmental threats. Their stances somewhat illustrate antagonistic political cultures, e.g. 'hierarchist' versus 'individualist-market', respectively (as theorized by Schwarz & Thompson, 1990); however, DGXI had to manoeuvre within the project of completing the EC's internal market.

Indeed, GMO regulation embodied market imperatives in several ways. The US system did so crudely, by imposing a cost-benefit analysis upon any 'additional' regulation. More fundamentally, both the US and EC-UK frameworks responded to industry demands for a safety imprimatur; GMO regulation was designed to establish the political conditions for biotechnology R&D and an eventual international market. By abstracting 'risk' from the context of intensive monoculture, regulatory procedures could standardize testable uncertainties of prospective commodities.

In summary, the US and EC frameworks can be analysed in a two-fold way: as encountering difficulties around the rational stereotype of safety regulation, yet also constructing a procedural rationality, capable of legitimizing its decisions. The US product-based system invoked first principles for demarcating between real/perceived risks in advance; this claim provoked political conflict over the detailed scientific criteria for imposing risk-management measures. By contrast, the EC's process-based system suspended any boundary between real/perceived risks, so as to negotiate a more credible one through the regulatory procedures, case by case; this precautionary approach came under attack as 'irrational'.

Each in their own way, US and EC regulators faced difficulties in justifying risk-management rules as warranted by a prior risk-identification method. When both critics and rulemakers advocated science-based regulation, each promoted a different cognitive framework, i.e. a model of the scientific uncertainty and its potential consequences, thus politicizing any 'science-based' policy. Regulators also faced the dilemma over how their 'additional regulation' could acknowledge the stigma associated with GMOs in a way which could overcome it.

Chapter 5

BRITAIN'S PRECAUTIONARY LEGISLATION

The EC Directive required each member state to incorporate its provisions into national law. Britain did so through the Environmental Protection Act 1990, whose Part VI regulated both the contained use and deliberate release of GMOs, from the R&D stage onwards. This was enacted before there could have been evidence of harm from GMOs designed for release, so the 1990 Act set a precedent for precautionary legislation in Britain.

Exactly how did the British government incorporate the process-based EC Directive into national law? How did the government specify and justify its precautionary features? How did the new statutory basis affect Britain's regulatory style?

This chapter will analyse:
* precedents and forces which shaped Britain's new legislation (section 1).
* its precautionary features (section 2);
* limits of GMO regulation (section 3); and
* dilemmas manifest in the statutory measures (section 4).

This chapter will refer to the Environmental Protection Act Part VI as 'the 1990 Act' in the main text, or as 'EPA' in bibliographic citations -- not to be confused with the USA's Environmental Protection Agency, analysed in Chapter 4. Some aspects are discussed in more detail elsewhere (Levidow and Tait, 1992).

1.0 SHAPING THE LEGISLATION

When Britain established a statutory framework for regulating GMO releases, it extended and integrated certain precedents. These included: a changed meaning for the code-word 'sound science'; voluntary self-regulation of GMO releases; and the dual role of those regulatory procedures, in anticipating both hazards and public fears.

1.1 Shift in 'sound science'

In British environmental policy, the concept of 'sound science' has served as a rhetorical device to justify setting stringent criteria for adequate evidence of harm. The government has often deferred environmental protection by citing economic considerations and counterposing

them to unproven environmental damage. Indeed, in the name of science-based regulation, Britain has often resisted EC regulatory proposals as 'threats imposed by unreasonable foreigners acting counter to scientific and economic rationality' (Boehmer-Christiansen, 1992: 22).

For example, at the 1972 UNEP Stockholm conference, the British government defended its policy of allowing waste emissions to utilize fully the 'waste-absorbing capacity' of the environment; this capacity was inferred from a dose-effect model. The criterion of 'best practicable means' (BPM) implicitly incorporated cost considerations, regarding whether reduced emissions warranted the higher cost of a less-polluting alternative means. However, other European countries opposed BPM with the criterion of 'best available technology' for minimizing waste emissions, thus subordinating cost criteria (Holdgate, 1983: 12-13).

For such EC countries, as well as the USA, the term 'best available technology' (or 'best technical means') was intended to force major technological improvements, beyond currently available standards. By contrast, Britain's consensual approach encouraged only incremental improvements (Vogel, 1986: 76--81). Often EC policy devised a compromise between those two approaches (Peachey and Macrory, 1983: 88).

Britain's traditional stance has been increasingly disputed within EC policy debates (e.g. Weale, 1992), and even within Britain, especially by the Royal Commission on Environmental Pollution. When the RCEP (1976) first proposed the 'Best Practicable Environmental Option', the BPEO was a procedure for extending the BPM criterion to integrated pollution control; this required considering systemic costs and benefits for the entire environment, rather than shift costs from one part to another. In its 11th report, the RCEP (1988) went beyond BPM, by giving BPEO a precautionary meaning: progressively reducing pollution through technical improvements, making value judgements explicit throughout a transparent decision-making procedure, recording those judgements for later review, and acknowledging some environmental costs irreducible to economic calculation. In a modest way, some measures for integrated pollution control were incorporated into the 1990 Environmental Protection Act.

In that Act, as in recent EC documents on environmental protection, BATNEEC has largely superseded the criterion of 'best practicable means'. BPM had been seen to imply an ambiguous balance between risk and cost (CBC, 1990: 10). BATNEEC can be interpreted as emphasizing either side and/or as balancing the two. The crucial change is not the specific inclusion of cost considerations, but rather the requirement to make all assumptions explicit, especially if decided via a BPEO procedure (RCEP, 1988: 21). Given that different protagonists may selectively emphasize either best technology or minimal costs, BATNEEC

offers a 'more contested and participatory approach'; it could challenge Britain's traditionally consensual, discretionary approach to risk regulation. It can also strengthen proposals for regulation to act as 'technology forcing' environmental improvements (O'Riordan, 1989: 116-17).

Also in 1990 the British government issued a White Paper on environmental policy, which offered a real-estate metaphor as a rationale for preserving natural resources: 'we do not hold a freehold on our world, but only a full repairing lease'. We must protect the environment 'by basing our actions on sound science and by taking precautionary action where justified', e.g. by anticipating the effects of new products and processes: 'This precautionary principle applies particularly where there are good grounds for judging either that action taken promptly at comparatively low cost may avoid more costly damage later, or that irreversible effects may follow if action is delayed' (HMG, 1990: 10-12).

With the latter phrase, 'irreversible effects', the government echoed the words of the EC Deliberate Release Directive (EEC, 1990: 15; cf. Smith, 1992: 9). By citing unacceptable consequences of hypothetical hazards, it signalled a more general tendency to anticipate and avert systemic damage; 'sound science' had taken on a more flexible meaning. As promoted by the DoE, this shift provided a conceptual precursor of GMO regulation.

1.2 Doubly precautionary

In Britain as elsewhere, public unease provided both the political necessity and scientific opportunity for efforts at anticipating hypothetical hazards from biotechnology. At a major conference on biotechnology regulation, the HSE emphasized the perceptual aspects. An official noted the relatively weak public opposition to GMO releases in Britain but warned, 'Nonetheless, there is public concern and there is a potential for greater public concern. The public want reassurance that there is a safe system of [genetic modification] work' (CBC, 1990: 14).

Such considerations had also influenced government in regulating the contained use of GMOs through the 1970s and '80s, mainly in medical laboratories (Wright, 1986; Bennett et al., 1986). By the mid-1980s the focus of public suspicion and safety debate had shifted to GMO releases, particularly as developed by agrichemical companies. The dual character of precautionary regulation was also extended, initially within voluntary procedures, and later given a statutory basis by the 1990 Act.

In the 1980s, the HSE had taken responsibility for regulating GMOs on the basis of the Health and Safety at Work Act etc. 1974 (e.g. ACGM/HSE, 1986, 1990; HSE, 1989). For GMO

releases, the HSWA could be extended to cover human health aspects, but not environmental aspects. When the HSE scrutinized the latter aspects of GMO releases, it was really mediating a voluntary self-regulation by the releasers.

Thus a new law would be needed for statutory protection of the environment, for which the HSE left the initiative to the DoE. Indeed, the HSE argued for exempting GMOs at the market stage if there was already sectoral product regulation, e.g. for medicines and pesticides (HSC, 1989). The HSE saw 'no scientific logic' in separately regulating GMOs (interview, 26 September 1991).

By contrast, the Department of the Environment developed scientific and political arguments for process-based regulation. Before drafting the Environmental Protection Bill (HC14, 1989), the DoE issued a consultation document on GMO regulation, which led to Part VI of the Bill. The document cited the potential for GMOs to become harmful 'pests', starting from the earliest trial releases. It also emphasized that public fear of GMOs may threaten wealth creation; it argued that extra costs of GMO regulation would be offset by the value to industry from increased public confidence. Without such regulation, 'A distrust of the industry by the general public could lead, as it apparently has in the USA and Germany, to the development of potentially wealth-creating products being held up by action on the part of concerned members of the public' (DoE, 1989: 19, 23).

The document proposed introducing a statutory system of consents with a duty of care (see section 2 below); this system formalizing the case-by-case, step-by-step procedure which industry was already developing through voluntary regulation. As DoE staff privately acknowledged, the extra administrative costs of obeying the new regulations might deter small firms and individual academic researchers; these were regarded as less likely to think through the safety and perceptual consequences, or to afford the cost of remedying any damage (interview, 15 February 1990). Thus civil servants did not entirely regret this regulatory barrier to entry into biotechnology.

In commenting on the DoE consultation paper, industry criticized some provisions as implying that GMOs pose exceptional risks; in this regard, industry privately expressed apprehensions about the DoE's greater role in regulating agricultural products. Nevertheless industry's written submissions broadly supported the proposed statutory system, partly in order to reassure the public. In our interviews, they cited the need 'to keep out the cowboys', whose behaviour might discredit biotechnology in general. Thus a hypothetical intruder served as a rationale for self-discipline, as well as for policing admission to the 'club' of GMO releasers.

Submissions to the DoE from various quarters illustrated the problem of stigma, which was to arise again in the Parliamentary debate. Industry officials complained that the DoE document implicitly associated GMOs with pollution, particularly when invoking 'the polluter pays' principle (CBI, 1989; CIA, 1989; cf. DoE, 1989: 11). In contrast, non-industry submissions expressed distrust towards the agrichemical companies which were producing GMOs, as well as towards the DoE for its failure to control pollution and its inexperience with biotechnology. Public-interest groups largely welcomed the proposed statutory basis for regulation, though they expressed reservations about its adequacy -- particularly for public access and market approval of GMO products.

In drafting the legislation, a key reference point was a long-awaited report on GMO releases from the Royal Commission on Environmental Pollution. It emphasized that GMO products offered potential environmental benefits 'which could be frustrated by public opposition motivated by fear of the unknown' (RCEP, 1989: 62). It also gave more scientific credence to potential harm from GMO releases, by drawing an analogy between GMOs and non-indigenous organisms which have become pests; this analogy was being downplayed or denied by other relevant bodies (NAS, 1987: 14; NRC, 1989: 37-53; OECD, 1990b: 16-17; OECD, 1992: 36). The RCEP recommended more stringent control measures and more public access than did the DoE paper or the subsequent 1990 Act.

Although the RCEP denied any inconsistency between its own report and the DoE paper, different emphases were perceived by many commentators. Cross-industry bodies stated, for example, that the DoE paper 'provides a more realistic and balanced approach to the proposed legislation', while the RCEP proposals on public involvement 'appear unnecessarily complex and wide-ranging'. On the other side, public-interest groups repeatedly cited the RCEP report when arguing for amendents to strengthen the the Environmental Protection Bill, as did some academics (e.g. Shackley and Sharp, 1989).

2.0 PRECAUTIONARY FEATURES

When the Environmental Protection Bill was passing through Parliament, Britain still had little sign of public controversy about GMO releases. The main features of Part VI found a broad acceptance among interested constituencies. The Opposition accepted Part VI as establishing a responsible regulatory regime, rather than contest the entire matter as a party-political issue, though its proposal for a Public Biotechnology Commission highlighted political choices involved in defining the environmental issues (see section 3).

The Opposition amendments were prompted by the Green Alliance in particular, backed up by some mass-media reports. In the final stage of the Bill's passage, the government conceded to such pressures by introducing major new clauses. One provided statutory backing for the government's advisory committee, ACRE (see chapter 6; Levidow and Tait, 1993: 198). The other new clauses established public registers of information for GMO releases, though with significant exemptions to the disclosure requirements (see section 2.7).

In other amendments proposed from the floor, Opposition MPs and Conservative backbenchers proposed to make existing clauses either more stringent or lax, respectively. In response, the government repeatedly emphasized that the Bill provided only 'enabling (or primary) legislation'. It tried to reassure MPs that the precise implementation would be clarified in the subsequent 'secondary legislation', later issued as draft regulations (DoE/HSC, 1991, 1992). These could be changed more easily than by amending primary legislation, and with less Parliamentary debate.

These disputes over the wording had two related sources. First, there were difficulties in translating regulatory lore into a precise technical-legal language. The latter invariably conflicted with the British consensual style and intensified industry suspicion of the DoE. Shortly after the 1990 Act passed through Parliament, a leading industrialist complained that this legislation would jeopardize the 'British pragmatic approach' which biotechnologists had been developing with the HSE, prior to statutory regulation. At the same time, he expressed impatience at the requirement 'to spend your time thinking about problems that might arise', because such an obligation 'would stop the science and product development' (interview, 22 March 1991).

Second, there were inherent difficulties in legislating against hypothetical hazards, as well as handling the perceived stigma of GMOs. Several precautionary features had an ambiguous scientific meaning or conflicted with the usual regulatory meaning of 'sound science'. This section analyses such conflicts -- around how to define GMOs, environmental damage, consents (licences), risk, the duty of care, and liability; and how to provide information disclosure.

2.1 Defining GMOs

In order to define GMOs, both the EC Directive and the British legislation distinguished between artificial techniques and natural processes. Although both documents named recombinant DNA as an artificial technique, they differed somewhat on other techniques. In particular, the Directive excluded plant cell fusion 'where the resulting organism can also be produced by traditional breeding methods', and excluded mutagenesis (EEC, 1990: 22). In

contrast, the Bill (and EPA, 1990: 116) took a broader scope, by not explicitly exempting any type of cell fusion, and by including the products of 'mutation-inducing agents'. An HSE official justified that wide scope by citing both process and product considerations: where planned release is concerned, 'the definition is further extended to cover *in vitro* techniques that would enable the construction of organisms with novel combinations of genes' (CBC, 1990: 13).

Some regulatory advisors felt that there was no scientific basis for the Bill to include mutagenesis; after all, this was a spontaneous natural process, which by definition could not be regulated anyway. Industry argued for recognizing the inherent safety of the additional techniques included in the Bill. In its submission to the RCEP and in discussions with ACRE, one company argued that its cell fusion products should be exempted from regulation, on the grounds that the products 'are not significantly different' from those produced by traditional breeding methods (Nickerson International, 1988).

In response to the published Bill, industry lobbied for amendments that would exclude mutagenesis and certain types of cell fusion, among other traditional techniques (CBI, 1990; CIA, 1990). Another amendment cited international guidelines on Good Industrial Large-Scale Practice for the safe use of GMOs (OECD, 1986: 34-35), in order to propose excluding GILSP organisms; otherwise, the regulation of GMO releases would apply to effluent from familiar industrial processes using micro-organisms, especially if the process of mutagenesis were cited to define an organism as a GMO. For the CBI, inclusion of GILSP organisms exemplified the negative tone of Part VI, which 'appears to be based on the premise that all GMOs are dangerous' (cf. CBC, 1990: 31). In interviews, industry complained that such a broad scope would waste their time and disadvantage them competitively, as well as extending the perceived stigma of recombinant DNA to other techniques.

When the industry amendments were debated in Parliament, a Conservative member argued against the broad definition of GMOs as unnecessary, especially because 'the commercial penalty would be too high a price to pay'. The government acknowledged that the definition of GMOs was wider in the Bill than in the DoE paper, but argued that it exemplified 'the precautionary principle at work, particularly as it seeks to control potentially new risks to our environment'; for example, the definition of the GILSP category might change over time (Hansard, 6 March 1990: 947-49; 2 July: 1954-56).

Key actors mentioned other reasons for the Bill's wide definition of GMOs. For example, 'The UK position to date is that it is better to cast the net too wide at this stage than to be too lax.... [This] indicates the problems that will constantly arise in relation to the role of public

opinion....', according to the chairman of ACRE (Beringer, 1991: 62). According to another ACRE member, the government had included all possible techniques in order to avoid having to explain to the public why any were excluded. Likewise, according to members of ACRE's predecessor committee, there had been reasons of safety and public reassurance for wanting the voluntary regulation to encompass all 'processes which artificially generate genetic novelty', such as inter-species cell fusion (Shackley, 1989: 217). One ecologist member had cited environmental problems even from the products of naturally occurring cell fusion (Williamson, 1988).

Thus, when the statutory definition of 'GMO' went further than prevailing scientific concepts of 'artificial techniques', this wording could find some warrant in ecological concepts of genetic novelty. It also acknowledged the stigma of any process perceived as unnatural.

2.2 Defining environmental damage

During the DoE's consultation period, industry expressed concern that GMO regulation might impose an endless burden of proof, e.g., by requiring applicants to 'eliminate concerns in relation to an open-ended, unsubstantiated series of effects' (BSPB, 1989; cf. ICI Seeds, 1989). Perhaps confirming that apprehension, the published Bill defined environmental damage not only as actual harm, but also as the mere presence of GMOs which are 'capable of causing harm to the living organisms supported by the environment'. Such 'harm' encompassed 'interference with the ecological systems' of which those organisms form a part (HC14: 85; EPA, 1990: 117).

Industry proposed changing this 'emotive and insensitive' wording to denote only actual harm, mainly 'to avoid the premise that damage to the environment necessarily follows from the presence of GMOs' (CBI, 1990). It argued that such an impression of government policy would discourage biotechnology investment in Britain, including foreign investors, who might misinterpret the government's intention.

The government defended the original wording on grounds that the regulation must be 'anticipatory in every respect'. Labour MP Ann Taylor took the argument further by asserting that the burden of proof of safety lies on those who want to use GMOs (Hansard, 6 March 1999: 961-965). By adopting a precautionary definition of environmental damage, the Act potentially imposed such a burden of evidence and provisionally stigmatized GMOs as suspected pollutants.

Indeed, some DoE staff identified with the pollution analogy, in the sense that the introduction of any novel organism can cause environmental perturbations. They sought more ecological

knowledge, so as to set a normal baseline from which one could detect deviations and assess environmental damage. The statutory wording, 'interference with ecological systems', could later be cited to make open-ended requests for evidence of safety.

The broad definition of environmental damage raised the practical problem that it could be construed as prohibiting the use of pesticidal biotechnology products. A Conservative backbencher coined the phrase 'beneficial damage' to denote the intended effect of biopesticides (Hansard, 6 March 1990: 963). In response, the government amended the relevant clause to permit exempting specified effects from the prohibition on environmental damage (EPA, 1990: 117). The additional wording presumed that any effect is harmful unless it is specifically declared not harmful; thus, despite permitting exemptions, the 1990 Act remained precautionary.

2.3 Consents for releases

Under the pre-existing voluntary system, releasers notified the HSE of each proposed GMO release and then reached agreement on appropriate conditions. As an HSE official stated, its notification system had already been operating 'as if it were a consent system' (CBC, 1990: 13). In effect the voluntary system issued negative consents: as the HSE routinely reported, 'there is no objection in principle to the proposed projects [GMO releases] with particular respect to the genetic modifications involved' (e.g., HSE letter to Rothamsted Experimental Station, 26 May 1987).

The 1990 Act formalized that procedure, by establishing positive consents, which accepted state responsibility for the safety of GMO releases. After submitting a risk assessment for the proposed GMO release, a notifier is told if a consent is required. If so, then the consent would specify conditions for the release, such as the experimental design (EPA, 1990: 118-23).

The Green Alliance lobbied Parliament for an amendment requiring a consent for every release, as recommended by the RCEP report and as required by the EC Directive. In the Parliamentary debate, a Labour MP tried to amend the Bill 'so that all work with prohibited organisms would require a consent' (Hansard, 6 March 1990: 986-87); in this argument, the statutory phrase 'prohibited acts' became 'prohibited organisms', thus confirming and formalizing the stigma upon all GMOs. In the House of Lords, a RCEP member supported the amendment by warning that any harm from a GMO release 'could be a recipe for disaster in the future', in terms of public worry (Hansard, 2 July 1990: 1973). The government retained the Bill's original wording, in order to maintain a more 'flexible approach', though the Environment Minister promised that the subsequent regulations would require a consent for every release (Wilkie, 1990).

According to our interviews, industry opposed formalizing such a standard requirement in the 1990 Act itself, because it would block the 'fast track' that they sought to establish eventually for some GMOs. Accommodating that aim, the subsequent regulations provided for a consent to authorize a series of similar releases over several years (DoE/MAFF, 1992).

In the Parliamentary debate, then, the legal requirement for a consent took on symbolic meanings about confirming or overcoming the stigma attached to GMOs. The government was put on the defensive to promise that the regulatory net would in fact catch all releases of 'prohibited organisms'.

2.4 Defining risk and the duty of care

In specifying the duty of care, the Bill defined 'risk' in a contentious way. Its wording prohibited a range of activities with GMOs if 'there is a risk of damage to the environment' (HC14: 89; EPA, 1990: 120). In an interview, an industry lobbyist criticized that phrase for compelling applicants to claim that a proposed release is safer than the available information may warrant. Industry proposed that the legislation instead prohibit 'an unacceptable' or 'an unreasonable' risk, arguing that all activities entail risks, and that any low risks could be balanced with large benefits from biotechnology products (CBI, 1990; CIA, 1990).

In the House of Lords, a Conservative Peer argued for the industry amendment as follows: 'The balance of advantage [benefit] over risk calls for very nice judgement. We ought not to make that nice judgement impossible by putting an unqualified ban on whatever may contain [entail] an aspect of risk.' Evading that argument, the government emphasized the need 'to eliminate the risk to the point where it becomes too trivial to warrant further action' (Hansard, 2 July 1990: 1981-82).

Thus the government reply justified the original wording as permitting only a *de minimis* risk, as well as overcoming any stigma of special risk from GMOs. In any case, the DoE's lawyers had recommended wording the Act to prohibit 'a risk', rather than 'an unacceptable risk' -- lest the government find itself on weak grounds whenever taking an offender to court. However, even the most stringent language could not clarify what 'risk' is being prohibited, relative to what baseline of normality.

Specifying the duty of care for GMO releases, both the EC Directive and DoE paper had required taking 'reasonably practicable measures' to avoid environmental risks. Similarly, the published Bill required releasers to 'take all reasonable steps' to know what are the risks and to take any appropriate precautions. But it also required releasers to use BATNEEC, 'the best

available technique not entailing excessive cost', except where the release is 'the subject of conditions attached to the consent'; in such cases, those conditions were to supersede BATNEEC (HC14: 89).

In the Parliamentary debate, disputes arose over the relevance of BATNEEC. The Opposition put forward an amendment to delete the BATNEEC provision for all GMO releases, in order to 'impose the duty of care, regardless of cost, on those who choose to release manipulated organisms' (Hansard, 6 March 1990: 988-89). The Opposition also suspected that the BATNEEC criterion might be cited retrospectively, to limit the releaser's legal liability for environmental damage (Hansard, 30 April 1990: 816).

The government did change the Bill's wording, but in the opposite direction to that demanded by the Opposition: the final Act applied BATNEEC to all GMO releases, including those subject to a consent (EPA, 1990: 123). Here the government emphasized the 'best available technique', thus rhetorically strengthening the duty of care and implying a more stringent meaning of BATNEEC.

What was its precautionary content? According to my interviews, regulatory actors held quite different views on how the BATNEEC principle might influence cost considerations, and the experimental design of GMO releases. For example, BATNEEC could mean tightly containing a release and/or carefully monitoring a less contained release, in order to obtain data relevant to the risk-assessment of subsequent ones (Levidow and Tait, 1992: 101). These ambiguities arose from the problem of legislating against unidentified hazards, prior to any consensus on what standard precautions might avoid or even detect them.

2.5 Liability for environmental damage

The government rejected environmentalists' demands to impose strict liability upon GMO releases, but the 1990 Act did establish two kinds of liability. First, the government could prosecute anyone for violating the regulatory procedures -- in which case the defendant would hold the burden of proof for compliance with the consent procedure and terms, in addition to compliance with the BATNEEC criterion, imposed on all GMO activities. Second, if a violation has resulted in environmental damage, then the releaser could be ordered to take remedial steps or to reimburse the government for doing so (EPA, 1990: 127-31).

With a series of 'probing amendments' -- none of them adopted -- the Opposition argued for strengthening liability. A releaser convicted of an offence and causing environmental damage should be liable under legal action initiated by a third party, not just by the government. Moreover, there should be strict liability for any damage -- that is, regardless of whether the

releaser violated any regulatory procedures; thus the releaser would have to prove non-negligence, rather than the plaintiff bearing the burden of proof. There were also calls for mandatory insurance to cover any such damage. As Ann Taylor MP argued, 'Opposition Members believe that the polluter should pay, though that is a somewhat simplistic principle when applied to genetically modified organisms' (Hansard, 6 March 1990: 993). In effect, her proposal was treating any GMO release as an exceptional or abnormal act (Levidow and Tait, 1992: 102).

Parallel with the 1990 Act, British case law could also consider GMO releases as subject to civil liability, which covers only damage to persons or their property. The government suggested that such case law would impose strict liability upon a GMO if there is some 'special use' entailing increased danger. Extending that argument, Lord Clinton-Davis noted that the RCEP considered any use of a GMO as 'potentially at least a special use which can bring substantial consequential risks'. For the purpose of liability, he asked, which types of GMO use should be considered special? (Hansard, 15 October 1990: 704).

There were sharply divergent views about liability, in written submissions and in my interviews. Linking this issue to the others discussed above, advocates of strict liability cited special risks of GMO releases, as well as special fears that might make them publicly unacceptable in the absence of such liability. There were also concerns about how to correlate any damage with a particular release; it was proposed to require incorporation of a unique genetic labelling sequence into all GMOs designed for release.

Industry felt that the published Bill adequately provided that all applicants would bear the regulatory costs of avoiding environmental damage, but it resented mention of the 'polluter pays' principle: after all, 'no pollution is involved' in GMO releases. Moreover, strict liability would present great difficulties for insurance premiums -- perhaps very expensive or even incalculable; for example, one company doubted that releasers would be able to obtain 'insurance cover against "unspecified risks to the environment"'. On the other side, public-interest groups doubted that a releaser would have the technical or financial capacity to remedy any damage. Yet strict liability might once again equate GMOs with pollution. Like other features of the 1990 Act, the liability issue illustrates dilemmas inherent in precautionary regulation of GMO releases.

2.6 Public information registers

The published Bill included no provision for information disclosure; the government undertook to satisfy such requirements of the EC Directive in the subsequent regulations. However, Opposition MPs and Lords pressed for a statutory provision, as the Environmental

Protection Bill had done for water pollution, and as the RCEP had recommended. One RCEP member warned that the potential benefits of GMOs may be 'frustrated by public opposition motivated by fear of the unknown unless that information is available' (Hansard, 18 May 1990: 538).

Opposition demands found backing in the national press, especially the *New Scientist*, whose articles deployed pollution analogies. Science journalists posed the question of 'why these organisms are being treated differently from other risks' (Watts, 1990). This was an 'anomaly' because the Bill included 'major concessions for other aspects of pollution' -- e.g., rivers -- but yet allowed 'secrecy' for GMOs (Milne and Watts, 1990).

At the final stage of the Bill's passage, the government conceded by introducing two new clauses on public registers of information. The first one incorporated the minimum requirements of the EC Directive (EEC, 1990: 20). However, contrary to the Directive, the second amendment permitted any detail to be excluded on three different grounds -- commercial confidentiality, potential environmental damage, and national security (EPA, 1990: 131-32); the first two grounds accommodated industry demands. Let us consider each exclusion in turn.

** *Commercial confidentiality*: Many participants regarded the method of gene insertion, the 'precise genetic construct', as the most confidential information. However, some public-interest groups considered such knowledge about the genetic modification process as essential for judging safety. Some industrialists privately acknowledged that this information would no longer be a trade secret by the time a GMO reached the stage of trial release. Moreover, as ACRE members, potential competitors had full access to release applications (see Chapter 6). Thus 'commercial confidentiality' could serve as a pretext for restricting substantive access to the risk-assessment procedure; on the other hand, such secrecy could aggravate the stigma of GMOs as suspected pollutants.

** *Environmental damage*: This referred to the prospect of politically motivated vandalism, where disruption of physical containment could mean 'damaging the environment' (Hansard, 30 October 1990: 901). The 1990 Act permitted withholding the site on these grounds. Yet such secrecy could stigmatize the GMO as hazardous.

** *National security*: Presumably this referred to biological warfare, an area where the putative distinction between offensive and defensive research has been contentious (Wright, 1990). As a science journalist noted, 'The national security clause is bound to encourage the belief that germ warfare products are being tested on an unsuspecting public, scarcely the

image the biotechnology industry wants to project' (Ince, 1992). Thus, even if this exemption were never implemented, it stigmatizes GMOs in general.

With the statutory register of information, the British government extended a general tendency to establish licencing systems which can authorize and justify hazardous activities. That is, wherever they grant licences with specific conditions, regulatory agencies are expected to explain the rationale behind decisions and to explain it to a wider audience than previously (Macrory, 1986: 68). In this vein, the government conceded to demands for guaranteed information disclosure on GMO releases. The broad statutory grounds for withholding information, however, illustrated pervasive dilemmas: how to handle the stigma of GMOs, and how to use information disclosure for minimizing public conflict.

3.0 LIMITS OF REGULATION

As described above, disputes over the technical-legal language remained formally within the 'risk' problem of preventing physically measurable harm from GMOs or their inserted genes. This scenario excluded broader accounts of the environmental issues, as manifest in public debate (see Chapter 3). For this reason, some pressure groups sought a Public Biotechnology (or Ethics) Commission in order to assess GMO products in terms of environmental benefit and/or socio-economic need.

This proposal met mixed responses. Some regulatory advisors saw such a body as helpful for clarifying policy issues outside ACRE's remit, or even controversial definitions of environmental harm relevant to the risk assessment itself. Other advisors doubted whether it could reconcile the different viewpoints being represented. Industrialists felt apprehensive about any Public Biotechnology Commission, though more amenable to an Ethics Commission -- perhaps because its remit could separate ethical from environmental issues, which could then remain the preserve of technical experts.

In the Parliamentary debate, Opposition MPs supported creating a public body additional to ACRE. As Bryan Gould argued,

> 'We can easily imagine the impact that GMOs might have in the hands of self-centred, multinational companies with laser-beam objectives... It calls into play the increasingly familiar worries about the moral propriety of mankind playing God... some people will be able to manipulate life for their own specific purposes' (Hansard, 6 March 1990: 952-53).

Another warned about 'some people latching on to the idea that we can fix the environment and that GMOs could solve our problems' (ibid.: 956). A colleague argued that the proposed Commission would provide reassurance for the public about 'over-commercial objectives and

over-rapid development' (ibid.: 977). Thus its proponents reconnected ethical, environmental and strategic R&D issues.

The government rejected the proposed Commission, with three main arguments. First, it would create 'a quango-like body interfering with the actions of the Secretary of State, who is answerable to Parliament and the people' (ibid.: 977). Second, it would obstruct technological advance and thus socio-economic progress (ibid: 955). Third, any environmental assessment remained separable from ethical questions; as the Environment Minister acknowledged, he took for granted 'separating ethics from the environment, and the environment from patents' (ibid.: 971).

In a subsequent round of debate, the Opposition challenged those separations by emphasizing 'the environmental impact of plants which have been manipulated to be resistant to herbicides, allowing broader application of those herbicides'. The government replied by exaggerating the remit of its scientific advisory committees: for example, 'the committee will be able to advise on pesticide development' (Hansard, 16 October 1990: 699-702). As ACRE later learned, that remit turned out to mean advising on GMO biopesticides, rather than the herbicide implications which were raised raised in public debate.

Thus the government devised several ways of handling environmental concerns which ran beyond ACRE's remit and perhaps beyond government regulation. It rhetorically stretched that remit, while appealing to ACRE's moral authority. It also relegated wider environmental concerns to some vague realm of 'ethics', as distinct from a testable realm of 'product safety', whose regulation might legitimize an otherwise contentious development. At issue here was not simply acceptable risk, but acceptable strategic purposes and forms of environmental control. (See also discussion of the Fourth Hurdle in Chapter 9, section 1.1.)

4.0 CONCLUSION: STATUTORY DILEMMAS

Britain adopted new legislation designed to provide a legitimate safety imprimatur for GMO releases. Previously GMO releases came under a voluntary system operated by the HSE, which saw no scientific basis for regulating them separately. Unlike the HSE, the DoE now articulated an explicitly precautionary rationale for doing so.

The new process-based legislation incorporated the dual aims of anticipating hazards and public unease about them; these aspects were not clearly separable, given that regulatory actors could cite divergent scientific accounts of plausible hazards. For its dual anticipatory

role, new legislation gave the DoE broad enabling powers, within which it could negotiate appropriate controls, case by case.

In particular, the 1990 Environmental Protection Act authorized the state to specify and enforce conditions for each GMO release, while flexibly allowing for different levels of control. Industry regarded such a licensing system as essential, both for restricting access to the 'club' of GMO releasers and for making their activities publicly acceptable. Although wary of extra regulatory costs, it regarded these as a necessary investment in political stability, as the government had argued.

Although biotechnology regulators claimed to base their policy upon 'sound science', its usual meaning was now altered, by shifting the burden of evidence onto the applicant. This shift was backed up by a stringent technical-legal language, which went beyond even the precautionary features of the EC Deliberate Release Directive. For example, the British law adopted an even broader process-based definition of GMOs, prohibited any release entailing 'a risk', and defined environmental damage as the mere presence of organisms 'capable of' causing it. The government defended this language as essential features of a precautionary approach.

Industry attacked the statutory language -- on grounds that it encompassed naturally occurring mutations, lacked any scientific basis, stigmatized GMOs as pollutants, and might require proof of zero risk for a range of unspecified hazards. This conflict arose partly from difficulties in legislating against hypothetical hazards, prior to any agreed risk-assessment method or cause-effect model of potential harm. The conflict also arose from industry fears that the DoE would jeopardize the consultative relation which biotechnologists had developed with the HSE, as in other regulatory areas (e.g. Weale, 1992: 104).

The statutory duty of care imposed the BATNEEC criterion, 'best available technology not entailing excessive cost'. As developed within pollution control, this criterion meant an explicit trade-off between cost and risk reduction, for example, by imposing costs to force technological improvements (O'Riordan, 1989; RCEP, 1988: 6). BATNEEC had a more ambiguous meaning when extended to GMO regulation, which lacked any agreed basis for deciding what hypothetical hazards warrant preventive measures, much less how to prevent them. At the same time, by making assumptions explicit, the BATNEEC criterion potentially offered an opportunity for public participation, especially if coupled with information disclosure.

Some aspects of the 1990 Act exemplify a more widespread tension, such as in regulating pollution or hazardous chemicals. Intended to facilitate long-term investment decisions, licencing systems attempt to provide clear safety standards, yet they do so by adopting a standard scientific language to encompass diverse types of pollution hazards (O'Riordan and Wynne, 1987: 394). This technical-legal integration often results in legal texts 'where the language employed appears to be scientific terminology but which in fact compromises to a significant degree the scientific approach' (Macrory, 1986: 70). For pollution or chemical hazards, symbolic language conveys an omniscient control, thus concealing or even denying the practical, case-by-case complexities of risk management.

In the case of GMO releases, Britain's new legislation likewise carried a symbolic language of safe control, yet its terms undermined the usual regulatory pretence of following 'the scientific approach'. In other areas, British regulators have negotiated appropriate controls, flexibly and discreetly, thus keeping the scientific basis implicit and apparently neutral (Jasanoff, 1986: 28-32, 80-81). For GMO releases, however, legislation adopted a broad technical-legal language which could encompass all hypothetical hazards, authorize regulators to request more evidence of safety, and hold releasers liable for any damage. This precautionary framework strained the 'rational' British image of science-based regulation; indeed, it implicitly acknowledged ignorance about cause-effect models of harm, even stigmatizing GMOs as suspected pollutants.

There was a related problem in defining legal liability: the government rejected proposals to impose strict liability, which might have resulted in incalculably high insurance premiums and conferred greater stigma upon GMOs. On the one hand, the 1990 Act authorized penalties only against GMO releasers who violate safety procedures, and authorized the state to remedy damage resulting from such violations; the state would act as a last-resort insurer, as in other industrial sectors (Lowi, 1990: 30). On the other hand, the 1990 Act allowed releasers to avoid liability for damage by demonstrating that they had complied with the duty of care, i.e. with all written conditions and the BATNEEC criterion; in this respect, the law might protect activities which turn out to cause harm (as in earlier pollution cases, e.g. Macrory, 1983: 161-62).

By imposing only limited liability for environmental damage, the 1990 Act left biotechnology more vulnerable to public suspicion of incalculable risks, as some government advisors had warned. Not only accidents, but even the suspicion of them, can undermine the regulatory facade of security. Historically, insurance measures have provided a consensual 'social compact against industrially produced hazards and damages', yet such measures can less credibly accommodate the incalculable risks of nuclear power, chemical industry and

biotechnology -- technologies which 'have suspended the principle of insurance' (Beck, 1992b: 100-105). In this regard, the 1990 Act had a limited capacity for legitimizing biotechnology: it authorized stringent government controls to prevent and even remedy harm from GMO releases, yet it limited legal liability to foreseeable harm.

Further limits to legitimacy were manifest in Parliamentary debate over how broadly to define the environmental issues. The precautionary remit of the 1990 Act was designed to anticipate how GMOs might cause physically measurable harm, but not how their use might aggravate systemic agricultural hazards. The latter concern partly motivated calls to establish a Public Biotechnology Commission, yet the British government rejected this proposal by simply equating technological advance with socio-economic progress.

This government stance made explicit the working assumption which underlay the procedural rationality of safety regulation. That is, it treated biotechnological 'risk' as a scientifically testable property of organisms, analytically separable from the benign environmental control provided by biotechnology. Thus, as the Parliamentary debate revealed, safety regulation had the problematic role of substituting for any consensus on 'progress', which normally gets defined by a private sub-politics, beyond state control (Beck, 1992a: 209).

Chapter 6

BRITAIN'S ADVISORY COMMITTEE

Incorporating the EC Deliberate Release Directive into British law, the Department of the Environment oversaw enactment of process-based legislation, as the Environmental Protection Act Part VI. In parallel, the government established the Advisory Committee on Releases to the Environment (ACRE). This move focused arguments on the appropriate administrative control and scientific rationale for regulating GMO releases.

How did the government designate the 'competent authority' for GMO regulation? How did it set ACRE's remit and composition? How did it define the relevant expertise for risk assessment? How was ACRE structured to handle underlying value conflicts? How did these changes relate to Britain's consultative style of safety regulation?

This chapter analyses how ACRE was constituted; it sets the stage for analysing ACRE's operation in subsequent chapters. This one discusses, in turn:

* ACRE's origins within the pre-existing regulatory system (section 1);
* ACRE's combined remit for both GMOs and non-indigenous organisms (section 2);
* ACRE's composition, representing diverse perspectives and interests (section 3); and
* tensions around ACRE's role (section 4).

Note: This chapter is developed from a paper which contains more detail on certain aspects, especially on ACRE's precursors and its statutory basis (Levidow and Tait, 1993: 195-98).

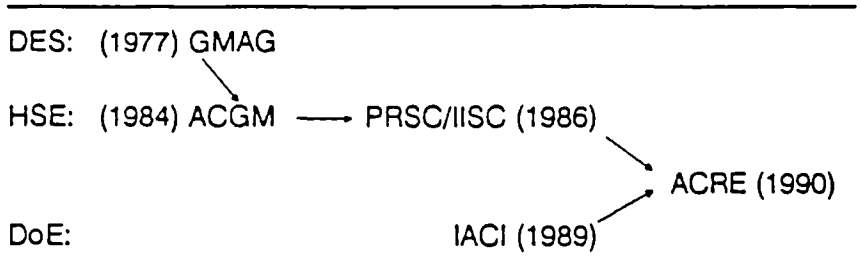
1.0 ACRE'S ORIGINS

A series of advisory committees has accompanied the transition from the contained use to the intentional release of GMOs (see Table 6.1). In the mid-1970s, concerns focused upon hypothetical health hazards from the laboratory process of genetic modification and the resulting organisms, particularly any escapes from the laboratory. For regulating the laboratory experiments, in 1977 the UK government established the Genetic Manipulation Advisory Group (GMAG), attached to the Department of Education and Science (DES). In constituting GMAG, the government faced some conflict between public concerns over

R&D priorities and the committee's limited terms of reference (Levidow and Tait, 1993: 195).

When GMAG was replaced in 1984 by the Advisory Committee on Genetic Manipulation (ACGM), the change signalled that public unease had subsided over GMOs in contained use. They were expected to enter large-scale industrial production; genetic manipulation would now be treated as a routine aspect of human health and safety, for which the Department of Employment, particularly the Health and Safety Executive (HSE), had statutory responsibility under the Health and Safety at Work etc. Act (HSWA) 1974. Within the standard tripartite structure of HSE committees, the TUC enlarged its representation on the ACGM but lost the argument for the new committee's remit to include ethical issues, which in any case lay beyond the terms of the HSWA 1974.

Table 6.1: ACRE's ORIGINS



Key to abbreviations (in alphabetical order)

ACGM:	Advisory Committee on Genetic Manipulation
ACRE:	Advisory Committee on Releases to the Environment
DES:	Department of Education and Science
DoE:	Department of the Environment
GMAG:	Genetic Manipulation Advisory Group
HSE:	Health and Safety Executive
IACI:	Interim Advisory Committee on Introductions
IISC:	International Introductions Sub-Committee
PRSC:	Planned Release Sub-Committee

1.1 Release committees

In 1986 the ACGM set up a subcommittee anticipating a new stage, the intentional release of GMOs, even before that prospect had generated much public concern in Britain. Initially named the Planned Release Sub-Committee, it was soon renamed the Intentional Introductions Sub-Committee (IISC). Subsidiary to the ACGM, operating within the HSE, the IISC followed the tripartite model of health & safety committees. Its 'specialist members' included a CBI nominee, a TUC nominee, and scientific experts drawn from academia and government-run research bodies. IISC included representatives from other government-funded bodies, such as the Nature Conservancy Council and the Association of Metropolitan Authorities; the latter was represented by an Environmental Health Officer.

Even in the case of TUC and CBI nominees, IISC members were appointed for their individual expertise, though this was flexibly defined. Worker safety has been the ostensible rationale for trade-union involvement in HSE committees, yet little concern was expressed about GMO releases posing health hazards, except for allergenic reactions to pollen. Some committee members informally described the TUC nominees on the ACGM and IISC as the 'public-interest' side. As an HSE official stated in retrospect, the HSE didn't think about getting representation from 'public-interest groups' on IISC, because the TUC played that role by representing workers (interview, 26 September 1991).

In addition to the 'specialist members', the committee included representatives of relevant departments, mainly the HSE, DoE, MAFF, DTI and DHSS. Previously such individuals had attended ACGM meetings; now their role was formalized as 'assessors' on IISC. The assessors did not officially shape the committee's advice but could influence their department's policy. Formally speaking, the HSE secretariat channeled the IISC's advice through the ACGM to the Employment Minister, though ACGM rarely discussed the advice in detail.

By the late 1980s, various pressures were mounting to broaden the IISC's composition. According to another study, most members thought the committee had sufficient ecological expertise, even though only two or three members were considered 'card-carrying' ecologists; one regarded himself as 'the only cautious ecologist' who regularly attended IISC meetings. Interested organizations outside the committee proposed that its ecological component be expanded, and that the DoE become the lead agency for

regulating GMO releases, so as to safeguard environmental concerns (Shackley, 1988: 79-81; 1989: 214).

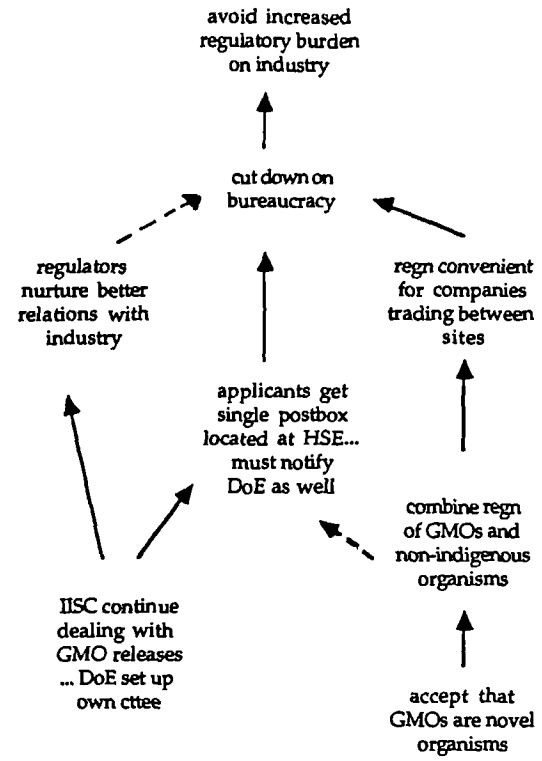
By 1989 the DoE was receiving advice on the same GMO release applications from a temporary DoE committee, the Interim Advisory Committee on Introductions (IACI), whose membership included several ecologists. Set up in 1989, that committee also advised the DoE on proposals to introduce non-indigenous organisms, for which the DoE had statutory responsibility under the Wildlife and Countryside Act 1981. For GMO regulation, the DoE had only an indirect role.

ACRE was now separated from its original parent body, the ACGM. The new committee assumed responsibility for advising on proposed releases of both GMOs and non-indigenous organisms. In this way, ACRE replaced both the IISC and IACI, respectively.

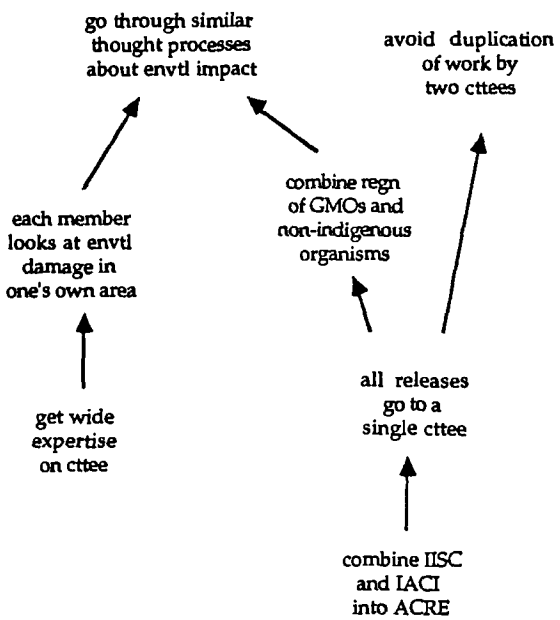
1.2 ACRE's Joint Secretariat (HSE/DoE)

In April 1990, the government created a new committee, ACRE, in parallel with statutory regulation of GMO releases. ACRE was constituted by combining all key features of its predecessor committees: that is, both the HSE and DoE; both human and environmental safety; and both GMOs and non-indigenous organisms, thus replacing both the IISC and IACI (see Table 6.1). How to involve their former host departments, the HSE and DoE, was an awkward political question, whose answer -- a Joint Secretariat -- found a scientific rationale.

During the regulatory transition period, the DoE proposed that the government continue 'the present arrangements which channel the advice on genetic manipulation... through a single committee (ACGM)'; it implied that the Environment Minister should take over full responsibility for regulating GMO releases (DoE, 1989: 8, 10). Meanwhile the Royal Commission on Environmental Pollution recommended that the advisory committee should be 'constituted as a committee in its own right', linked to the ACGM through an overlapping membership and joint secretariat, and replacing both the IISC and IACI (RCEP, 1989: 59-61). Similar proposals arose in various submissions replying to the 1989 DoE consultation paper.



Map 6.1: Officer of industry interest group (individual code I1, same as for Map 6.5)



Map 6.2: CBI nominee on ACRE (individual code C3, same as for Map 6.6)

Eventually the government clarified the arrangements for the new committee: ACRE was to be located in the HSE, financed by the DoE, and handled by a Joint Secretariat involving both departments. Most importantly, the Environment Minister would take all decisions; in a slip of the tongue, the government speaker clarified that the Department of Employment 'will have no direct responsibility for any releases of pollution into the environment' (Hansard, 6 March 1990: 996).

Industry had preferred to keep the relevant committee within the HSE. In interviews, one industrialist complained that the DoE had neglected to consult industry before setting up the IACI, which included no industry representatives; he was concerned to avoid any difficulties with the DoE. Consequently (see Map 6.1, left-hand side), he preferred that the 'IISC continue dealing with GMO releases, operating within the HSE, rather than have the DoE set up its own committee for GMOs'; that way, applicants would 'get a single post box located within the HSE, rather than have to notify the DoE as well'. (For a guide to the cognitive maps, see Chapter 2, section 5.)

This industrialist also expected that 'regulators would nurture a better rapport with industry' through the HSE, than through the DoE. That preference reflected the comfortable working relationship that applicants had developed with the IISC and the HSE through the experience of voluntary regulation. Industry's concern about the DoE's expertise, much more than a technical matter, implied misgivings about the DoE's environmental perspective.

An industry lobbyist (individual code I2) gave similar reasons. In an HSE-based committee, moreover, 'members would have a background in genetic modification from the ACGM', in contrast to a DoE committee; thus ACRE would have adequate expertise to 'reject any release lacking sufficient control to prevent a gene from escaping'. In the name of careful safety precautions, this rationale privileged laboratory-based over ecological expertise. In preferring the HSE over the DoE, industrialists cited ostensibly scientific reasons which narrowly defined the risk problem.

A related issue was whether to combine the environmental and health aspects. During 1989 civil servants were discussing proposals to separate them. That is, the DoE's IACI would expand its role by taking on all the environmental considerations for GMO releases, as well as for non-indigenous organisms. Meanwhile the HSE's IISC would consider only the human health aspects (DoE interview, 15 February 1990).

Ultimately, the government favoured minimizing the number of committees, partly for administrative convenience, as did industry (see Maps 6.1 and 6.2). In this vein, the Health & Safety Commission advocated combining consideration of human health and environmental safety: to separate them 'would be unacceptable to industry and inefficient in terms of the machinery of goverment' (HSC, 1989) -- even though these aspects were in fact separated in other regulatory areas. As a scientific rationale, an HSE official later reflected, 'We recognized that there are environmental considerations in contained use, and they [DoE] recognized that there are health and safety implications in releases' (interview, 26 September 1991).

Underlying that issue was a more substantive one: which Minister would grant consents for GMO releases. 'We suggest that the authority co-ordinating these administrative aspects should be the HSE, which is already running the existing notification system', argued the Health and Safety Commission (HSC, 1989). Perhaps as a compromise, it suggested forming an HSE/DoE Joint Secretariat, which was needed 'to publicly signal the involvement of the DoE in these structures and the responsibility of their Minister' (HSC, 1989).

However, other advisors regarded the DoE's leading role as essential for fulfilling the perceptual and safety aims of precautionary regulation. The DoE's symbolic importance was emphasized by the chair of IISC (and subsequently of ACRE), John Beringer, in his commentary on the 1989 DoE consultation paper: 'it is important for the "Department of the Environment" to be seen to be concerned about the Environment'. In an interview, an RCEP member likewise remarked that the Environment Minister must be made responsible for GMO releases, in order for the regulatory system to have public credibility.

By designating the DoE as the responsible authority, within a Joint Secretariat for ACRE, the government could fulfill several aims: it provided continuity with the IISC and HSE, enhanced the DoE's role, combined environmental with human health considerations, and gave applicants a 'single postbox'. ACRE provided a framework for reconciling the different perspectives of the HSE and DoE, for accommodating public and industry concerns, and for negotiating any conflicts within confidential procedures. This move had a scientific rationale which could also serve as an *ex-post* justification for an administrative compromise.

2.0 GMOs AS 'NOVEL ORGANISMS'

When the formation of ACRE was announced in April 1990, the committee's remit was defined as follows: 'to advise on all aspects of the human and environmental health and safety of the introduction into the UK environment of genetically modified and other novel organisms; and in particular to advise on proposals for specific introductions, on research needs, and on proposed regulations and written guidance' (DoE/HSE, 1990). Each of those aspects provided opportunities for the committee to develop a precautionary approach. Its content was both justified and circumscribed by the key term, 'other novel organisms', which implied a naturalistic framework for the risk problem, somewhat abstracted from intensive monoculture.

In particular, 'novel organisms' lent support to the analogy between releasing GMOs and introducing non-indigenous organisms into Britain. Similarly, ACRE's parent committee had noted that 'the deliberate release of novel types to foreign habitats could occasionally disturb the natural equilibrium of those habitats' (ACGM/HSE, 1990: 5). A DoE official later made the analogy more explicit: 'Since a GMO is regarded as a "novel" organism, parallels have sometimes been drawn with the introduction of non-indigenous or exotic organisms into the environment, some of which have caused harm to the environment in the past' (Smith, 1992: 9).

Although the government was not officially classifying GMOs as 'novel organisms', there was wide agreement upon initially regulating their intentional release as if they were such. Here the novelty denoted new genetic combinations which were made possible by the genetic modification process. On this rationale, the regulatory procedure would require similar scientific expertise for assessing both GMOs and non-indigenous organisms proposed for release.

Industry welcomed the combined remit for ACRE. As one CBI nominee on ACRE stated (see Map 6.2, right-hand side), the government should combine the existing committees and their remits in order to 'go through similar thought processes about potential environmental impact' for both types of organism. Provisionally accommodating the analogy, (Map 6.1, right-hand side), industry should 'accept that GMOs are novel organisms', so that government can 'combine regulation of GMOs with non-indigenous organisms', so that industry would obtain a 'regulation convenient for companies trading between sites', as well as the advantages of dealing with the HSE for both categories. Through such means, this industrialist sought ultimately to 'cut down on bureaucracy' and

'avoid an increased regulatory burden' on industry. Similarly, an industry lobbyist (I2) favoured a combined remit, preferably within the HSE; otherwise the industry would face regulatory 'chaos'.

Moreover, by citing the analogy to non-indigenous organisms, regulators could more readily justify process-based GMO regulation in scientific terms. For example, a TUC representative on ACRE spoke for many other members when he later wrote,

> There is no inherent danger in an organism produced by genetic modification, or any other technique which changes the genetic material. There may be a danger associated with the introduction of an alien organism into a new environment (Kinderlerer, 1992: 23).

In this sense, he regarded a process-based approach as warranted only insofar as the genetic modification process might turn familiar organisms into 'alien' ones.

Similarly, as ACRE members stated in my research interviews, they saw a scientific basis for imposing a special regulatory procedure -- not for GMOs as such, but for genetic novelty, regardless of its source, whether genetically modified or non-indigenous. ACRE's combined remit for both kinds of 'novel organisms' provided, in their view, a better scientific rationale for the committee's existence than would regulating GMOs alone. For them, the process of genetic modification served as a signal for genetic novelty, and thus for ecological uncertainty, not for any inherent hazards from the process as such.

For the DoE, the genetic novelty of GMOs warranted imposing additional regulation, for reasons manifest in the published risk-assessment criteria: reproduction methods, host range, etc. (ACGM/HSE, 1986). In their view, any genetic change could generate an ecological perturbation, which regulators must try to anticipate. Ecologist members and some DoE staff particularly favoured ACRE's combined remit for 'novel organisms' because it would facilitate scrutinizing GMOs for enhanced selective advantage, a problem already manifest by some non-indigenous organisms introduced into Britain.

By treating GMOs as 'novel organisms', the DoE could cite potential weediness as a relevant, documented phenomenon for that overall category of organisms; thus the regulatory system could describe itself as preventing familiar as well as novel hazards. With that analogy to documented hazards of non-indigenous organisms, the DoE could better justify its precautionary approach, which nevertheless was anticipating hazards not already documented for GMOs. Such anticipation, seeking evidence of safety, might be more difficult to justify in terms of scientific rationality.

Like the DoE, the HSE also favoured replacing two committees with one, but mainly for administrative reasons, not particularly in order to combine GMOs with non-indigenous organisms. The combined remit 'was nothing to do with us', stated an HSE official (interview, 26 September 1991). Nor could the HSE easily imagine the analogy to non-indigenous organisms being confirmed, especially for plant crops. With its statutory responsibility for human health, the HSE was most concerned to scrutinize genetically modified vaccines based on live viruses, perhaps shortly to be tested on people. For such vaccines, however, the HSE could not imagine an analogy with non-indigenous organisms.

Industry accepted the conceptual similarity between GMOs and non-indigenous organisms, but did so in order ultimately to prove their dissimilarity. In the present political climate, 'You can't really get away from the fact that GMOs are novel organisms', acknowledged one industrialist (code I1). While regretting the stigma thereby attached, industry expected the case-by-case assessment procedure would eventually remove the stigma: according to a CBI nominee (C1) on ACRE, the procedure would exonerate GMOs derived from familiar crops, while confirming that the special risk assessment is warranted mainly for non-indigenous organisms. At a symbolic level, the hypothetical analogy acknowledged the stigma associated with GMOs, in a way which could overcome it; given the spectre of GMOs running out of control, the regulatory procedure could translate this into scientific terms.

In this way, ACRE's combined remit could provisionally reconcile process-based regulation with its industry critics. This remit accommodated conflicting views, regarding whether or why GMO regulation was scientifically warranted. These conflicts could now be negotiated within a common framework for risk assessment of 'novel organisms'; thus a hypothetical scientific analogy served to avoid a political-administrative impasse.

3.0 ACRE's COMPOSITION

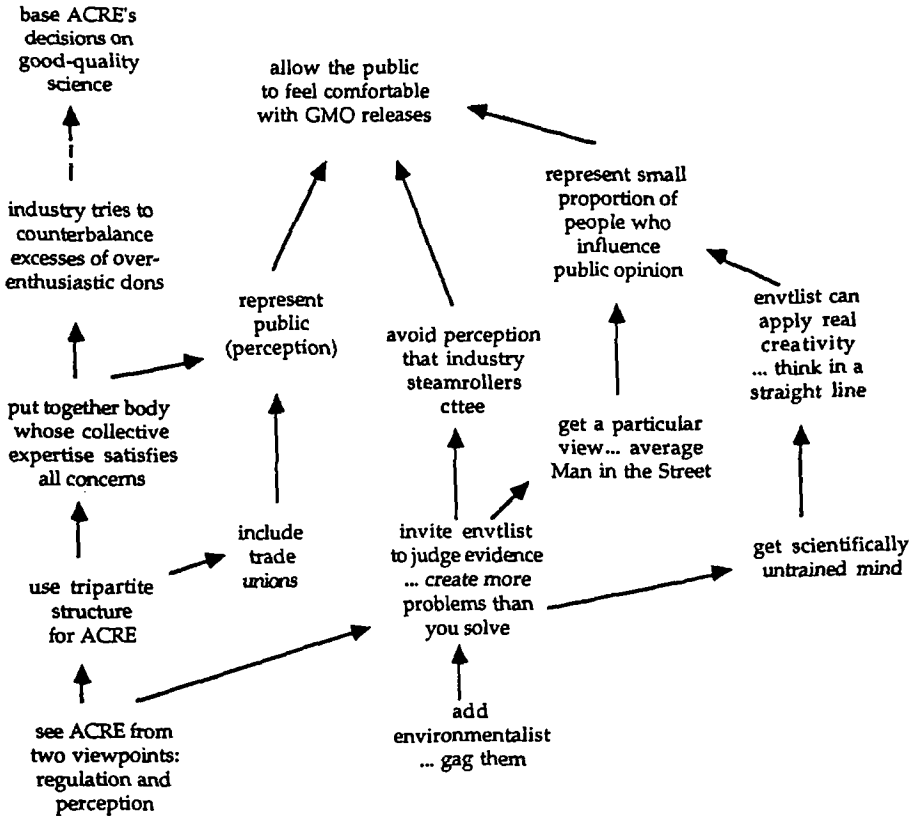
During the Parliamentary debate on the Environmental Protection Bill, Part VI, the government came under pressure to demonstrate the independence of safety regulation from commercial pressures. In response, it repeatedly cited the high reputation of its advisory committee; this claim partly explains why the government ultimately amended the Bill to make the committee statutory (Levidow and Tait, 1993: 198). For similar reasons of legitimacy, the government gave ACRE a broad composition; it sought a membership which would incorporate public concerns yet achieve an apparent consensus, thus protecting the neutral image of regulatory science. Constituted with these aims, ACRE embodied an inherent tension between its expert basis and its implicitly social remit.

In numerical terms, ACRE's membership totaled 22, as compared to the IISC's 13, apart from the officials representing various government departments (see Levidow and Tait, 1993: 202). Expanding on the HSE tripartite structure, the Joint Secretariat increased the number of ecologists, and increased the CBI and TUC nominees from one to three each. Two of the latter had no specific scientific expertise, as was the case for two other appointees -- a 'farmer' and an 'environmentalist'. This meant stretching the 'expert' category beyond scientific disciplines.

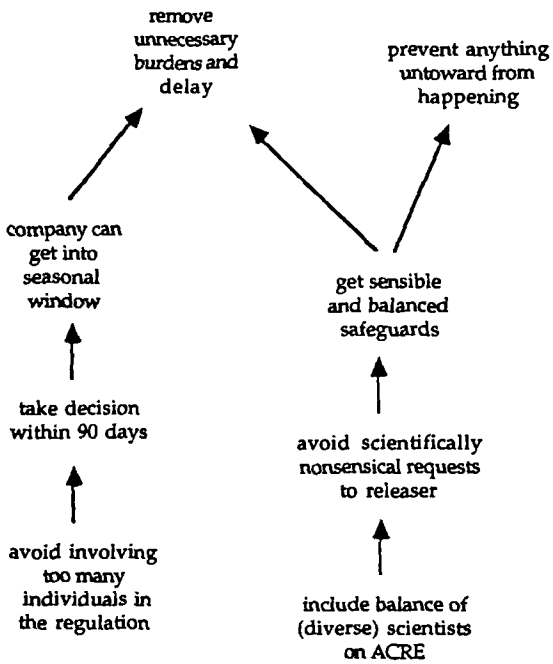
3.1 Scientific expertise

In terms of scientists, ACRE's composition included more ecologists and a lower proportion of members engaged in genetic modification work, as compared to IISC. ACRE included some ex-members of IACI, the DoE committee which had considered mainly non-indigenous organisms. By adding expertise in plant agronomy and ecology (including population biology, population genetics and virology), the DoE was responding to the increased number of plant GMOs being released.

The ecologists' role was enhanced amidst an international controversy on hypothetical hazards, with conflicting risk perceptions among scientific disciplines (see Chapter 1, section 1.2; Chapter 4, section 1.2). In this context, ACRE's broad composition could better explore ecological uncertainties and legitimize regulatory decisions. As one ecologist member noted, 'We are here' as a result of government sensitivity to public unease about GMO releases (interview, 26 June 1991). For similar reasons of public perception, industry too had advocated adding 'independent environmental scientists', in commenting on the 1989 DoE consultation paper.



Map 6.3: Officer of industry interest group (individual code I3)



Map 6.4: CBI nominee on ACRE (individual code C2)

Yet industry also sought a diverse expertise as a safeguard against unreasonable requests. According to one industrialist, 'the regulation should be run by non-industry people who understand industry'. As shown in the cognitive map (see Map 6.3, left-hand side), the government should 'use a tripartite structure for ACRE', including ecologists, so as to 'put together a body whose collective expertise satisfies all concerns', within which industry could 'try to counterbalance the excesses of over-enthusiastic dons', presumably meaning over-regulation. Such a balanced composition would help to 'base ACRE's decisions upon good-quality science'.

Likewise, according to a CBI nominee on ACRE (see Map 6.4, right-hand side), the government should 'include a balance of expertise on ACRE', whose diverse composition would help regulators to 'avoid scientifically nonsensical requests to the releaser'. Industry would 'get sensible and balanced safeguards', which would both 'remove unnecessary burdens and delays' and 'prevent anything untoward from happening'. Similarly, an HSE official regarded such 'industrial realism' as an essential part of ACRE's composition and risk-assessment discussions. However, the notion of a 'balanced judgement' stood in tension with efforts to represent public concerns, suggesting that more than science was involved.

3.2 Representing the Public

In public debate on the new committee's composition, some proposals had gone beyond adding ecologists. When public-interest organizations had lobbied Parliament to put forward amendents making ACRE statutory, their proposed wording would have also guaranteed that the committee represent a wide range of expertise and interests (Levidow and Tait, 1993: 198). In particular, the Association of Metropolitan Authorities sought to ensure a role for its Environmental Health Officers, who were already represented on ACRE; the Green Alliance sought representation for 'wider environmentalist interests'.

When the Environment Minister initially rejected any such amendment, he stated that 'I have stopped short of putting anyone on the Committee from any green lobby' (Hansard, 6 March 1990: 976). Nevertheless, ACRE's Joint Secretariat largely followed the Opposition's proposed categories when appointing the membership, announced only six weeks later. Accordingly, the government appointments encompassed diverse expertise and views, and expanded the implicit public-interest representation, including an 'environmentalist'. What might have led to that shift?

Donna Haber, a TUC nominee on ACGM and later on ACRE, had urged broadening the composition as a way to handle public unease. Appealing to industry, she proposed that public-interest groups be invited to raise their concerns in the advisory committee. Otherwise, she warned, they will do so 'in the press and outside the committee and other places, where perhaps unnecessary controversy will be caused, which in turn will do damage to your industry' (CBC, 1990: 43).

Although Haber also expected greater safety to result from such representation, industry apparently accepted her proposal more in terms of public perception. In the DoE (1989) consultation exercise, before ACRE's formation, industry submissions had emphasized the importance of winning public confidence: for example, 'the legitimate concerns of the public must be addressed in a way that allays their fears'. Accordingly, the committee's membership should include 'independent environmental scientists', as well as 'non-experts (wise men)' or 'laypersons'. One company even proposed including 'representatives of environmental and consumer groups acting on behalf of the general public'.

In subsequent interviews, industrialists elaborated upon their reasons. As one said (see Map 6.3, left-hand side), 'We need to see ACRE from two standpoints: as a regulatory body and the public perception of it.' Given that the trade unions claim to represent a large proportion of the public, including farmworkers, TUC nominees would help the committee to consider public perception, more than scientists alone would do. Decision-making would then 'allow the public to feel comfortable with GMO releases'. Moreover, he noted, a widened composition would help avoid the risk of an appeal against ACRE's advice. These comments illustrate the dual meaning of precautionary regulation for GMO releases.

While largely welcoming ACRE's diverse composition, industry expressed unease that an excessively wide participation could undermine the committee's grounding in specialist expertise. In particular, industry opposed the explicit 'public-interest representation' advocated by some pressure groups. One CBI nominee on ACRE argued, for example, that such an official designation would usurp the Environment Minister's authority as the elected official responsible to Parliament and therefore his public-interest authority. That objection expressed a dilemma about how to widen the committee's membership, while restricting its remit and the non-scientists' role on the committee.

If not 'public-interest' representatives, then why not appoint additional ACRE members nominated by a particular constituency? The TUC's Donna Haber had advocated such a

basis, so that such members would feel secure in their position on the committee. Reflecting on GMAG's role in regulating the contained use of GMOs, she noted that the 'public-interest representatives', appointed as individuals, had lacked authority by not formally representing a constituency (CBC, 1990: 43). In effect, Haber's proposal would have more formally extended a feature of Britain's traditional regulatory approach, by using advisory committees to encompass representatives of relevant constituencies.

However, most ACRE members and civil servants felt that committee members should primarily represent diverse backgrounds and expertise, rather than organizations as such. Although the ACRE Secretariat solicited nominees from the CBI and TUC, it saw no rationale for choosing a particular organization to nominate a public-interest representative, who anyway would have little means for consulting a relevant constituency. All those arguments coalesced in the decision to appoint a 'farmer' and an 'environmentalist' -- as individuals, not as organizational representatives.

3.3 'Environmentalist'

As Parliamentary officer of the Green Alliance, Julie Hill was the only person from an environmentalist organization who had requested a meeting with DoE staff to discuss details of the Environmental Protection Bill. In so doing, the Green Alliance demonstrated its interest in the technical-legal issues of the Bill, similar in form to the procedural rationality of ACRE itself. In representing the Green Alliance at a key public conference (CBC, 1990), she had raised various issues which the DoE in particular expected ACRE to discuss.

Before the government decided to appoint her, an HSE interviewee had expressed some ambivalence about choosing someone from 'an environmental pressure group' (15 February 1990). After her appointment, another HSE official described the decision in more positive terms: she was appointed not as a representative but 'as a specialist who has access to a more general environmental constituency', by analogy to TUC members of scientific advisory committees: 'Because they're not so closely associated with the science of the issue, they can often get to the heart of the matter much better than scientists can.' In this view, ACRE most needed someone 'who had a greater feel for broad-brush environmental issues', stated an HSE official (interview, 26 September 1991).

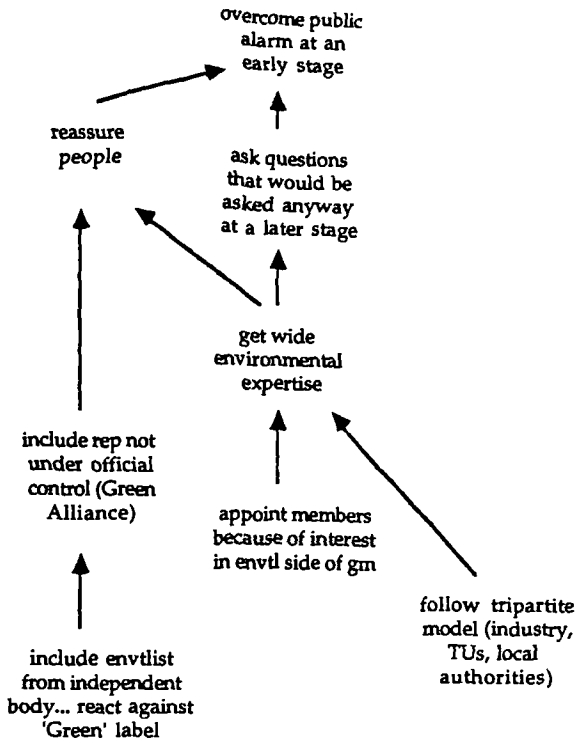
According to Julie Hill, her membership was solicited mainly by DoE officials, who acknowledged that the issues are not just those for science (interview 24 July 1991). They

wanted her to bring 'a broader environmental view', one not conditioned by directly representing a particular constituency. She was expected 'to ask the awkward questions', meaning not technical questions but second-order questions about how far the scientific uncertainties have been considered.

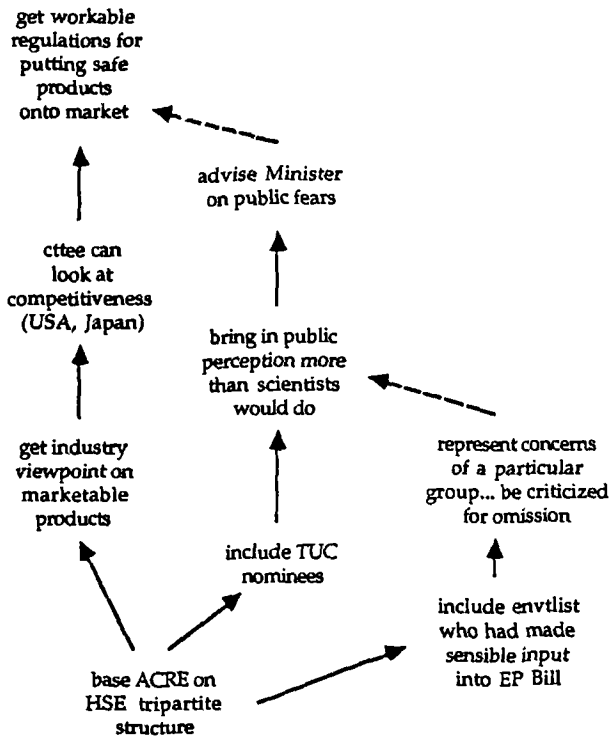
For the Green Alliance, a lobbying rather than campaigning organization, such participation in ACRE seemed not to conflict with any other action it might want to take. Before accepting her appointment, Hill raised the issue of co-optation with various environmentalist groups, which on balance thought her participation in ACRE would help promote their aims. In particular, given that the committee's remit includes advising on regulations, she expected her membership could help promote public access to information (cf. Milne and Watts, 1990: 22). They foresaw such access as strengthening the position of the more cautious committee members.

Hill's appointment met approval by some industry figures, apparently sharing Donna Haber's trade-union view. According to one industrialist (see Map 6.5), government should appoint ACRE members because of their interest in the environmental aspects of genetic modification. Industry should welcome in particular an 'environmentalist from an independent body, rather than react against the "Green" label'; thus the committee could 'include a representative not under official control', by implicit contrast to the government-funded Nature Conservancy Council. Such wide environmental representation would help regulators to 'reassure people', to 'ask questions that would be asked anyway at a later stage'; thus they could 'overcome public alarm at an early stage'.

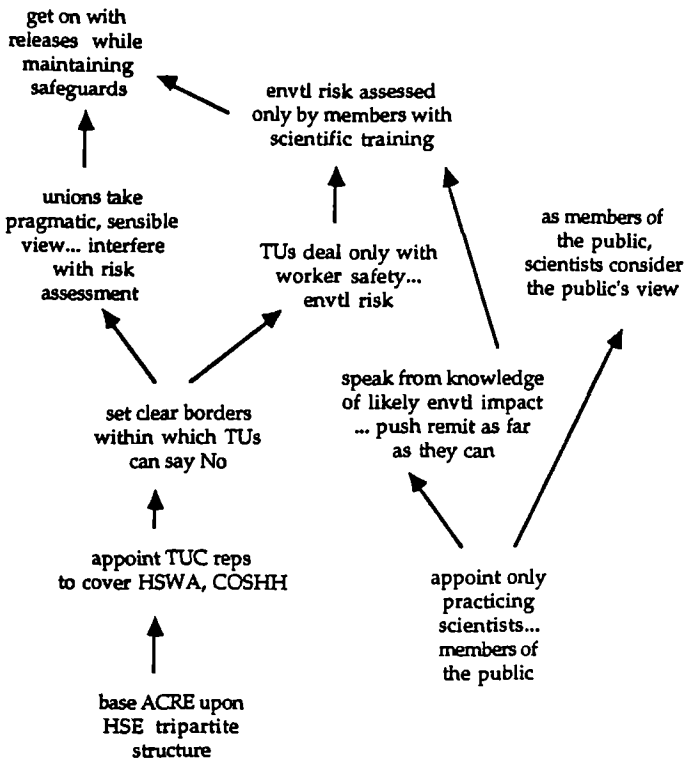
According to a similar industry view (Map 6.3, middle), ACRE should invite an environmentalist to judge the evidence on GMOs; her role would help 'avoid any public perception that industry steamrollers the committee or gives backhanders to the trade unions'. More positively, she would 'represent the small proportion of people who follow the issue and who might influence public opinion'. Moreover, a scientifically untrained mind could 'apply real creativity, rather than simply think in a straight line'.



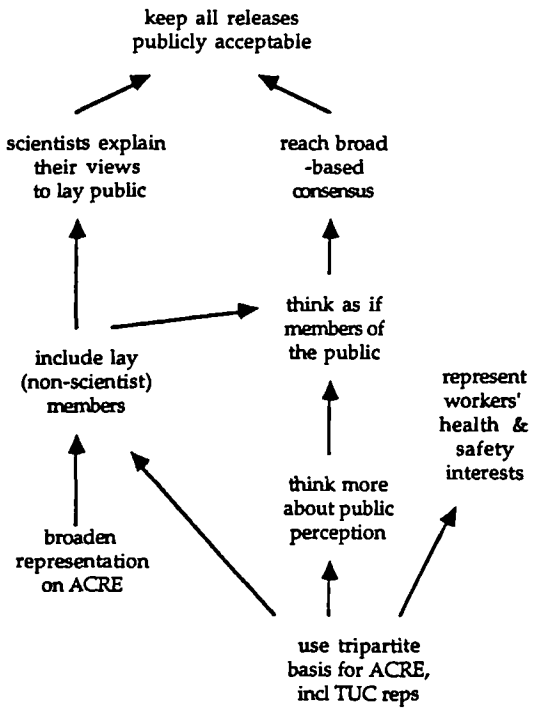
Map 6.5: Officer of Industry Interest group (Individual code I1, as for Map 6.1)



Map 6.6: CBI nominee on ACRE (individual code C3, as for Map 6.2)



Map 6.7: Officer of Industry Interest group (Individual code 12)



Map 6.8: REPRESENTING THE PUBLIC Regulatory advisors' composite map

One CBI nominee on ACRE (Map 6.6) supported including this environmentalist who, as the Green Alliance lobbyist, 'had made a sensible input into the Environmental Protection Bill'. Thus ACRE would 'represent the concerns of a particularly relevant group, rather than be criticized for omitting them'. Lay members would 'bring in public perception more than scientists alone would do'; regulators could then 'advise the Minister on public fears'.

However, her appointment met disapproval from other industry figures. Another CBI nominee on ACRE (individual code C1, map not shown) favoured including environmentalists 'only if they try to understand ecology objectively' and thus contribute a different scientific perception. He saw this appointee as mainly a political lobbyist, not representing any constituency or adding an environmentalist understanding.

Similarly, another industrialist (Map 6.7, right-hand side) favoured appointing only 'practicing scientists, not members of the public'. He expected that scientists, as members of the public, would adequately consider the public's view of GMO releases. Only they could 'speak from scientific knowledge about the likely environmental impact of GMO releases' -- unlike lay members, who might 'try to push the committee's remit as far as they can', even using non-scientific reasons to block releases. Such comments presumed that ACRE's advice clearly distinguished between scientific and policy matters; yet, in practice, the government had drawn no such distinction for ACRE -- notwithstanding earlier government arguments against establishing a Public Biotechnology Commission (see Chapter 5, section 3). In any case, a credible precautionary approach could not pre-empt how to define the risk-generating system and the relevant science.

Indeed, if specialist scientific expertise was the main criterion for ACRE membership, then why include TUC nominees? The industry official quoted above (Map 6.7, left-hand side), who was particularly anxious to restrict ACRE's remit, assumed that the TUC nominees would enter only those discussions which concerned the Health and Safety at Work etc. Act (HSWA) or the Control of Substances Hazardous to Health (COSHH); that basis would 'set clear borders within which trade unions could say no' to a proposed release. Besides, these particular TUC nominees were known for taking a 'pragmatic, sensible view' of biotechnology; their participation would help industry to 'get on with releases while maintaining safeguards'. Similarly, said the CBI nominee quoted above

(C1), the TUC nominees had a 'common-sense' expertise, presumably unlike an environmentalist lacking industrial experience.

Thus, in drawing such distinctions between trade-union and environmentalist members of ACRE, industry interpreted its remit as less about scientific expertise than about a 'pragmatic' approach to regulatory practicalities.

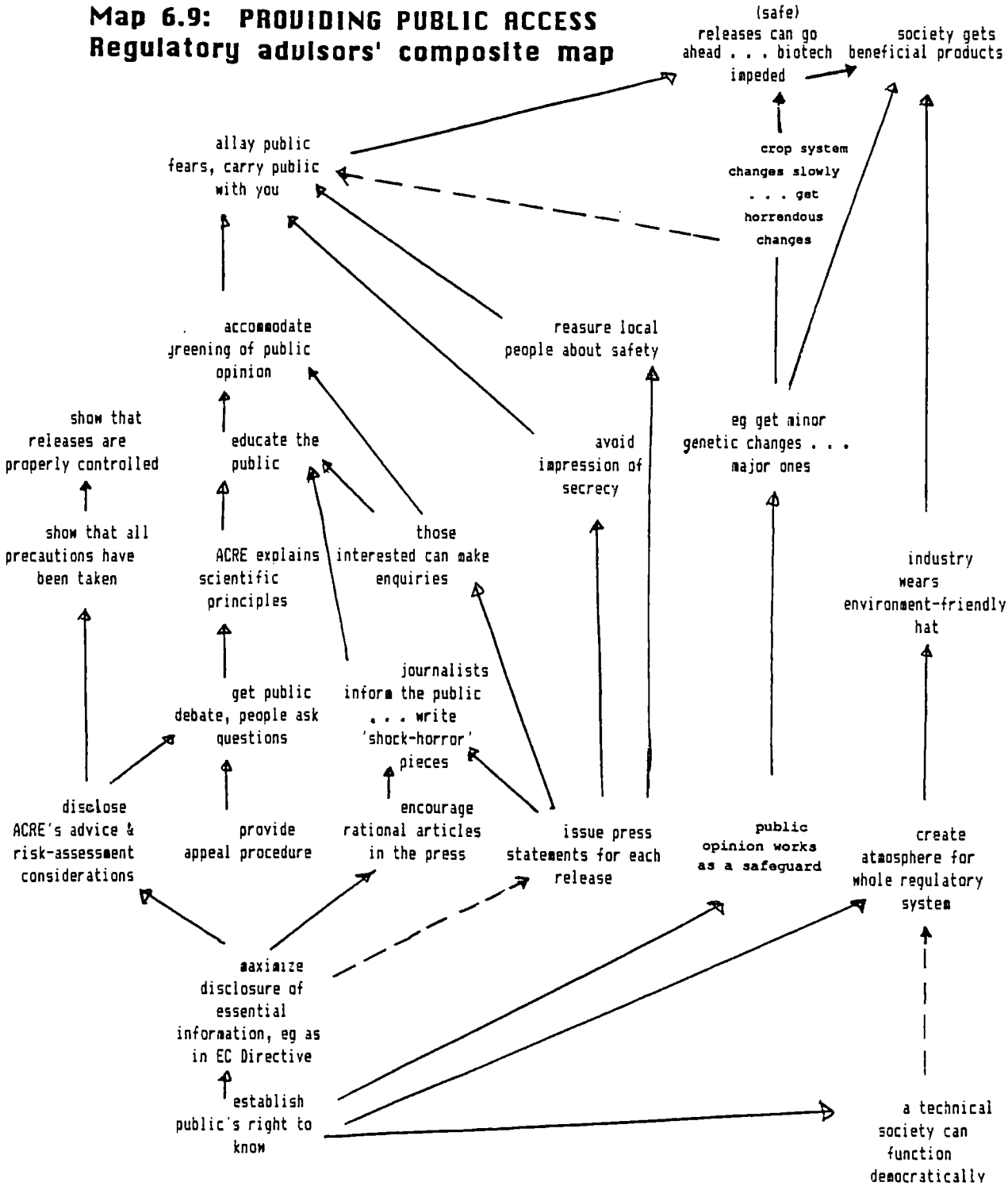
3.4 ACRE members' aims

According to my interviews with various ACRE members, they expected that the committee's broadened expertise would help clarify what precautions are warranted for GMO releases. As compared to the IISC, the new membership had relatively less vested interest in promoting GMO releases, so they could better reflect the public mindset and public interest -- rather than, for example, rely upon a contentious quantitative risk assessment for safety assurances. However, as one member lamented, government expenditure cuts have made academic staff rely more upon industry finance, which generally favours molecular biology: in his view, such dependency hinders biology departments from developing ecological expertise and from providing truly independent members for an advisory committee.

Although some members were wary of including an 'environmentalist', there was wide support for including 'lay' persons, whose presence would encourage the committee to 'think as if they were members of the public' and would encourage scientists to explain their views to non-scientists. This dynamic would help the committee to reach a broad consensus and to keep releases publicly acceptable (see Map 6.8, ACRE composite map). However, these comments downplay awkward conflict between public versus scientific perceptions of risk, or between wide participation and industry's needs.

Such tension appeared more clearly in comments from CBI nominees on ACRE. One (Map 6.4, left-hand side) accepted the need to include lay persons and avert hazards, but he preferred to 'avoid involving too many individuals in the regulation', so as to 'take regulatory decisions within 90 days' and allow a company to conduct a release within the 'seasonal window'.

Map 6.9: PROVIDING PUBLIC ACCESS
Regulatory advisors' composite map



According to another CBI nominee, the committee should incorporate public opinion, rather than leave itself vulnerable to criticism (Map 6.6, right-hand side). Yet the tripartite arrangement would help regulators to 'get an industry viewpoint on marketable products', so that the advisory committee could 'look at competitiveness' vis a vis the Japanese and US biotechnology industries (Map 6.6, left-hand side). He acknowledged some difficulties in reconciling all these aims within the regulatory procedure.

Also reflected within ACRE was a tension around the purpose of information disclosure. ACRE members regarded public-access measures as a way to 'carry the public with you', lest public unease 'turn indifference into hostility' and impose 'unnecessarily strict regulation'. By avoiding such obstacles, safe releases could go ahead, and society could benefit from new products (see composite map, Map 6.9, left-hand side). These views echoed the advice that 'secrecy breeds fear' (Hansard, 2 July 1990: 1978; cf. RCEP, 1989: 62); this simple slogan also implied the converse, i.e. that popular consent would be reliably achieved through greater transparency.

Yet some members wanted public-access measures to influence R&D agendas, and not only on safety grounds. For example, information disclosure was essential so that 'a technical society can function democratically'. Advance information on prospective products could 'open the door for the environmental lobby', pushing industry to 'wear an environment-friendly hat' (see Map 6.9, right-hand side). These comments may substantiate industry fears that some ACRE members might 'push their remit', though the committee had no formal role in public-access measures and little scope for deterring apparently safe releases. In any case, the statutory measures on information disclosure did not come into effect until February 1993 (DoE/MAFF, 1992).

4.0 CONCLUSIONS: ACRE'S POTENTIAL ROLE

The British government constituted ACRE in a way which could legitimize regulatory decisions. With ACRE's statutory basis and mandatory disclosure of its advice, the committee could gain credibility for its own independence. By accommodating and negotiating potential conflicts within confidential regulatory procedures, the government could more effectively avoid external challenges to its authority. In key features of its remit and composition, ACRE embodied the dual character of precautionary regulation -- anticipating hypothetical hazards and public unease about them. At the same time, ACRE

contained a tension between its scientific expertise and policy issues irreducible to technical evidence.

ACRE held a central importance to the social legitimacy and consultative character of GMO regulation, as manifest in the restructuring of Ministerial links around the committee. ACRE combined the main features of the predecessor committees which it replaced: that is, by considering both human and environmental safety, by regulating both GMOs and non-indigenous organisms, and by joining both the HSE and DoE in a new Secretariat, along with representatives from other Ministries. Although regulators justified this structure in scientific terms, it had several political rationales: under a Joint Secretariat, ACRE could continue industry's congenial working relation with the HSE, could lend the DoE's imprimatur to this new area of environmental regulation, and could reconcile the different safety perspectives of those two departments.

With its remit for 'novel organisms', ACRE provided a common framework for exploring the hypothetical analogy which ecologists had drawn between GMOs and non-indigenous organisms. ACRE members welcomed this remit as providing a scientific basis for regulating GMO releases -- on grounds of genetic novelty rather than the genetic modification process as such. Although biotechnologists had earlier dismissed the analogy to non-indigenous introductions, British industrialists now favoured constituting ACRE on this basis; this was partly for reasons of administrative convenience, though industry also recognized the political need for credibly disproving the analogy. Symbolically, the term 'novel organisms' acknowledged the stigma associated with GMOs, in a way which could overcome it through regulatory experience; risk-management procedures could be initially imposed upon all GMOs, without stigmatizing the genetic modification process as such. In this way, ACRE's remit offered a compromise route around the 'process versus product' debate (see Chapter 4, section 1.2).

In giving safety assurances about GMO regulation, the government often cited the high reputation of its advisory committee -- a claim which became fulfilled in the new committee's composition. In extending the HSE's tripartite model from the IISC to ACRE, the Joint Secretariat also stretched the notion of 'expertise'. As well as adding more ecologists, it expanded the implicit 'public-interest' representation, with more TUC nominees and in particular an 'environmentalist' from the Green Alliance. Other ACRE members welcomed the presence of lay people who could provide a broader environmental perspective and forewarn the regulatory system of public sensitivities.

Thus with ACRE the British government extended its earlier strategy of 'responsible co-optation', offering consultation as a privilege to 'respectable' organizations, whose leaders could be expected to behave 'reasonably' (Vogel, 1986: 51-52). The participation of the Green Alliance replicated that pattern but tamed no activism, given the organization's previously limited role as a Parliamentary lobby. Its potential role on ACRE was double-edged: on the one hand, in concert with ecologists, it could press 'awkward questions' about environmental uncertainties; on the other hand, its presence could legitimize the project of translating value conflicts into technical criteria (see Chapter 3, section 2.2). It remained to be seen whether, as in chemicals regulation, non-technical members of advisory committees would exercise little influence on the group's deliberations (Jasanoff, 1986: 58-59).

Also ambiguous was ACRE's remit for 'all aspects of safety', as regards any putative boundary between science and policy, such as environmental or ethical issues which lay beyond testable uncertainties of GMOs. This ambiguity was convenient for a government prone to exaggerating ACRE's remit. It faced public expectations that some legitimate authority would act as 'clerk-of-works to the New Creation', not simply make our future safe (Levidow and Tait, 1992: 103; cf. Wynne, 1982: 172). Although ACRE had no such power, it could influence R&D by disputing whether evidence of safety was adequate or relevant; some members sought information disclosure as a means of strengthening public pressure for more beneficial forms of biotechnological innovation.

In this sensitive political context, some industry officials invoked a sharp boundary between regulatory science and policy. On this basis, they argued that ACRE's membership should have been restricted to a scientifically defined 'expertise', and feared that lay members would 'push its remit' into policy matters. At the same time, industry welcomed 'reasonable' lay members of ACRE -- especially TUC nominees -- who understood the practical problems of observing the safety procedures and getting competitive products onto the international market.

In all these ways, ACRE incorporated conflicting imperatives. Although nominally evaluating uncertainties and assessing safety, its procedure could also accommodate public unease and market pressures. These tensions arose not only among regulatory actors but also within each actor, as depicted in the cognitive maps (e.g. Maps 6.4, 6.6 and 6.7).

Such tensions add a twist to an earlier analysis of British regulatory culture, often called a consultative or consensual model. European countries such as Britain rely upon 'pluralistic

advisory committees that can resolve both technical and political issues... The effect of this institutional approach is to protect the image of science as a neutral and rational decision-making tool...' (Brickman et al., 1985: 310; cf. Jasanoff, 1986: 66).

GMO regulation replicated this pattern by stretching the definition of 'specialist' expertise, and by provisionally adopting a hypothetical analogy to documented harm from 'novel organisms'. This cognitive framework broadened the range of 'perceived risks' which should be investigated as if they might be real. In this way, paradoxically, the government could construct a procedural rationality which maintains the neutral image of regulatory science and legitimizes its decisions.

Chapter 7
CONTAINING PERCEIVED RISKS

The previous three chapters analysed the institutional frameworks devised for regulating GMO releases. A putative international consensus, on permitting a step-by-step relaxation of containment, was cited as the basis for markedly different regulatory systems. Unlike the USA, the EC & UK's process-based system subjected all GMOs releases to a risk-management procedure; Britain justified this precautionary approach partly by drawing a naturalistic analogy between GMOs and exotic introduced organisms.

In practice, then, how did the step-wise procedure relate scientific and public perceptions? What range of perceived risks was treated as potentially real? In devising safety measures, how did risk management follow from risk assessment -- or perhaps vice versa? What risk perceptions were accommodated, deferred or excluded?

Focusing on Britain, this chapter analyses control measures as symbolically 'containing perceived risks', in several senses: accommodating images of GMOs as nature potentially out of control; demonstrating safe control of a carefully managed 'step'; and thus deferring wider issues. The chapter discusses:

* diverse ways of constructing some boundary between 'real/perceived risk' (section 1);
* how Britain's regulatory procedures symbolically contained perceived risks, towards ritually normalizing GMOs (section 2);
* how pollution imagery was evoked by two particular types of GMO releases: a herbicide-resistant crop (section 3) and a viral insecticide (section 4);
* in summary, how the stepwise procedure encountered difficulties of social legitimacy (section 5).

A terminological note: Henceforth, as in common regulatory parlance, some GMOs shall be called 'gm' or 'transgenic' organisms. Microbial GMOs may be called GEMs, an early acronym for 'genetically engineered micro-organisms'.

1.0 REAL VERSUS PERCEIVED RISKS?

According to the standard dichotomy, 'real risks' are the remit of risk management, while 'perceived risks' are a problem for public education, e.g. by popularizing scientific risk

assessment. For the intentional release of GMOs, this dichotomy was reiterated by many biotechnologists, especially in the USA (e.g. in Batra and Klassen, 1987: 168; Huttner, 1991). However, scientific disputes fuelled wider public debate over how 'real' risk should be defined and investigated.

For overcoming these disputes, the OECD proposed a stepwise procedure: that is, 'progressively decreasing physical containment', through a 'logical, incremental step-wise process whereby safety and performance data are collected'. More controversially, however, it suggested that the risk assessment 'can be approached by analogy with the existing data base gained from the extensive use of traditionally modified organisms in agriculture and the environment generally' (OECD, 1986: 29, 41). With that analogy, the OECD downplayed ecologists' analogy to non-indigenous organisms, while implying that any familiar hazards already came under adequate regulation.

Both the US and EC regulatory systems claimed to follow the OECD recommendations, but they differed sharply over the basis for imposing risk-management procedures upon GMOs. Emphasizing predictability, the OSTP in particular constructed an *a priori* boundary between 'real/perceived risks'; by contrast, the EC initially left open such a boundary (see Chapter 4). Each approach entailed practical dilemmas for how the regulatory procedure would establish a credible boundary.

This problem was mooted at an international conference on 'biosafety results', its title emphasizing the presumed evidence of safety (MacKenzie and Henry, eds, 1990). A leading research manager echoed the OECD's reassuring analogy to agricultural experience. He foresaw no environmental risks from transgenic products, because they could cause harm only to agriculture, if at all; thus he conceptually excluded agriculture from the environment. This perspective justified restricting demands for evidence of safety:

> The amount of information [provided by the applicant] can be realistic, based on the relevant experience base, or it can be open-ended or 'what-if'. A 'what-if' approach will preclude commercialization of many GEOs [GMOs] because of the cost to obtain the information and the prolonged time to approval and market introduction. (Hardy, 1990: 239, 245)

However, other conference participants emphasized the opposite problem: that inadequate safety data might jeopardize the commercialization stage. As USDA speakers argued, 'The real versus perceived risks of biotechnology products may prove to be a difficult factor as these products enter the marketplace.' Biotechnologists had to overcome perceived risks through safety science, not simply through educating the public about the technology and its benefits: 'It is therefore imperative that risk assessment efforts go beyond that which is merely sufficient, to provide solid evidence of acceptable risk that can be communicated to the public

at large with scientific assuredness and without vaccillation' (MacKenzie and Henry, 1990: 278, 273).

Thus, paradoxically, the USDA warned industry that an official safety imprimatur might remain politically inadequate. This dilemma arose from a putatively 'risk-based' regulatory system, which pre-empted the boundary between real vs perceived risks, for the sake of denying the stigma popularly associated with GMOs.

The dilemma took a different form within the EC regulatory framework, which initially regulated all GMO releases. A leading European biotechnologist acknowledged that 'the regulations must not only be technically adequate, but must also be perceived by members of the public as an adequate response to their concerns, which are linked to their perception of the technology'. Yet, he lamented, process-based regulation 'creates a perception of inherent riskiness of biotechnology, thereby leading to reinforcement of the demands of the public for further regulatory constraints' (de Greef, 1991). That is, regulatory scrutiny might intensify rather than overcome the stigma popularly associated with GMOs.

A similar dilemma was described for Britain's regulatory system, even for the earlier stage of GMOs in contained use. ACRE's chairman, John Beringer, publicly acknowledged that some academic institutions were ignoring the legal requirement to keep full records or to notify local biosafety committees of all laboratory work on GMOs. Legally speaking, they should treat their laboratory work 'as though the organisms were dangerous', but he doubted that that most academics would do so; he regretfully advocated 'a draconian system of punishment for people not following regulations' (CBC, 1990: 47). As he later clarified, exemplary prosecutions were warranted in order to show that the regulatory authorities take safety seriously -- even where the laboratory work was considered safe and routine. 'Then, again, the [political] risk would be in making people think that this [genetic modification] is a major threat.' On balance, though, he foresaw greater public alarm resulting from lax enforcement (interview, 19 April 1990).

Beringer also acknowledged that biosafety research entails an ambiguity between real/perceived risks. After all, reassuring the public 'is perhaps the most important goal' for the biotechnology sector of safety research funded by the European Community. Indeed, 'This [goal] can be met simply by throwing money at projects with appropriate sounding titles. There has been some criticism of the sector on this basis -- [criticism] which has not been entirely groundless' (Beringer, 1990: 75). However, 'appropriate' research could be defined in different ways, depending upon how one evaluates ecological uncertainties.

A similar ambiguity extended to the types of GMO releases being carried out. In testing GMOs, trial releases have self-consciously tested both the regulatory system and public reaction. At an international biotechnology conference, 'The general feeling was that we should make a number of obviously "safe" releases (e.g. engineered maize) as soon as possible, in order that release of genetically engineered organisms is not perceived as being inherently dangerous', reported a British ecologist (Crawley, 1988: S2). Similarly, in interviews with industrialists and regulators, they preferred limiting early GMO releases to minor, benign modifications of familiar crops; for some interviewees, that meant avoiding micro-organisms, which posed greater ecological uncertainty, and herbicide-resistant crops, which conveyed the wrong image for biotechnology, though such crops did go ahead anyway (see this chapter, section 3).

By 1991, trial releases in Britain had included genetically modified strains of the 'lead crops', e.g. sugarbeet, oilseed rape, tomatoes, potatoes. Crop releases tested for the efficacy, stability and/or unintended transfer of the inserted gene, or for any selective advantage. Transgenic crops had inserted genes which were expected to make no behavioural difference, except in the sense of a selectable marker gene, such as resistance to a herbicide or to the antibiotic kanamycin (see this chapter, section 3). A viral insecticide had been genetically modified for reduced persistence before its release in 1986 (see this chapter, section 4). Releases of nitrogen-fixing *Rhizobium* underwent the regulatory procedure, though they had been modified *in vivo* and so were not generally regarded as GMOs.

On the negative side, when an academic scientist proposed to conduct a trial release of *Drosophila* flies with a genetic marker in 1988, the regulatory system effectively discouraged the release by requesting additional information. Some advisory committee members felt that the applicant showed little sign of having considered safety or public alarm; that the experimental design allowed no way to ensure the insects could be eliminated once released; and that unmodified flies could have been used instead to achieve the experimental purpose of tracking the flies (according to personal communications from IISC/ACRE member, 10 July 1989, 7 January 1993). ACRE members probed scientific uncertainties which encompassed diverse risk perceptions, without necessarily identifying a specific hazard.

In general, broad uncertainties were also accommodated by the design of releases which did obtain regulatory approval. According to interviews with members of ACRE's predecessor committee in 1987-88, 'many committee members feel that a number of the precautions recommended appear to have been taken to reassure the public rather than for purely scientific reasons' (Shackley, 1989: 218). More subtly, the initial precautions allowed regulators to avoid disputes over how to define 'purely scientific reasons'.

Consider for example Prosamo, a biosafety research project in Britain (see further Chapter 8, section 1). A published paper cited scientific grounds for having incorporated safety measures into the experimental protocol, as well as subsequent evidence of safety as grounds for relaxing those measures (Dale et al., 1992: 74). However, they also had a symbolic role, as the project leader acknowledged:

> There are certain things which mainly MAFF asked us to do which we felt do not have a good scientific basis. [In 1987] we went along with them because they argued that we should do it because of public perception, or [at least] their perception of public perception. That includes the sterilisation of boots and tools that we used. And they wanted us to deflower the potato plants every day, even though you can prevent pollen dissemination by debudding every five days, if you do it early enough... For the 1988 release, we persuaded MAFF that sterilisation was not warranted (Philip Dale, interview 27 June 1991).

On the other hand, the original experimental design did not incorporate some other precautions, again partly for symbolic reasons. For its stated scientific purpose of tracking gene flow from the crop, the Prosamo experiment could have used a non-GMO, e.g. a crop strain with a naturally occurring pigmentation marker. Indeed, the advisory committee had cited such an argument when discouraging the *Drosophila* proposal (see above); in contrast, the committee regarded the Prosamo experiment as an opportunity to clarify scientific uncertainties, while carrying along the public with a GMO release:

> The regulators want to be challenged, to think about the question of what [GMOs] go out and what the problems are. So we decided to use transgenic plants because that's what Prosamo is about. Putting [transgenic] plants out in the field is a way of informing the community, of explaining the releases, so that people become comfortable with them (ibid.).

Thus, by using a genetically modified marker, this release could push forward the regulatory system, in ways which had both a scientific and symbolic content.

2.0 SHAPING RISK PERCEPTIONS

As analysed above, the stepwise procedure had various symbolic roles: to demonstrate safe control, to accommodate public perception, to carry the public with the regulatory system, etc. While some participants felt that precautions exceeded any scientific basis, the stepwise procedure permitted regulators to defer drawing any sharp boundary between real/perceived risks. How, then, did ACRE negotiate diverse risk perceptions? To answer that question, this section draws upon interviews with ACRE members, who are identified according to the following code: C1-C4 (CBI nominees), T1-T2 (TUC nominees), S1-S12 (other specialist members), D1-D7 (departmental assessors); see also Chapter 2, section 4.

ACRE members generally foresaw the most serious risks from non-commercial GMOs, such as selective biological weapons (T2) or 'a Pandora's box of real horrors', such as genetically

modified insects (D3). Few members mentioned significant environmental risks from the sorts of GMO products that they expected industry to develop, especially those derived from the lead crops. For such releases, some members suggested that the negative impact may be more perceptual than environmental; for example, 'the risks are more apparent than real' (D1), or 'worry about public acceptance, rather than the technology itself' (T2).

In this vein, members acknowledged the dual purposes of safety measures. The committee 'may want to show that there are robust precautions, but we may want to prevent escape anyway' (S11). That is, the experiment may contain the GMO and/or its pollen for a combination of reasons, without necessarily distinguishing them.

Regarding that 'containment', by biological and/or physical means, several members regarded the term as misleading. 'By definition, a release cannot be truly contained, or even semi-contained' (S8). 'You can only limit the spread of an organism, not entirely contain it; we should refer to the experimental design, or to the inherent characteristics of the organism, not "containment", which is a catchy public-affairs term' (C1). Regulators should 'acknowledge difficulties in defining containment, as well as the environment' (D4). Given this ambiguity, 'containment' can be understood as a symbolic framework for negotiating diverse risk perceptions, as the following sub-section illustrates.

2.1 Containing perceived risks [cognitive map]

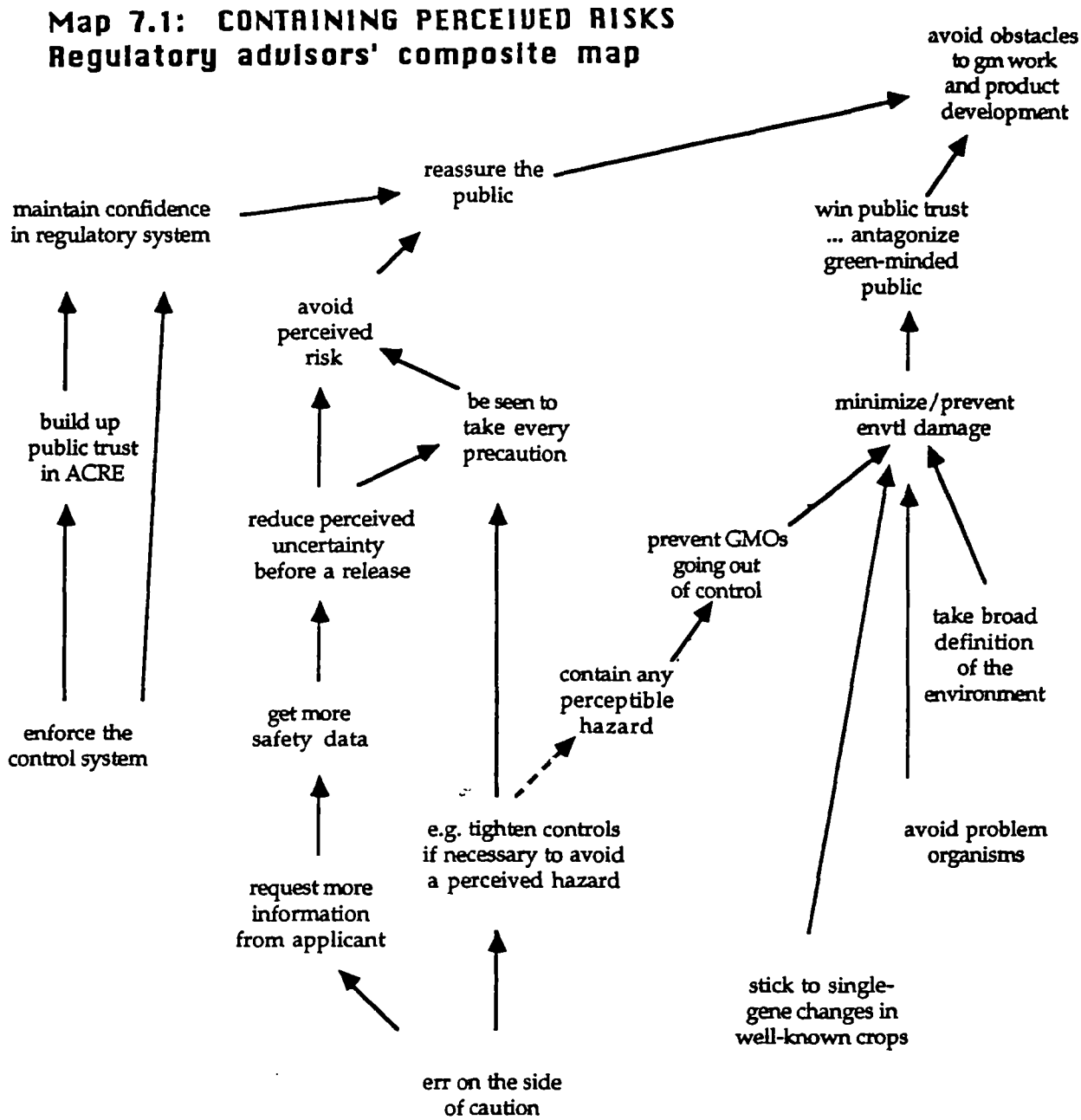
The composite cognitive map, 'Containing Perceived Risks', shows how regulatory advisors related scientific and symbolic aspects of risk regulation. Here all actions lead to the goal, 'reassure the public'; for many interviewees, that leads to a higher goal, 'avoid obstacles to genetic modification work and product development'. Otherwise, they feared, all of biotechnology might be impeded (T1), there might be a ban on releases (T2,S2), regulations might become unnecessarily strict (D9), and beneficial products might not go ahead (S1), such as biological control of plant pests (S11).

The map includes many measures which could be understood or justified as necessary to avert potential environmental harm, but whose rationale may be ambiguous, even in the regulators' minds. All the measures are grouped together under the following penultimate goals:

* maintain confidence in the regulatory system;
* avoid perceived risk;
* avoid/minimize environmental damage.

Let us consider each of these penultimate goals in turn, moving from left to right on the map.

Map 7.1: CONTAINING PERCEIVED RISKS
Regulatory advisors' composite map



'Maintain confidence in the regulatory system'

Certain prominent measures were considered necessary in order to maintain confidence in the regulatory system. At least two members (S5,T2) emphasized the need to enforce the control system, in order to 'get the public behind you' (T2); that complemented the chair's public call for exemplary prosecutions of anyone who violates the regulatory procedures. One member mentioned a perceptual reason for providing the special regulation of GMOs with statutory backing: so that 'risk assessment is seen to be done' (S7). The system should apply the regulations to all GMOs and so 'avoid any difficulty in explaining exemptions to the public'; thus the system will 'be seen to take every possible precaution' (T2).

A public-relations rationale was mentioned for the decision to use the term 'genetic modification' rather than 'engineering' or 'manipulation'. According to one member (D6), the chosen term helps clarify that the Environmental Protection Bill really does implement the EC Directives, presumably in the sense of being seen to provide an adequate control system -- at the same time as avoiding 'negative' connotations of the earlier terms.

Several members regarded the control system as complementing the need to 'build up public trust in ACRE', 'win public confidence', etc. One saw the government as having structurally accommodated public perception by broadening the committee membership, especially its ecological expertise: 'After all, we are here' (S10).

One member (S2) wanted GMOs to continue undergoing separate regulation, even at the commercial product stage; such control would help regulators to 'regain public trust', to overcome a legacy of arrogant technofixes disbelieved by the public. Although he expressed concern about genetic fluidity and the unintentional creation of human pathogens, his basic rationale was to anticipate 'the unknown that may come out and bite you', more than to avert any specific identifiable risk.

'Avoid perceived risk':

In justifying precautions, several members mentioned the need to 'avoid perceived risk', particularly by accommodating 'the 1990s green public', 'the green-minded public', 'the greening of public opinion', or the 'extra dimension of public environmental awareness' (e.g. D4,R2,S1,S7). It could do so, for example, by testing the extent to which recombinant DNA transfers to other organisms (D4). Acknowledging great scientific uncertainty, one member

even suggested that 'public disagreement among experts' could helpfully 'provide a safety valve in case of a mishap' (S6).

How, then, could the regulation avoid perceived risk? 'Request more information from the applicant, get more experimental data on file, and thus reduce perceived uncertainty before a release' (C3,S1). Given that we should 'anticipate a greater perceptual impact than environmental impact', said one member (D1), the regulation should 'take a slow, deliberate approach'. For similar perceptual reasons, the regulation should 'try to find a problem for each new gm variety' and thus 'convince the public you're doing the regulation properly' (C1).

Reducing scientific uncertainty was considered more important for potentially sensitive releases. For a genetically modified baker's yeast, one member drew a hypothetical analogy to *Candida*, thrush-causing yeast. Only by getting more data could regulators really know that the gm yeast behaves the same as the unmodified yeast, rather than merely *think* that it does (S1).

The regulation should 'err on the side of caution, guarantee safety, and so give the public confidence', or else the regulators would 'meet retribution' (C2). For all the CBI nominees, among others, this task meant evaluating similar risks for GMOs and non-indigenous organisms, in order 'to show that all relevant questions have been asked' (C2), as one of them put it.

Members cited ambiguous reasons for containment measures. Some acknowledged that they take into account the possibility of physical disruption when assessing potential risks (e.g, C3); that is, safety should not depend mainly upon physical containment (S9). In another view, the design may 'use containment to lower the risk from any intrinsic hazard, and so keep the risk within an acceptable level'; but the committee may also 'anticipate public reaction in order to modify the experimental design and/or prepare a fact-based reply' (S7). They should 'rely upon the interplay of diverse expertise and lay positions, e.g. tighten containment if the public perceives a risk, and so remain within the bounds of what society accepts' (S6).

Likewise, the committee may 'balance [match] risks and perceived risks with control measures, in order to set appropriate containment'; they should 'feed public concerns back into the regulatory mechanisms; develop a pragmatic, proactive approach; and thus show the Green-1990s public that the technology is properly controlled' (D4). The regulation should 'control releases more strictly than would be warranted on scientific grounds alone' (T2); regarding unintended gene transfer, this could mean removing plant buds far more frequently than flowers could appear. Eventually it would be necessary to 'assess potential hybrids with

genetically modified plants on a world scale', in order to 'reassure the public that all precautions have been taken' (S5).

In some cases, such precautions can go as far as to 'request more information or refer to unknown risks', in order to delay or discourage a release that might alarm the public. One member (S8) suggested that the genetically modified *Drosophila* had been blocked, in effect, 'to avoid irrational fear of mobile creepy crawlies' [see this chapter, section 1.0]. Regulators should 'balance benefits against publicly perceived risks', and so 'avoid unjustified releases likely to cause public outcry' (D9). In these ways, regulators could indirectly limit releases to 'benign' ones, such as familiar crops and *Rhizobium*, a nitrogen-fixing bacteria (S8).

Some regulators mentioned concerns beyond environmental risk as such, partly for perceptual reasons. The regulation should somehow consider effects on nutrition and on Third World exports, by screening prospective products at an early stage, so as to avoid a 'negative breakthrough in public perception' (D3, S4). [For disputes over a 'Fourth Hurdle' beyond risk regulation, see chapter 5, section 4; and chapter 9].

Genetically modified (or transgenic) mammals presented a special case; ACRE had not considered such applications because no one proposed to 'release' them. However, some interviewees participated in other advisory committees which considered the ethical and health aspects of creating transgenic animals. One member (D5) was concerned to avoid harming the experimental animals; with more graphic language, another was concerned to avoid creating 'a deleterious mutant' (S6), presumably meaning harm to the animals. Regulators should exercise 'great caution'; for example, the regulation should withhold transgenic animals and even the control animals from the food chain in order to avoid any perceived risk (C4, D5). Particularly in this ethical context, but also more generally, few members distinguished 'perceived' from 'real' risk.

'Avoid/minimize environmental damage':

In the right-hand section of the composite map are shown measures which some regulators consider adequate or necessary to avert potential environmental damage.
It was proposed to 'require containment if there is a perceptible risk' (T2), a term implying real risk -- for example, to prevent GMOs 'going out of control', or to lower risk to an acceptable level (S7). The strongest examples cited were problem organisms which had not yet gone beyond experiments in fully contained conditions; ACRE had not assessed hazards of their intentional release. One member (D5) was concerned to avoid creating a 'super-pest',

particularly from transgenic animals. There was also concern about animal hazards from using viral vectors (S6) or live viral vaccines, which might be high risk (D5).

A common assurance was that GMO releases were being largely restricted to single-gene changes in well-known crops (S5,C1), which were not expected to present environmental problems. In particular, long-established non-indigenous crops were unlikely to be frost-hardy or to have weedy relatives, thus precluding problems of unintentional propagation or gene transfer. More generally, 'It is more difficult to maintain something in the environment than to envisage it becoming rampant' (S7); some saw the environment as a threat to transgenic crops, more than vice versa.

However, some members had worries about current releases of GMOs derived from familiar organisms which they regarded as inherently problematic. Given that kanamycin has been used in human therapeutics, one (D2) expressed unease at kanamycin-resistant genetic markers being used in sugarbeets, which produce pollen and have weedy relatives in Britain, unlike potatoes. For some GMOs, a member (S1) felt applicants couldn't adequately answer all the committee's questions without doing large-scale releases, at which point it might be too late to catch the organism 'before it goes', presumably out of control, such as a superweed; partly for that reason, he preferred to ban any transgenic versions of crops known to have a weedy potential, such as oilseed rape. That view contrasted with assurances from others (eg S5,C1) that oilseed rape grows wild on roadside verges only because they are 'disturbed environments'.

Lastly, there was some disagreement about whether some potential effects should be defined as environmental damage, such as increased problems for farmers. Some members advocated taking 'a broad definition of environmental damage' (S1, S8), again partly for perceptual reasons: the environment includes farmland. Other members regarded some undesirable effects as remediable: for example, if weeds were unintentionally to acquire herbicide resistance, then farmers could simply switch to another herbicide (e.g. C1). Another expressed indifference about damage to farmland as such, except insofar as 'factory farming' might damage the 'semi-managed environment' beyond it (S11).

2.2 Whose perceived risks?

In summary the composite map reveals members' cautious attitude towards environmental harm and public perception. These were not necessarily distinguished, when agreeing upon safety measures, as suggested by the cognitive map. Beyond the logic depicted there, members also expressed more ambivalent or divergent views.

ACRE's chairman commented in 1990, 'The committee has no policy on how to deal with public perception. I'm expecting some comment [from the government] on what we should do.' True, there was no official or formal policy. However, other members indicated that informal policies on public perception were already in operation: 'It is taken terribly seriously. In fact you sometimes get the impression that the whole thing isn't an exercise in environmental protection, but that it's an exercise in public opinion.' He (S8) drew an analogy to a court which unrealistically asks jurors somehow to forget a piece of inadmissable evidence. Likewise with the committee, he said, 'One can have no idea of the extent to which the things they talked about in their widest discussion would influence their eventual decision.'

According to another member (S11), the special regulatory procedures exist...

> because GMOs are unpredictable and irretrievable, but also because of public perception, which may have a completely unrational basis. Because of the political aspect, the precautionary principle could mean that you never develop anything; it's a difficult balance to make, in scientific and political terms... GMO regulation is different because of lower confidence in your conclusions and because public perception colours the risk assessment -- rightly, in my view.

In 1991 an ecologist (S10) reflected back on 1989, when the same release applications were being considered by ACRE's precursor committees, both of which anticipated public unease:

> There was a reinforcing mechanism between IACI and IISC, with each anticipating what [precautions] the other committee might come up with. That initially led to tight constraints on releases, when I couldn't conceive what the risk was. ACRE has now arrived at the position where I was at several years ago.

In contrast to the those quoted above, three ACRE members dissociated the committee's advice from public perception. For a civil servant (D6), the committee respected a putative boundary between scientific advice and policy: 'The Minister is our expert in public perception.' A CBI nominee (C1) insisted that 'no public-affairs person would claim to know what the public think; it would be arrogant for us to do so.' Although emphasizing scientific uncertainty, another member said (S9): 'If ACRE were to stop a release or impose stringent conditions solely because of public perception, that would undermine the committee's credibility to make scientific judgements.'

Thus, unlike some other ACRE members, those three portrayed the committee's advice as exclusively scientific. Their comments can be interpreted not simply as defensive, but also as expressing a tension within ACRE's role: namely, how to translate diverse values and risk perceptions into technical criteria. What made this translation possible?

2.3 Regulation as judicial ritual

Speaking self-confidently about minimal 'real risk', an ACGM member (S12) feared that ACRE would attempt to 'pacify unreal environmental considerations [and thus] impede a good working relationship with the government'. He distinguished ACRE from its predecessor committee by emphasizing its Green role: 'In the title it is the E [environment] part which is different.' He also emphasized symbolic control:

> If you see a royal salute fired in Hyde Park to mark the Queen's birthday, there's a chap standing in the back stiffly at attention behind the guns. Well, he has always been there because it was his job to hold the horses' heads. The fact that there haven't been any horses for years is irrelevant. We hold horses' heads all the time.

His analogy compared GMOs to the imaginary threat of a wild creature going out of control, and its ritual containment. The analogy can be taken as more than a humorous aside, if we understand ritual itself as more than a repetitive, empty or superstitious ceremony.

As a social anthropologist has argued, the term 'ritual' denotes 'actions and beliefs in the symbolic order', toward mediating 'the gulf between personal meanings and public meanings'. Many societies enact rituals in 'expressive action specialized and apart from instrumental action'. In secular society, however, often 'the symbolic meanings are implicit in [the] instrumental action' (Douglas, 1973: 20, 38).

In that vein, GMO regulation has symbolic meanings which may bridge a gulf between concepts of risk, e..g risk as a technical measure versus cultural danger (see Chapter 3). The latter aspect was acknowledged by HSE Director-General John Rimington: 'The really important ethical question concerns the business of human beings messing about with too much power -- the Faustian question.' He drew an analogy to the nuclear programme, where 'the feeling that people were messing about with too much power unfortunately coincided with a number of other indications that all might not be entirely well' (CBC, 1990: 8).

Similarly, one regulatory advisor (S10) articulated the intangible ethical concerns bound up in risk perception:

> People assume there is greater potential risk when tinkering with the nature of species; there is a worry about what plant breeders are doing, and ethical questions. A fear of the unknown, rather than a worry about environmental safety, has led to it [the risk regulation], which is something that can be solidly done.

A cultural anthropologist has also emphasized the psychological rupture of crossing the species boundary: 'Because biotechnology breaks new ground and disturbs established presumptions, there is a need both for careful definition of issues (through debate) and for ritual normalization of acceptable positions...' (Fleising, 1989: 52). Risk assessment, even 'solidly done', cannot avoid the perceived abnormality of GMOs and their normalization.

The stigma was implied by the precautionary language of Britain's 1990 Environmental Protection Act (see Chapter 5, section 2). As one industry lobbying group had complained, 'The implication is that each GMO is guilty of a range of undefined offences against the environment until proved innocent'; thus the releaser might face a 'requirement to eliminate concerns in relation to an open-ended, unsubstantiated series of effects [environmental hazards]' (BSPB, 1989).

Industry's worst fears may have been realized by the adversarial language of an ACRE member (T2), 'We consider novel organisms [e.g. GMOs] as guilty until proven innocent.' Another member (S1) chose a more consultative type of judicial metaphor:

> 'The procedure is inquisitorial, not adversarial; we're trying to be friendly and arrive at the truth.... A proposed release is not presumed to be safe or unsafe, but you are required to prove that it's safe -- perhaps the equivalent of the presumption that it's not safe.'

That presumption was codified by provisionally classifying GMOs as novel organisms. Rather than simply put the applicant on the defensive, the analogy imposed a suspicion of risk which the risk-assessment procedure could confirm or allay, while helping the committee members to clarify their own views.

That is, the discussion helps to translate an otherwise inchoate unease into terms amenable to scientific evidence. As an extreme case, the 'environmentalist' on ACRE preferred that people did not 'feel the need to throw around GMOs in the environment' (quoted in Chapter 3, section 2.2). According to another member(C1), the committee takes seriously any member's unease about a proposed release by helping the person to formulate their reasons.

Each application could serve as a dress-rehearsal for defining adequate and relevant evidence of safety:

> Very often members recognize at the outset that the proposed release is a straightforward, low-risk thing, that the discussion is play-acting, treating the application [its safety aspect] seriously but as a trial case for establishing the range of questions, the protocols of information to be requested. The committee is using the application to probe at the issues. In one or two cases, the committee has said 'no' because insufficient information or bad presentation meant that we couldn't assess whether or not there was any risk (S11).

In this 'play-acting', apprehensions about abnormal organisms can be translated into technical terms; a potentially reckless activity comes under safe control. Note the resonance with an anthropological insight: 'Both in its plot and its symbolism, a ritual is an epitome of the wider... social processes in which it is embodied', according to an anthropologist (Turner, 1967: 273).

As in other modern rituals, then, symbolic meanings operate in the instrumental action of risk regulation. Starting from a presumption of figurative guilt, due to biological abnormality, GMOs can undergo a ritual normalization into innocence, at least for a particular step. Under the controlled conditions of trial releases, evidence for the absence of environmental harm can eventually be treated as evidence of safety, depending upon how one defines the relevant uncertainties.

In summary, the ritual aspect mediates a gulf between different public meanings, not simply 'between personal meanings and public meanings' (Douglas, 1973). By symbolically containing perceived risks, precautionary regulation may mediate between technical safety judgements and ethical qualms about crossing the species barrier; it may even substitute safe experimental control for the 'Faustian question' of sinister environmental control. However, such gulfs became difficult to bridge in two cases where GMOs became associated with pollution threats, as discussed in the next two sections.

3.0 HERBICIDE-RESISTANT CROPS

Perhaps the most controversial development of GMOs has been the genetic modification of plant crops for herbicide resistance. Industry has portrayed such transgenic plants as environment-friendly, while opponents have criticized them on ecological, agronomic and ethical grounds. Safety concerns include the unintentional transfer of the herbicide-resistance gene to weedy relatives, especially relatives of oilseed rape or sugar beet in Britain, as in the cases described below. Critics also raised systemic issues about crop-herbicide linkages, irreducible to the safety of the crop as such (see Chapter 3, section 1.4).

Herbicide-resistant plants represented roughly half of all transgenic plants released in field trials in the USA in the late 1980s (Goldburg et al., 1990). By contrast, there were no known releases of herbicide-resistant crops in Britain until 1990. This section will contrast two different local experiences in that year: an industry field trial which elicited no apparent reaction, and an academic field trial which provoked local resentment.

3.1 Lincolnshire 'weedkiller test'

In 1990 the Maribo Seed Company began small-scale field trials of sugar beet which had been genetically modified for resistance to Roundup, also known as glyphosate. ACRE had recommended approval of the small-scale field trials, under specified conditions, though some members had qualms about longer-term implications (according to my interviews).

As described in the company's 1990 press statement, 'Tolerance to Roundup was achieved by transferring a gene developed by Monsanto into Maribo Seed sugar beet breeding material'. The statement avoided the term 'genetic', except in mentioning the 'Advisory Committee for [sic] Genetic Manipulation'. The 1991 press statement used the term 'transformed', a standard technical equivalent of 'genetically engineered'; it also acknowledged that Roundup is manufactured by Monsanto. According to the press statements, the releases would investigate the plants' characteristics under unsprayed conditions, with a view towards producing 'an improved sugar beet variety' (Keyline Publicity, 1990, 1991). The statements also emphasized the widespread view that glyphosate was more environmentally benign than other herbicides then in commercial use.

Both statements were distributed widely to the local, national and farming press. The *Lincolnshire Echo*, which had an agricultural correspondent, published an article based on the first press statement, with no additional commentary. Independent Television interviewed a Maribo representative and broadcast an excerpt as part of a Leeds-based feature on GMO releases. The company was not asked to advertise the releases and did not do so (telephone interview with Maribo, 3 June 1992).

The Lincolnshire trials came to national attention only when a London-based science journalist learned about ACRE's discussion of the proposed 1991 release, long after local announcements of the 1990 release. His newspaper article had the alarming title, 'Sugar beet mutant in weedkiller test', whose wording implied that the field tests sprayed herbicide. The article quoted critical comments on the agricultural implications: 'It is highly questionable whether any so-called advance which increases the use of any pesticide is helping the environment or consumers', stated Friends of the Earth (Erlichman, 1990). Soon Maribo announced further trial releases which would spray the plants with glyphosate (Keyline Publicity, 1992). Throughout the entire period, however, there was apparently no local reaction.

3.2 Cornwall 'genetic test fears'

Also in 1990, different herbicide-resistant crops were released in North Cornwall. These were oilseed rape resistant to the herbicide glufosinate, or Basta; the seeds came from Plant Genetic Systems, a firm which was developing these GMOs as commercial products (Crawley et al., 1993; Fishlock, 1993). The North Cornwall releases were part of the Prosammo programme of biosafety research, which was testing for unintended effects of the genetic modification rather than for its efficacy (see further Chapter 8, section 1.2).

In the 11 October 1990 issue of the *Cornish Guardian*, there appeared a closedly-printed advert, barely legible, which announced field trials of oilseed rape which had been 'genetically engineered' for resistance to the herbicide Basta. The ad explained that the trials, carried out on Forestry Commission land, would 'compare the growth and survival of conventional and engineered varieties'; it also explained some safety precautions.

According to the research manager, Michael Crawley, he had delayed publishing the ad until after obtaining a MAFF licence for the trial releases (personal communication, 17 July 1992). By the time the ad appeared, the releases had already occurred -- as journalists soon discovered. The next month, the same newspaper featured an article with the headline, 'Genetic test fears', which reported public resentment (Anon/Wreford, 1990). In May 1991, Crawley attended a special meeting of concerned Cornwall residents to answer their questions.

In contrast to Lincolnshire, the Cornwall public reaction cannot be explained simply by Crawley's behaviour, e.g. the delayed advert and apparent secrecy, nor by having used the term 'genetically engineered' rather than 'transformed'. Several reasons can be found in the *Cornish Guardian* article:

* Inadequate consultation: Although the local Environmental Health Officer had discussed the releases beforehand with the chair of the environment committee, he had taken the matter no further: 'We do not view the local council's involvement as being that great. Prime responsibility lies with the Health and Safety Executive.'
* Choice of herbicide-resistance gene: Basta had not yet been licenced for commercial use in Britain.
* R&D priority: 'It is appalling. It proves once again that Cornwall and Scotland, where other tests are taking place, are regarded as expendable. These people should be looking at something of benefit to the world rather than herbicide resistance', declared Jenni Thompson, a local councillor, also a member of the South West Environmental Protection Agency (ibid.).

According to the local journalist, people also feared that the experiment itself would be spraying Basta (Alistair Wreford, personal communication, February 1991). This was a misunderstanding, though not merely so: it perceived this particular 'step' as already bearing and promoting likely consequences of an eventual commercial product. This unease also focused upon the inserted gene for resistance to Basta, as an unlicenced herbicide. By contrast, according to my interviews, ACRE members felt relatively less concerned about any problems from trial releases of Basta-resistant crops than glyphosate-resistant ones: that is, existing herbicide usage would not be disrupted by any mishap from the former releases, such as unintended gene transfer to weedy relatives of crops (see Chapter 8, section 2.1.5).

Local people also feared a threat from large-scale commercial forces. They foresaw the stepwise procedure taking a quantum leap, beyond their control. Although they acknowledged that the Prosamo results could enhance regulatory control over safety, they also regarded the release as a step towards rewarding commercial motives; these were perceived, for example, in the DTI's involvement, in the use of Forestry Commission land, and in the patent on the herbicide-resistance gene (Martin and Tait, 1992: 41-49).

They also cited more immediate, tangible threats: that the transgenic material would disrupt local crops, harm bees, or contaminate honey. They regarded the prior testing as inadequate for averting these risks, though the safety measures were designed to prevent pollen spread (ibid.). Subsequently a national newspaper published an article on 'mutant honey', about potential health hazards from genetically modified pollen (Watts, 1991).

Informally, some regulators attributed their Cornwall difficulties to contingent circumstances, such as the delayed advertisement and recent events there. In a 1988 accident in which the water supply was accidentally poisoned with aluminium, after which the authorities initially denied the mishap and then denied the health damage. Moreover, many residents had settled in Cornwall to escape the contaminations of industrial society.

These special circumstances may have strengthened a collective cognitive basis for perceiving risk more broadly; by articulating pollution threats, they expressed resentment at a sinister environmental control. While local people identified some environmental uncertainties which perhaps could have been tested, they also evaluated this 'step' in terms of the values and commercial forces which it embodied. In effect, their response challenged the stepwise procedure -- which treats biotechnology as a benign environmental control, identifies testable uncertainties, progressively extends the realm of safe experimental control, and so eventually demarcates between 'real versus perceived' risks. Even within Britain's precautionary approach, the stepwise procedure had difficulty containing perceived risks within a particular step.

4.0 VIRAL INSECTICIDE

Another difficult case was a viral insecticide, also known as a baculovirus. The applicant, David Bishop, had pioneered a precautionary approach, in the dual sense of generating evidence of safety and consulting environmental groups. As he stated,

> We have been cautious in our science, in a way that is probably unwarranted in terms of risk; we have done so because it is unprofessional for us to do otherwise. Indeed, our step-by-step approach has affected the regulatory procedures in general. In ten years from now, that careful approach may be seen as unnecessary for our baculovirus,

> but we would rather prove that it is unnecessary by establishing the scientific basis with a track record. (interview, 25 September 1991)

Nevertheless, his R&D trajectory turned out to strain any regulatory consensus on a step-by-step approach.

The test organisms were developed by Bishop's team in Oxford at the Institute of Virology and Environmental Microbiology (IVEM), attached to the Natural Environment Research Council. The unmodified parent organism was a baculovirus called the AcNPV. Although mass produced by Sandoz, the AcNPV was not registered for commercial use in the USA until 1994, and it has not been proposed for registration in Britain.

A baculovirus can fatally infect a susceptible larva which ingests sufficient quantities of virus. In the case of a nuclear polyhedrosis virus (NPV), the protective protein coat is broken down in the larval gut; the virus multiplies in the gut cell nuclei, eventually reproduce their polyhedron coat, and then are released from the larva when it dies and liquefies. The virus may repeat this cycle and thus generate an epizootic (or epidemic). Requiring several days to kill the host, baculoviruses are used more widely in forestry, where trees can tolerate and repair considerable pest damage, than in agricultural fields (Payne, 1986).

The *Autographa californica* NPV (AcNPV) is named after the insect from which it was first isolated. This virus has an irregular host range within the *Lepidoptera*: the most susceptible species are members of the Noctuidae family, while members of other *Lepidoptera* families tend to be susceptible at much higher doses.

Before conducting the first releases of genetically modified AcNPV, IVEM sought to clarify the host range by testing various insect species, selected in consultation with the Nature Conservancy Council (Bishop et al., 1988: 153). According to the NCC Director, later also an ACRE member,

> We asked them [IVEM] to test a range of other species, which they did. The different reactions of very closely related butterflies illustrate the ecological unpredictability.... David Bishop's group are actually exemplars in the way they have tackled both the risk assessment and the publicity end of it. (Derek Langslow, interview 28 August 1991)

In testing the virus' host range, the insect species were chosen partly for their ecological importance, such as moths in the food chain of early-reared birds (Bishop interview, 10 August 1992).

In 1986 the HSE's ACGM recommended approval of IVEM's proposed experimental design. The AcNPV was genetically modified to incorporate a marker gene, designed for tracking the virus' spread and persistence; insect larvae were fed the virus particles and then placed on sugarbeet plants within plexiglass-covered subenclosures, in turn surrounded by netting.

Monitoring showed that the virus persisted within the subenclosures for 6 months, before that area was disinfected. No virus was detected outside the subenclosure, nor inside it after the formaldehyde treatment (Bishop et al., 1988).

4.1 'Crippled' virus

For subsequent AcNPV releases in 1987-89, IVEM deleted the gene for reproducing the polyhedron coat. As the 'crippled' baculovirus would have a reduced persistence, some members of the ACGM's IISC felt all the more comfortable with recommending approval. During that period, 'Other members thought the baculovirus harmless because it was engineered not to persist in the environment', according to one member. However, some were concerned about how the insecticide might develop as a commercial product.

Meanwhile IVEM made great efforts to inform local people about the releases. Bishop emphasized that physical and biological containment measures provided extra protection for an intrinsically safe release. He also cited the potential environmental benefits of eventually substituting a baculovirus for chemical pesticides. There was no reaction from local environmental groups, such as Friends of the Earth.

However, a leading FoE officer expressed concern about an ultimate commercial product. Speaking at a public conference in 1988, he argued that the IVEM trial releases gave a misleading impression of likely GMO products, which surely would not be modified for reduced persistence. He described the crippled baculovirus as 'a Trojan horse for the genetic engineering industry'. Lees quoted a well-known ecologist, Professor Freda Taub, from the University of Washington: 'Engineering [for] efficiency and safety... cannot be addressed simultaneously' (Lees, 1990: 138).

Bishop insisted that these criteria were compatible: 'We know that the "crippled" virus is an efficient biopesticide' (in Wheale and McNally, 1990: 138, 151). However, its efficacy had been demonstrated mainly in laboratory tests. In further field trials, under adverse weather conditions, the 'crippled' baculovirus killed few of the pre-infected larvae (Possee et al., 1992: 49; IVEM, 1991b, Appendix 1).

Beforehand IVEM staff had emphasized the in-built biological safety measure, for example, by claiming that the crippled virus 'should be even safer than the natural virus' (Possee et al., 1990: 58). However, as IVEM shifted its R&D strategy back to the uncrippled virus, Bishop downplayed any difference in safety:

> The polyhedrin-negative [crippled] virus is not preferable for the final product, but it would be preferable for setting up a model system to ask questions about hazards. We want to study how the virus moves among infected caterpillars by using a genetically

> marked virus. If the virus degrades away, there is no environmental risk, but studies showed that its half-life was too short to be useful. We had hoped that it would be effective, but it wouldn't be efficient as an insecticide. So we are now going back to a marked polyhedron-positive virus. I cannot imagine any difference it would make for safety in the trial releases or in the final commercial product. (Bishop interview, 25 Sept 1991)

4.2 Scorpion-toxin virus

For its next test organism, the IVEM team retained the gene for the polyhedrin coat, thus restoring the original virulence of the virus. They also changed the experimental host organism to a more 'permissive' (susceptible) insect, *Trichoplusia ni*, to facilitate an epizootic. Moreover, they inserted a scorpion gene, so that the baculovirus would produce an insect toxin for killing the host somewhat faster, as they had already demonstrated in laboratory tests (Stewart et al., 1991). IVEM was now collaborating with Wellcome Environmental Health, Berkamstead, possibly with a long-term view towards developing a commercial biopesticide. However, the new insect host was not indigenous to Britain, much less a common pest there.

Why choose a gene for scorpion toxin? From an early stage of the AcNPV research, IVEM had anticipated making the baculovirus more lethal. In 1988 Bishop had stated, 'We prefer to insert genes from the caterpillar itself, for example caterpillar hormone genes' (in Wheale and McNally, 1990: 151). As he later clarified,

> We would like to use the hormone because it presents less risk than the scorpion toxin; the hormone gene has been around for the virus [hypothetically] to pick up.... However, the caterpillar hormone [gene] so far is not producing a phenotypic change, even though the gene is expressed. (interview, 25 September 1991)

In their June 1991 application to the ACRE Secretariat, IVEM proposed to test the new baculovirus for insecticidal efficacy under field conditions, by spraying particles onto the larvae on the cabbage leaves. IVEM proposed a further change from the previous design: to contain the subenclosures with netting rather than plexiglass; they would use only a single-barrier containment, on grounds that no virus had been detected beyond the subenclosures in previous trial releases.

ACRE considered the IVEM application at their 9 July 1991 meeting. Some members expressed unease that the experimental design no longer had the in-built biological containment of the crippled virus, nor the double physical containment. Consequently, they attributed greater significance to the virus' persistence, which could multiply any small risk over a long time period (interviews with ACRE members, September 1991). Subsequently the HSE corresponded with IVEM on both environmental and human safety issues, as follows.

Regarding the host range, IVEM's 1989 application had reported the results of laboratory tests on numerous *Lepidoptera* species which were fed the AcNPV at quantities of 10^2-10^6 virus particles. For the unmodified virus, the permissive (susceptible) species included a rare UK butterfly, *Boloria euphrosyne*, the pearl-bordered fritillary (Table excerpted in Rechaussat and Williamson, 1989, Appendix M: 8-9). Yet its June 1991 application defined insects as permissive only if they were fatally infected by 10^5 particles or less; and its list of species included no butterflies (IVEM, 1991a).

Consequently, the HSE asked IVEM why its latest application had a Table of tested insects which included fewer species than in 1989, and which omitted endangered species in particular. In this context, the HSE also expressed concern at the AcNPV's wide host range. The HSE even suggested that IVEM withdraw the application (points cited in reply from IVEM, 1991b).

In his August reply, David Bishop stated that 'We do not wish to withdraw the application since we consider that the answers provided below clarify all the issues raised by ACRE.' He argued that it was more prudent for a Table of permissive species to be based upon repeat tests, comparing the modified virus to the wild type; for this comparison, the selection had been 'biased towards those insect species which are more likely to be susceptible to the AcNPV' (IVEM, 1991b). Thus IVEM investigated only whether the genetic modification altered the host range of the unmodified virus, whose safety was taken for granted.

Moreover, in its June 1991 application IVEM had already dismissed any prospect of the AcNPV causing an epizootic: 'The modified virus would require a continuous replicative chain in permissive species to persist in any environment. This is considered to be an unlikely scenario' (IVEM, 1991a). In its August reply to the HSE, IVEM insisted that an epizootic was unlikely, 'given these [physical] precautions' which would contain the virus (IVEM, 1991b); thus the official safety claim became somewhat qualified.

Unofficially, Bishop discounted any epizootic by emphasizing ecological obstacles more than physical ones:

> In realistic field conditions, it is difficult to see how each insect would find, much less eat, more than 10^1 virus particles at the first instar stage (or 10^2-10^3 at the second instar stage). More relevant than the technically 'permissive dose' is the hundred years experience of epizootics. For example, when the Germans tried to use a baculovirus to control the gypsy moth, no epizootics in other species were observed.... A dead caterpillar could produce 10^9 virus particles, but they would likely get diluted before another insect found that material. From our experience, a second instar needs 10^2-10^3 particles/cm^2 in order to set off a lethal infection (Bishop interview, 10 August 1992).

Thus IVEM cited familiar experiences, including past epizootic studies, as evidence of its experimental safety -- almost regardless of whether the AcNPV might escape from the experimental site.

Challenging IVEM's rationale, an ACRE member asked why the AcNPV is so readily found in the environment if an epizootic is so difficult to achieve. Regarding the virus' host range, 'IVEM has tested only about five butterflies, but we [Britain] have about twenty of them, and butterflies are what people get excited about', he stated. Moreover, he drew an analogy between the AcNPV and the chemical pesticides responsible for eliminating butterflies from the environment.

ACRE members also expressed concern about the scorpion toxin. According to a toxicologist, reluctant to say very much, he had inquired about 'a possible homology between the scorpion-derived insect toxin and molecules of biological interest' (personal communication, 10 February 1992). Other members stated the concern less euphemistically: IVEM had not carried out a computer search for any similar substances toxic to humans. The ACRE Secretariat invited another specialist to provide advice on that question at the 9 July meeting. Consequently the HSE letter (as above) asked IVEM to clarify data on the scorpion toxin's toxicity to mammalian species.

In its August reply, IVEM argued that organisms could not be harmed simply by ingesting the toxin in plausible quantities. Moreover, IVEM regarded toxicity to non-susceptible organisms as an irrelevant issue because the scorpion gene could produce the toxin only by intracellular means in infected insects: therefore the virus' host range superseded any wider range of the toxin. And any 'homology' was irrelevant for a toxin already shown to be insect-specific (IVEM, 1991b). Bishop resented suggestions that he redo toxicity tests already conducted and published by other scientists (interview, 25 September 1991).

That rejoinder raised the stakes for confidence about the virus' narrow host range. In laboratory tests, IVEM had fed virus particles to insects from various genera of *Lepidoptera*, in order to ascertain the LD_{50}, the dose which would kill half the host population. From some ecologists' standpoint, however, such figures wrongly assumed that the infection and kill rates were determined entirely by the number of virus particles, regardless of other factors. Moreover, there was no scientific understanding of why the LD_{50} varied by several orders of magnitude for different insects, including closely related ones, though the standard taxonomy itself was based largely on aesthetic characteristics.

According to one ACRE member, the issue of insect-specificity took on greater importance for contextual reasons. HSE had the statutory authority to forbid a GMO release on human safety grounds, under the HSWA 1974, though not on environmental grounds. The 1990 Environmental Protection Act was not yet implemented, so neither was the statutory requirement on information disclosure. Bound by confidentiality, ACRE members felt that they could not divulge details and publicly raise the safety issues.

The only overt challenge came in a published letter from an ACRE member, who argued that the virus' sporadic host range conflicted with the EC's risk-assessment criteria. He cited the plausible scenario of an unintended epizootic harming non-target insects; in this way, he questioned the technical criteria for how to define a 'permissive' host (Williamson, 1991). His query had some basis in the inherent complexities of modeling a baculoviral epizootic -- for which science had no methodological consensus (e.g. Hochberg and Waage, 1991).

4.3 Containing uncertainty

Given all these concerns, some ACRE members had suggested that IVEM withdraw its proposal, or at least strengthen the physical containment. IVEM instead reasserted its safety claims, e.g. by citing laboratory evidence on the virus' host range and toxin's insect-specificity (as described above, IVEM, 1991b). ACRE members accepted claims that the virus' delivery system was specific to insects, and that a plausible amount of ingested toxin could not harm any mammal. In autumn 1991 the HSE informed IVEM that it was now satisfied with the human safety of the proposed release.

There still remained all the uncertainties about environmental safety, for which IVEM sought the DoE's agreement, even though it was not legally required. Eventually IVEM offered to surround the experimental site with an additional fence and water-filled trench. ACRE's April 1992 meeting recommended approval of the release with the extra containment. As one member reflected, 'We delayed the approval for nine months, but for no longer... Experimental protocols were traded off against uncertain risks -- though that cannot be done for all risks.'

In sum, although IVEM had pioneered a precautionary approach, its R&D trajectory strained the very notion of a thinkable 'step'. By abandoning the in-built biological containment of the crippled virus, the IVEM proposal created a dilemma for ACRE members, who felt reluctant to rely upon the physical containment for safety. In effect, they used the ambiguous pre-statutory situation to request additional evidence of safety, even to challenge the acceptability of IVEM's evidence (Levidow, 1995).

From previous releases, IVEM could cite some evidence for its capacity to identify and contain the virus, but not for the virus' persistence, much less for the basis of its host range in the dynamics of an epizootic. On the other hand, ACRE members had scant basis for directly opposing the release -- especially without evidence of harm or public protest. Although they had some grounds for safety concerns, they were also projecting hypothetical hazards of large-scale use onto this small-scale field trial.

In so doing, and in drawing pollution analogies, they were perhaps 'thinking like members of the public', as some members had advocated (see Chapter 6, section 3.4). In this way, the committee's internal dynamic epitomized a wider social process of accommodating public unease, even prior to official disclosure of the release. Yet such efforts could at most delay the logic of taking the next step towards a more 'efficient' pesticide, while containing uncertain risks in the experimental design.

5.0 CONCLUSION: LEGITIMIZING A 'STEP'

Early GMO releases were intended to push forward the regulatory system, while publicly demonstrating safe control. The experimental design featured biological and/or physical containment measures, though regulatory advisors preferred not to rely upon the physical barriers for ensuring safety. Some advisors regarded the precautionary measures as 'avoiding perceived risks' and so avoiding public alarm.

The safety measures can be interpreted more subtly, as leaving open the stereotypical boundary between real/perceived risks. By anticipating public perception, the regulatory procedure strengthened the hand of advisors who proposed more stringent controls, requested more evidence of safety, or proposed more monitoring. By providing opportunity to challenge safety claims, the procedure effectively reversed the usual meaning of the government slogan, 'sound science' (i.e. awaiting evidence of harm). To some extent, pollution analogies informed this precautionary approach: hypothetical hazards had to be 'perceived' before they could be translated into scientific terms, incorporated into safety measures, and/or empirically tested.

Although advisors held diverse risk perspectives, they could generally reach a consensual response to specific proposals. Such consensus was made possible by formally restricting risk assessment to the particular 'step' at hand. In this way, the stepwise risk-management procedure framed risk assessment, contrary to the stereotypical sequence, which presumes a prior agreement on identifying 'real risk'.

The safety procedures can be interpreted as a 'judicial ritual', as an instrumental action which produces symbolic meanings. The concept of GMOs as novel organisms provided a common symbolic framework for negotiating diverse risk perceptions within the regulatory procedure, which scrutinized each proposed release for suspected guilt of running out of control. The ritual aspect potentially bridged awkward gulfs: e.g. between small-scale safety and larger-scale implications; between technical safety and ethical qualms; or between a 'safe' experimental control and a sinister environmental control. However, such gulfs proved awkward to bridge in at least two cases, a herbicide-resistant crop and a viral insecticide.

In a low-key local protest in North Cornwall, residents emphasized commercial forces involved in the design and future effects of a herbicide-resistant crop. Although they identified short-term scenarios of potential harm, they also evaluated this modest 'step' in terms of its systemic implications for the future. They responded to the GMO as a pollutant in several senses, e.g. as a territorial invasion, as contaminated food or seeds, as a link to an unlicensed herbicide, and as a chemical-dependent programme for agriculture. Indeed, they characterized the herbicide-resistant crop as a sinister environmental control: a NIMBY impulse merged with a NIABY stance of 'not in anybody's backyard' (cf. Tait, 1988, 1990; Schwarz and Thompson, 1990: 20).

The Cornwall episode indicated some regulatory difficulties in formally separating the 'risk' of a release from its R&D trajectory. It resonated with local protest against GMO releases in the USA, where 'The political rhetoric of the popular culture stressed control over its environment' (Krimsky and Plough, 1988: 108-9); the US protest has been interpreted as a 'cultural rationality' confronting the 'technical rationality' of risk assessment. However, as Britain's procedure illustrates, the safety regulation too had a socio-cultural content: in taking precautions beyond technical evidence of risk, it kept GMOs symbolically under safe control, while promoting the advance of biotechnological knowledge.

In the case of a viral insecticide proposed for trial release, the GMO became problematic within the risk-assessment procedure. Some ACRE members associated this GMO with pollution imagery. They questioned the experimental design, especially its reliance upon physical containment for safety; they also transposed long-term uncertainties onto the 'step' at hand.

In requesting more evidence of safety, some members were discouraging the proposed release and its R&D trajectory. Similarly, in other regulatory controversies, opponents have recast a political judgement about acceptable risk into a scientific judgement about acceptable evidence (cf. Jasanoff, 1990: 160, 232). With the viral insecticide, however, more meaningful

evidence of safety could not be readily provided without carrying out and monitoring further trial releases, in turn driven by attempts at enhancing efficacy. Within the regulatory procedure, safety sceptics could only delay an experiment designed to advance knowledge towards a commercially viable pesticide.

In both those difficult cases, a pollution imagery articulated safety concerns, even resentment at an undesirable technological development. To some extent, the precautionary content depended upon such imagery: hypothetical hazards had to be 'perceived' before they could be formulated in scientific terms, incorporated into an experimental design, and empirically tested (if possible). By facilitating this technical translation, the regulatory procedure was containing perceived risks, in several senses of the verb; it was maintaining a 'safe' stepwise control, while displacing anxieties about a sinister environmental control.

Each in its own way, the two difficult cases also illustrate a pervasive tension within the stepwise regulatory procedure. Such tension arose from a procedural rationality which abstracted out technical 'risk' from the commercial forces which constitute the biotechnological project. The authority of safety judgements depended upon treating the particular 'step' alone as the risk-generating system, as if the R&D trajectory were desirable or simply not in question (cf. Wynne, 1982: 172). Nevertheless, with few exceptions, the regulatory procedure successfully demarcated between an acceptable present 'step' and some future step. Thus it could eventually establish a more credible boundary between 'real/perceived' risks.

Chapter 8
A PRECAUTIONARY 'SOUND SCIENCE'?

As described in the previous chapter, Britain's regulatory procedure was symbolically containing perceived risks. The procedure could generally accommodate diverse risk perceptions about small-scale field trials. Officially, relaxation of those initial controls was to be based upon gaining evidence of safety from earlier steps (OECD, 1986: 29, 41).

Given that Britain claimed to base its 'precautionary approach' upon 'sound science', what did these terms mean in practice? What was its basis for making risk assessment more 'objective'? How did it define the range of uncertainty relevant to potential harm? Where and how did value judgements arise in these efforts?

This chapter analyses how Britain's regulatory system prepared for relaxing initial controls. It discusses:
** how biosafety research defined testable uncertainties (section 1);
* how regulatory advisors acknowledged and justified value judgements in risk assessment (section 2); and, in sum,
* how a precautionary 'sound science' remained a contradiction in terms (section 3).
In citing comments from members of Britain's advisory committees, this chapter will identify them by the coding system used earlier (see Chapter 7, section 2): T = trade-union nominee, C = industry nominee, S = other specialist member, D = departmental assessor; also R = member of Royal Commission on Environmental Pollution. This chapter excerpts parts of their cognitive maps in text form, rather than reproduce all the maps; the dash (--) denotes the phrase 'in order to'.

Terminological note: Also as in Chapter 7, here the term 'genetically modified' is often replaced with 'gm' or 'transgenic'.

1.0 UNCERTAINTIES TESTED BY PROSAMO

For regulating GMO releases, the British government declared its intention 'to reduce the risk of harm to people and the environment through precautionary controls supported by rigorous research to improve our understanding' (HMG, 1990: 183). Towards this end, GMO releases used genetic markers to monitor the movement of the organism or the inserted gene.

However, according to ACRE members, most releases provided minimal monitoring of effects relevant for the step-wise relaxation of controls. This was partly because the releasers prioritized testing for the efficacy of the inserted gene or of containment measures. Moreover, the experimental design often limited what could be learned from the release. As one ACRE member said, 'The MAFF people are concerned mainly about the safety of the present small-scale trial release; but if you take precautions to make it safer, then you lose information' (cf. OECD, 1993: 23-24). The results lend themselves to declaring that 'There was no evidence of untoward effects', rather than 'There is evidence of safety' on particular criteria, though the distinction could be ambiguous.

For clarifying scientific uncertainties, there arose an interdisciplinary research effort, promoted by new journals such as *Molecular Ecology*. This research used genetic markers for tracking genes and organisms, thus learning more about ecological relationships. One ACRE member welcomed the opportunity for 'much more rigorous studies' of dispersal and competitive advantage, though he doubted this would fulfill regulators' expectations for a predictive ecology: 'the best that can usually be done is some explanation after the event' (Williamson, 1992: 5). Other biologists emphasized difficulties in studying organisms' behaviour in nature, even by using the new molecular techniques, which could yield misleading results (e.g. van den Eede and van Montagu, 1992).

Nevertheless, the regulatory system attempted to specify research which could inform the step-by-step relaxation of controls. Many countries funded biosafety research designed to clarify particular uncertainties. In Britain, these included various DoE-funded projects and the Prosamo programme, as analysed below.

The DoE funded a diverse range of projects, including basic ecological research relevant to GMOs though not using them. These areas initially included: improving techniques for identifying, tracking and isolating organisms; detection and impact of gene flow to feral populations; identifying factors which facilitate invasion; and developing techniques for monitoring the impact of introduced organisms on established communities (DoE, 1991).

Prosamo, the 'Planned Release of Selected and Modified Organisms', began in 1989 as a three-year £1.5m research programme, jointly funded by the DTI, AFRC and industry. Its sponsors expected the research to resolve key uncertainties, so as to justify relaxing initial controls on GMO releases. Unlike its microbial research, the plant research used GMO releases -- specifically, seeds for transgenic crops already closest to the market stage (Fishlock, 1993).

Although Prosamo used the genetic markers to research safety questions, the marker genes had been inserted for commercial purposes.

Prosamo's initial aims were three-fold: to develop better methods for detecting specific micro-organisms, to detect any enhanced competitiveness of transgenic plants, and to detect gene flow from crops (Prosamo, 1989; Young, 1989). The rest of this section will examine the three areas, in turn, while juxtaposing Prosamo with the wider risk debate.

1.1 Microbial monitoring

In general, GMO regulation faced greater difficulty in assessing microbial releases than plants. For some regulatory advisors, this was partly because the intended effect of a transgenic plant is more direct than that of a transgenic micro-organism intended to carry out an indirect effect, e.g. a biopesticide. Moreover, recent studies indicated that 'natural' gene transfer goes beyond the limits observed in the laboratory and beyond the microbiologists' classifications of microbial species (Davies, 1990; Maynard Smith, 1991). This greater knowledge could imply greater ecological uncertainty, warranting further research.

By 1991 the only release of transgenic bacteria had been *Rhizobium*. As it forms nodules on plant roots, *Rhizobium* was considered more readily detectable than other micro-organisms. At the same time, the root environment was associated with ecological uncertainty: 'Because roots leak nutrients into the soil, organisms can grow relatively rapidly in the rhizosphere. You find them in high densities, which maximise the possibility of genetic exchange between microbes and plants, or among microbes' (interview with ex-IACI member, 24 March 1991). Research projects other than Prosamo were investigating this 'microbial hot spot', so labelled by rhetorical analogy to radiation hazards.

For microbes in general, better detection techniques were sought in order for trial releases to enhance scientific knowledge about bacterial survival, mobility and gene transfer. Prosamo focused upon developing techniques for marking and detecting two representative soil bacteria, *Pseudomonas fluorescens* and *Bacillus subtilis*. The latter, whose genetics was well known, had long been used as a model organism for studying gram-positive bacteria. Prosamo sought to detect low numbers of those microbes, amidst a large background of indigenous organisms.

Prosamo awarded contracts to two academic departments, each for a different detection technique, to be used initially for monitoring microcosms. Professor W.A. Hamilton at Aberdeen University led a research project which genetically modified bacteria by inserting a Lux gene, whose expression lights up each GMO cell. By using a special microscope, direct

observation of this bioluminescence could detect just a single colony in a treated soil sample, and thus see where the gene has gone.

Meanwhile Professor Tim Gray at Essex University led a project using automated flow cytometry (AFC). AFC rapidly sorts large numbers of individual cells according to their binding with immunofluorescent antibodies; it can also store selected cells for subsequent culturing or further tests. Its automated facility can detect lower-intensity fluorescence than the human eye could do.

The AFC machine was originally devised by medical cytologists for quantifying animal cells. Subsequently, other institutions developed it for identifying specific bacteria in water and in soil (Pickup and Saunders, 1990; Page and Burns, 1991). By extending AFC to the two soil organisms designated by Prosamo, Essex University found that the machine not only could identify them within soil samples, but also could distinguish between the vegetative and spore forms of *Bacillus subtilis*.

How might this technique assist monitoring a microbial release? According to Tim Gray, its rapidity would allow monitoring to look at a greater proportion of the soil microflora than previously possible; detecting spore forms is particularly important, as they could act as a long-term genetic reservoir. However, he remained 'healthily sceptical' about how well such sampling could represent the population at hand, especially in field conditions:

> You might not get a representative sample because the bacteria are not uniformly distributed throughout the soil sample; they will occur in clusters in specific places, partially inside organic particles, and be hidden. For that sort of reason, microbial ecology is based on the supposition that you are dealing with a non-uniform environment. And microbes may have a different physiology in the soil than they have in the test tube. [By contrast] laboratory microbiology takes for granted a more or less uniform environment that you've constructed, and supposes that you can keep the cells going under constant conditions. From our background in microbial ecology, we are more concerned about what we're missing than what we're finding in our samples (Tim Gray, interview 24 March 1991).

His cautious view may indicate why the Prosamo committee short-listed bids only from institutions which had backgrounds in microbial ecology, even though other laboratory microbiologists had already developed similar techniques.

What were the prospects for requiring the routine use of AFC for monitoring a GMO release? As the machine involves a level of cost and sophistication similar to an electron microscope, institutions might have difficulty buying one, though conceivably they could send soil samples for AFC analysis elsewhere. Its prospects could depend upon the machine's sensitivity: 'What we're trying to do is to increase the sensitivity, to detect a smaller number of cells in a bigger background; so that, if we're doing a depth or survival curve, we don't have to extrapolate

downwards; we can actually measure it downwards' (ibid.) According to a DoE-funded assessment, however, AFC was 'judged to represent poor value for money, requiring extensive development for utility' (DoE, 1991). Thus, perhaps echoing the BATNEEC criterion, this 'best available technology' apparently entailed excessive cost.

In any case, even by identifying individual microbes, science would remain far from establishing the 'baseline of normality' which some ecologists were seeking for risk assessment. And even if better detection techniques could identify individual microbes, regulatory policy faced scientific disagreements over how and even why to monitor gm microbes.

Such issues arose publicly at Regem 2, the second international conference on the 'Release of Genetically Engineered Micro-Organisms' [GEMs], held in August 1991. Some participants, mainly among the few ecologists present, anticipated GEMs perturbing an ecosystem in unpredictable ways, possibly generating hazards not yet identified. An official from Britain's Health and Safety Executive posed the question: how can monitoring measure a GEM's impact, unless the ecological baseline is known?

In that spirit Professor Jim Lynch, from the AFRC Institute of Horticultural Research, welcomed the use of genetic markers to study the impact of introductions on a natural microbial community, measured against its critical baseline factors, especially by monitoring its dominant members. Rather than attempt to detect all prevalent microbes in a population, some ecologists proposed to survey its collective properties. That is, by measuring a metabolic profile, a microbial population could be monitored for unusual changes after introducing a GEM (reported in Colwell, 1992; Levidow, 1992a).

By contrast, some Regem 2 participants regarded a perturbation in itself as irrelevant to assessing whether genetic modification could or does make an organism more harmful. Laboratory scientists in particular wanted to focus any such anticipation upon identifiable hazards, some of which were deemed acceptable. According to John Beringer, the Chairman of ACRE, the multiplicity of organisms in an environment means that knocking out one species probably wouldn't matter (ibid.: 57). Thus different concepts of environmental stability favoured investigating a different range of natural facts.

There was also a conceptual divide over whether novel niches are limited by genetic novelty and/or by environmental constraints (see Chapter 4, section 1.2). According to recent ecological research on a particular micro-organism, only a few genetic variations are found across diverse environments. Different scientists interpreted these same results in opposite

ways: i.e., to suggest that niches are limited by environment or, alternatively, by natural genetic recombination (ibid.: 57; Bale et al., 1992; Young and Wexler, 1988). The latter model implied greater ecological unpredictability from releasing GMOs.

In summary, new evidence could lend itself to different models of the scientific uncertainty relevant to risk assessment. Conversely, environmental values could influence priorities for biosafety research, even the criteria for meaningful detection techniques, as in Prosamo. Thus the regulatory system faced dissensus on what 'uncertainty' had to be reduced.

1.2 Competitive advantage of transgenic plants

The early GMO debate featured a dispute over the 'excess baggage hypothesis': Would the metabolic demands of an inserted gene weaken the competitive ability of an organism? Or alternatively, could an inserted gene induce pleiotropic effects which, for example, make a crop more weedy?

Speculation on competitive advantage was further complicated by differences in conceptualizing 'the natural environment'. As a US ecologist argued, 'whether or not certain natural communities will reject new species [e.g. a GMO] will often be an irrelevant issue, since much land is obviously disturbed and much that looks natural is not really natural' (Regal, 1987: 78; cf. Dixon, 1988: 21, 24). This argument could work both ways: a 'disturbed environment' could explain away documented weedy behaviour as a special case, or it could warn against presuming behavioural predictability in any environment.

Scientists' views on predictability have depended somewhat upon how they conceptualize familiar crops and weeds. In particular, some ecologists have identified up to twelve plant characteristics which correspond to weedy behaviour. Rating some well-known crops, one ecologist drew a sharp division between those crops and weeds; accordingly, pleiotropic effects would need to change several characteristics in order to transform a crop into a weed (Keeler, 1989).

Other ecologists criticized her selectivity, and even the entire rating system, for exaggerating the difference between crops and weeds. Indeed, the distinction becomes particularly misleading for some plants which are treated agronomically as a crop in one place and as a weed in another (Fitter et al., 1990). The latter authors argued for taking special precautions with GMOs derived from crops which are already minor weeds; for example, oilseed rape grows on roadside verges and potatoes persist in following crops (Williamson et al., 1990).

Some of these uncertainties were addressed by the Prosamo programme, in studies done by Michael Crawley of Imperial College (see also Chapter 7, section 3.2). He proposed to carry out sufficient GMO releases in order to draw meaningful generalizations from the results, but encountered regulatory pressures to limit the releases. According to him, the DoE's earlier advisory committee (IACI) took the view that Prosamo was trying to do too much, too quickly; they saw it as too ambitious, going beyond the step-by-step approach (interview 10 July 1990). As one MAFF official explained, they wanted to ensure that the GMO releasers 'would have adequate resources to deal with unexpected conditions', and to avoid widespread dispersal of transgenic pollen which might harm human health (interview, 27 April 1990), though Prosamo eventually overcame these reservations.

Crawley advocated approaching ecological complexities with 'reductionist tools', by isolating testable parameters to answer simple questions: e.g. in the absence of any obvious selection pressure, would genetic modification itself enhance the competitive advantage of a crop? He initially carried out trials to provide baseline data on the persistence and invasive capacity of familiar crops. Subsequently he compared the behaviour of transgenic crops with their unmodified versions.

In the Prosamo trials through 1991, the transgenic crops had genes inserted for kanamycin resistance and herbicide resistance -- without, of course, applying those chemicals in the fields. In 1990 Crawley carried out trials on oilseed rape, at four different sites, with four different habitats. In all the habitats without cultivation, not a single seed reproduced; in some cultivated habitats, the transgenic versions were slightly less viable than the unmodified crop (Cherfas, 1991; Crawley, 1990, 1991). Similar patterns were confirmed after two generations and with more varied habitats (Crawley et al., 1993).

He announced his early results as meaningful evidence of safety: 'The preliminary results of the Prosamo experiments suggest that transgenic rape plants are unlikely to pose more of a threat to the environment than their conventional counterparts' (Crawley, 1991: 148). After several such trials on potatoes, maize and oilseed rape, a brochure concluded: 'Although repeats are still needed, to allow for our variable climate, early results indicate that these crops, at least, are unlikely to pose significant problems' (Prosamo, 1991).

These reassurances conflated 'crops' with 'crop-gene combinations', as if pleiotropic effects were independent of whichever gene might be inserted. Moreover, some ecologists had expressed greater concern about inserted genes which could more plausibly enhance viability, such as for a toxin which provides resistance to insects. Crawley did not expect much differential effect from such a gene, as he regarded competition with other plants as a more

important factor than insect predation (Cherfas, 1991), though he later reserved judgement (Crawley et al., 1993), as did his Prosamo colleagues (Dale et al., 1993: 15). Thus there remained a methodological indeterminacy over how an experiment could best simulate the conditions in which a genetic modification might turn a plant more weedy.

1.3 Gene flow from transgenic plants

With the prospect of unintentional gene transfer from a transgenic plant, safety questions are extended to all relatives with which it might hybridize. Not only pleiotropic effects, but also resistance to pests or herbicides, could be transferred to weedy relatives. Although such 'leakage' back and forth is nothing new, the transgenic origin and character of the inserted gene broadens the range of possible effects; this new uncertainty met different scientific interpretations.

As some ecologists argued, there are already documented cases where gene flow from crops has generated more aggressive weeds, which can be more difficult to control, especially where they mimic the crop. Moreover, while traditional breeding has generally selected for traits which would be maladaptive in weeds, genetic modification can more readily insert genes intended to confer a fitness advantage. From this perspective, past agricultural experience serves as a warning: 'The hazards created by crop-weed hybridization are not unique to genetic engineering' (Ellstrand and Hoffman, 1990; cf. Young, 1989). By contrast, some scientists cited past experience to downplay potential problems: 'Evidence from crosses between weed species and conventionally bred varieties indicate that hybrids tend to become more crop-like rather than aggressive weeds' (Dale, 1991). This reassurance took for granted a naturalistic model of the uncertainty, conceptualizing the agricultural context as merely environmental variations.

For early GMO releases, risk assessment considered the traditional agronomic practice of maintaining a standard isolation distance in order to protect a crop's purity from contamination by weedy relatives. That precaution was widely regarded as inadequate for GMO releases, for several reasons: effective pollen contribution from a crop to a weed might be different than vice versa (Ellstrand and Hoffman, 1990); and an acceptable level of crop contamination by a weed might be regarded as an unacceptable level of weed contamination by a GMO (ACRE, 1992: 5). The prospect of generating a more competitive weed, which could displace other wild plants or invade agriculture, raised the stakes for knowing more precisely the extent and effect of transferring the inserted gene. However, argued one ACRE member, long-distance gene flow depends upon so many factors that it is 'almost impossible to conceive of trying to measure it' (Chris Gliddon, quoted in Young, 1989).

In Prosamo, all these ecological-agronomic complexities were analytically reduced to two questions: What is the extent of unintended gene transfer? What is the viability of the unintended hybrid? The investigation was carried out by Professor Richard Flavell and Philip Dale at the AFRC Institute for Plant Science Research (which moved from Cambridge to Norwich, becoming part of the John Innes Institute).

In order to measure gene flow, they planted transgenic crops, with an inserted genetic marker, near their unmodified counterparts and/or weedy relatives. In the case of oilseed rape, which is insect-pollinated, transgenic progeny more than 100cm from the transgenic source were so few in number that further experiments would be needed to substantiate the figures (Prosamo, 1991). Another release planted out transgenic Desiree potatoes, also insect-pollinated, near its *Solanaceous* relatives; after screening the progeny, no evidence of crossing could be found (Phil Dale, interview 27 June 1991). Next on the experimental list would be sugar beet, which is wind-pollinated; its pollen was already known to travel more than a kilometer and to hybridize with weedy relatives, so it might provide less reassuring or less reproducible results. For each gm plant, 'We attempted to design an experiment that would give a statistically significant answer for the environment in which it took place', rather than attempt to represent a wider environment (Richard Flavell, interview 27 June 1991).

Second question: What would be the viability of any hybrid? From greenhouse studies of attempted crosses between potatoes and their relatives, Prosamo had 'no evidence of any hybrid being produced'; using high-tech means to hybridize oilseed rape with a close relative, the research found that the hybrids 'tend to be sterile, which acts as another barrier to gene spread' (Cherfas, 1991). The barriers for potato were confirmed by a Dutch plant breeder in attempting to transfer disease-resistance genes from another nightshade; he attempted thousands of pollinations with embryo culture but produced no viable hybrid (Philip Dale, interview 27 June 1991; cf. Dale et al., 1992: 75).

What blocked the hybridization process? Here Prosamo took a null result as cause for further investigating why, rather than for presuming safety. The explanation mattered because, according to Philip Dale, 'The further it gets through the [hybridization] process, the more likely it is that that rare event will happen' (quoted in Young, 1989).

1.4 Demonstrating safety?

What safety conclusions could be drawn from Prosamo's results? Industrialists, as well as some ACRE members (e.g. D5), hoped that Prosamo would help regulators to categorize crops according to their safety and predictability for GMO releases. They sought to vindicate particular crops of suspicion of unintended behaviour, such as gene transfer, regardless of the

inserted gene. Otherwise, it would be extremely expensive to carry out Prosamo-type experiments on every crop-gene combination intended for release.

In this vein, a Prosamo contractor spoke about gene flow:

> It would be difficult to extrapolate from genes inserted now, to those inserted in the future. So we decided to concentrate our efforts on the crop factors, of which the most important are cross-compatibility, and the distance that pollen will travel and give cross-fertilization. Once we have generated data on those two factors, it can be used for all subsequent field releases with those crops, starting with potatoes and oilseed rape (Philip Dale interview, 27 June 1991).

On the basis of such data, the experimental protocols were simplified for small-scale field trials of GMO releases, by allowing a shorter isolation distance and the presence of weedy relatives (Dale et al., 1992: 76).

A public-relations account of Prosamo soon appeared in an industry-sponsored exhibition, *Biotechnology for Europe '92*. In the section entitled 'Demonstrating Environmental Safety', it summarized the Prosamo results as follows: 'Careful studies with modified plants show that gene dispersal is minimal' (CIA, 1992). Although technically accurate, the claim implied that the results demonstrated the safety of transgenic products. Similar reassurances came from Prosamo itself (Prosamo, 1991; Fishlock, 1993).

However, some ACRE members regarded the Prosamo results as relevant mainly for assessing small-scale field trials, rather than for resolving longer-term, large-scale uncertainties. 'An experiment may be related to the component parts of an ecosystem, but not to the totality; I'm not sure Prosamo understands that' (S2). One member (T2) had anticipated that the results 'would probably confirm the suspicions on which the committee has been acting', e.g. regarding isolation distance. Another (S10) put this more strongly,

> Prosamo will be of no use to us because it is looking at whether a minor modification has an effect; each organism's ecology is unique, so an aspect of ecology could affect one crop but not others. We are now getting better data on gene flow, but the rare, long-distance event is often the most important one. Knowing the isolation distance is useful at the preliminary stage but irrelevant for commercial introduction.

Prosamo contractors acknowledged some limits to the safety conclusions. As Michael Crawley stated, 'There is no way that you would carry out an introduction based on it [the GMO] being a supposedly safe distance from a potential recipient, if the product of that cross-pollination would be seen as hazardous' (interview, 10 July 1990). His Prosamo colleague concurred:

> The isolation distance derived from our data would be used in the evaluation phase [small-scale field trials of a GMO]. During that period, a decision has to be made as to whether the gene would be safe if it got into adjacent crops or wild species. Once a gene is accepted as having no adverse consequences, then isolation could no longer be practiced... If you were particularly concerned about a gene transferring, then you

> should question whether that gene [in a GMO] is an appropriate release (Philip Dale, interview 27 June 1991).

Regarding competitive advantage, even the most cautious ecologist did not expect a few trial releases to yield evidence of an invasive problem; any pleiotropic effect would be a rare occurrence, and enhanced viability even rarer. As Philip Dale acknowledged, any test for competitive advantage would require the presence of some relevant selection pressure for the inserted gene. Yet how would such interaction be meaningfully tested?

Taking up this question, an ACRE member proposed a more daring test of potential consequences: 'A better experiment [than Prosamo] would be to take a gene from oilseed rape which changes a protein in the seed, and put the gene into weedy turnips.' As a *Brassica*, that plant is a wild relative of oilseed rape; and the protein change in seed could change the rate of predation, one way or the other (cf. Williamson, 1992: 4). Such an experiment could better simulate the few cases where unintended gene transfer might enhance viability under some plausible selection pressure.

As some ecologists further argued, the effects of slightly different environmental conditions 'are likely to be minor compared to the different management practices or habitat factors (such as predators) that will be experienced'. Consequently it might be difficult to determine which habitats are appropriate for testing the weedy potential of a GMO (Perrins et al., 1992: 48, 54). Those systemic factors also pose difficulties for making behavioural predictions on the basis of trial releases, especially for crops which already have weedy characteristics, such as oilseed rape, potatoes and sugar beet (Williamson, 1992: 3).

Taking their logic even further, one could imagine the following 'thought experiment': insert a herbicide-resistance gene into a weedy relative of a crop, plant it near fields where the herbicide is being sprayed routinely on the crop, and monitor the weed. Of course, such a simulation of hazard might be regarded as too hazardous or alarming -- hardly 'allowing the public to feel comfortable' with GMO releases (see Chapter 7, section 1). This thought experiment illustrates an inherent dilemma in finding acceptable ways to test plausible hazards.

Moreover, the different interpretations of Prosamo's results derive from different concepts of the environment, e.g. as stable or fragile. Portraying the environment mainly as a threat to crops, some industry officials posed a semi-rhetorical question about unintended consequences, such as gene flow: '(Why) does it matter?' (cf. OECD, 1993: 27). Trial releases could not answer that question by analytically reducing ecological complexity to testable uncertainties; yet neither did the tests simulate hazardous effects.

Lastly, for the hypothetical hazard of GMOs enhancing weedy behaviour, science lacked even consensual criteria for defining such a phenomenon. In a DoE-funded survey, scientists were asked to rank plants on an ordinal scale of weediness: in their replies, members of different disciplines gave significantly different scores to the same plant. As the authors note, 'a weed classification can depend almost as much upon the interests of the scientists producing it as the weediness of the plants themselves' (Perrins et al., 1992: 54). Thus evidence of weediness depends upon one's cognitive framework -- in designing research as well as in interpreting its results; safety tests invariably favour some account of the uncertainty rather than another.

2.0 VALUE JUDGEMENTS IN RISK ASSESSMENT

Surveying some high-profile biosafety research, the previous section described some problems of reducing environmental complexities to testable uncertainties, so as to minimize value conflicts over unintended outcomes. This section describes parallel problems in risk assessment, by drawing upon comments from members of the regulatory advisory committees, particularly ACRE and its predecessor committees. (Again, excerpts from individual cognitive maps use the dash -- to denote 'in order to'.)

Alongside pressures to contain perceived risks (see Chapter 7), ACRE members felt under various pressures to accept proposals submitted for GMO releases. According to one member (S9), industry and MAFF members often expressed the view, 'Let this technology go forward' for the sake of expected benefits, though not to push through any particular GMO release. 'In real terms, the individual members are under pressure from industry to move faster' (S2). And that pace became formalized in rules requiring a government reply to each release application within 90 days: 'I doubt you could have a full, open debate within that short timescale' (S1). One member expressed some resentment (S8): 'The people pressing for releases are either manufacturers themselves or scientists in the pay of the manufacturers; it is definitely profit-driven.'

Implicit government policy sometimes hindered obtaining additional evidence of safety: 'The committee must follow the government line to regulate releases, rather than obstruct them -- accept that GMO release will go forward, rather than press one's reservations -- accept that desired (though trivial) safety data may be missing' (excerpt from cognitive map D3). Regarding such data (S1), 'The committee is under commercial pressures in deciding the policy question of what testing we can reasonably expect a company to do.' Complained one member (S10), 'The committee is stacked in favour of GMO releases because of ACRE's remit: it has to prove that a release will be an environmental hazard, and that's difficult to do.'

To some extent, those tensions become personified within the committee.

> Some members are out to find the problems, and then look for safety reassurances. Other members see the burden of proof the other way; their value judgement is that the release is safe unless someone produces facts to show otherwise. The latter view comes mainly from those with an academic background in genetics, molecular biology or microbiology, almost regardless of their official role (e.g. trade union, industry, independent, etc.). The civil servants are cautious; industrialists are in favour of release but will be as cautious as anyone on the committee (S10).

Said another (S11), 'In the committee discussion you can get a hawks-doves split, but it's a great mixture and it depends upon the proposal.'

According to another member, the committee 'walks a finely balanced line between safety and innovation', towards making risk-assessment criteria and administrative costs more predictable: 'The committee accepts the duty to formulate a standard protocol -- industry knows the extent of the testing requirements -- industry can decide on investment in particular GMO categories' (excerpt from cognitive map S8). In all these ways, diverse pressures become translated into criteria for generating, evaluating and eventually standardizing new scientific information.

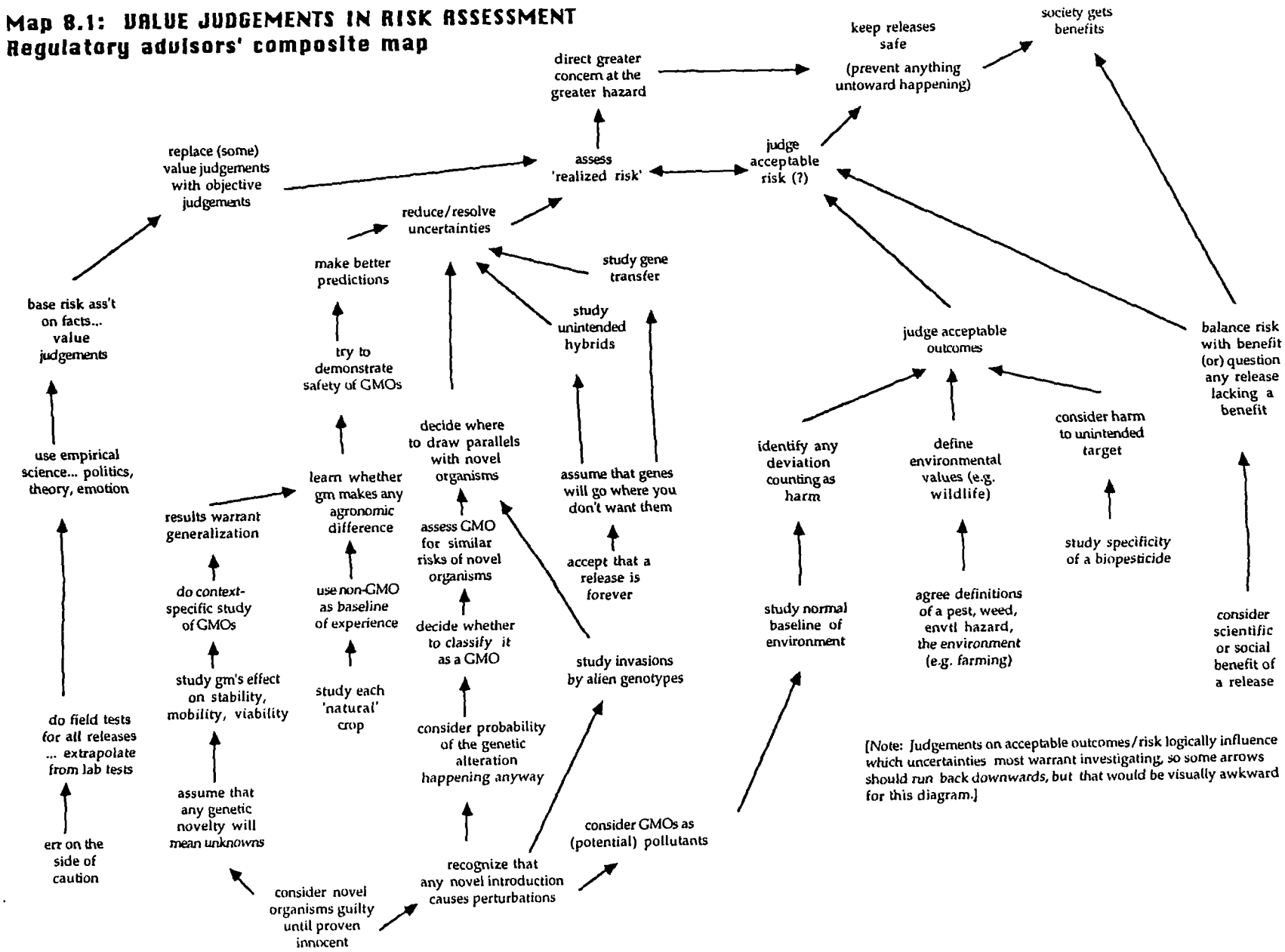
2.1 Regulatory advisors: composite map

Drawn from interviewees' comments, Map 8.1 depicts the sorts of value judgements which arise in risk assessment, especially in preparing to relax controls. Interviewees generally interpreted the term 'value judgement' to mean the likelihood of harm from a GMO release. When asked about the acceptability of definition of environmental harm, some interviewees gave interesting answers, though many were reluctant (see sections 2.1.5-7).

Regulatory advisors expressed different views on how to make value judgements, as explained below. Their differences did not lend themselves to entirely distinct maps which would consistently distinguish some advisors from others. Therefore a single composite map encompasses all of them (see Chapter 2, section 5.2).

In this map, all the concepts lead to 'prevent anything untoward happening', in order to 'keep releases safe', so that 'society gets benefits'. Of course, the former aim leaves open the question of whether most releases would be just as safe without the precautionary measures or special regulatory procedures. Acknowledging that ambiguity, one member (C3) emphasized that regulation should 'prevent *potential* environmental harm'. That aim entails conflicts over how to assess the likelihood or acceptability of undesirable outcomes, as indicated on the left and right-hand sides of the map, respectively.

Map 8.1: VALUE JUDGEMENTS IN RISK ASSESSMENT
Regulatory advisors' composite map



The map links the lower-order concepts to intermediate ones, near the top. Moving from the left to right, these concern how to:

* replace value judgements with objective judgements;
* detect any agronomic difference;
* draw parallels with 'novel organisms';
* trace gene flow;
* judge acceptable outcomes; and
* consider benefits of GMO releases.

Formally, the cognitive map depicts these penultimate concepts leading to the higher ones, e.g. judge 'realized risk' and 'acceptable risk'. Informally, the sequential logic also runs back downwards (see section 2.1.7).

2.1.1 Replace value judgements (column 1):

For reasons of safety and legitimacy, though with varying emphases between the two, there was wide agreement on taking a cautious approach. For example, 'err on the side of caution' (S8,S7); indeed, 'be almost over-cautious' and thus avoid even minor environmental damage, such as a plant going weedy (S7). Similarly, 'overdo controls with pioneering examples' (C2). Hence the widely accepted need to 'do field tests for all releases, rather than extrapolate from lab tests' (eg S8,C3).

Such experience would enable regulators to 'use empirical science, rather than politics, theory or emotion' (e.g. C1,S8) and thus to 'base risk assessment on proven facts' (D9,D2,D5). Additional scientific information would enable the risk assessment to 'replace value judgements with objective judgments', at least to some extent (D9,S1), and to deal with potential effects 'in a rational way' (D3).

Some members, especially CBI nominees, suggested that science could entirely replace value judgements; one (C1), for example, aimed to 'get beyond the art of plant breeding', presumably to some truly objective science. Some (C4,C3,D5,D9) advocated quantifying real risks for each release; eg 'reduce unquantified risk into a more precise form' (C4). By collecting appropriate evidence, one said (C3), ACRE could answer the 'what if?' question by ascertaining a negligible risk, rather than have to make awkward value judgements on its acceptability. Another saw the quantification helping to allay public fears: 'find the chances [risks] are small at each step -- give a fair degree of safety -- the public feels regulators are aware of its anxiety' (excerpt from cognitive map S12).

By contrast, others (S1,S8,S10) ridiculed attempts at quantifying risks. At least initially, 'The regulation boils down to a few pragmatic statements of principle, all these cliches they churn out; the risk assessment is based on all manner of fictions' (S8). And others (T2,R1) emphasized that the committee exists in order to make value judgements about uncertainties,

not to cite pure facts or to quantify risk; after all, value judgements are integral to ecology (R2).

One member (S1) emphasized that the people involved in GMO releases won't act exactly as expected, so actuarial information from minor accidents should be added to the monitoring data. Whenever farmers allow herbicide spraying to go outside their fields, for example, their behaviour would affect any weeds which acquire herbicide resistance. His emphasis on agronomic practice challenged any naturalistic account of making risk assessment 'objective'.

2.1.2 Anticipate any agronomic difference (columns 2-3):

As a commonly stated aim of safety precautions, members sought to 'learn whether genetic modification makes any agronomic difference'. In the context of the 'product versus process' debate (see Chapter 4, section 1.2), a subtext was how uncertainties might arise from the genetic modification technique and/or its resulting novelty.

Some members mentioned the gm process as a possible source of uncertainties: for example, the genetic stability of mobile vectors (D3) or of gm vaccines (D5), or factors inadvertently altered by gm (D5), or potential behavioural changes due to the fact of gm, not just from the type of gm (S8). All these uncertainties needed to be tested. For industry, 'You need to take precautions until you are sure of a new technology' (C3), almost as if the gm process itself were on trial.

For most members, however, the risk problem arose mainly from the genetic novelty. The starkest formulation came from one member who accepted that 'gm is generally safer and more predictable' than earlier techniques, but the committee rightly considered 'novel organisms as guilty until proven innocent' (T2). In that cautious view, 'assume that any genetic novelty will mean unknowns, rather than assume that a precise genetic change makes the results more predictable' (S8,D3,D6,S1). Some GMOs could not have arisen naturally, so we should recognize their potential for a striking impact (R2). For example, the added gene might make the organism or its wild relatives more weedy (C2,D3,S1,S10). By contrast, other members (S5,C1) felt that GMOs are benign, provided the introduced gene doesn't provide a competitive advantage; they implied that science can readily know or ascertain whether the gene would do so.

Suggesting greater predictive complexity, some emphasized that ecological behaviour such as weediness depends upon environment, as an analogy to GMOs' potential behaviour (D3,T2,S1). Some advocated context-specific monitoring of unexpected effects (S8,S2,S1), so that the trial-release results would warrant generalization for diverse contexts. Emphasizing uncertainties about what makes micro-organisms pathogenic, one ecologist expressed concern that 'a new piece of genetic information could lie there until an advantage comes about'; he proposed adopting 'a Gaia model of mutual equilibrium between organism and environment' (S2).

Members advocated studying the possible effect of gm upon genetic transfer or instability, as well as the organism's mobility and viability -- albeit for somewhat different reasons. Some (D2,S12) expected that GMO releases would show that gm confers a disadvantage for survival and dispersal, according to the 'excess baggage' hypothesis. Others, particularly ecologists (e.g. S8,S10), criticized that assumption.

It was considered necessary to study the 'natural' or wild-type form of each organism as a baseline of experience (S5), e.g. so that trial releases could monitor GMOs for enhanced weediness or genetic transfer from the organism. Thus, in assessing evidence of a GMO's behaviour, they could 'learn whether the gm makes any agronomic difference'. By the same token, it was necessary to study non-gm, live vaccines, for making comparisons to gm vaccines (D5).

From those comparisons, accumulated experience and a database (C2,D4,D2), regulators could 'make better predictions'. By eventually codifying data from field tests, they could 'build a case law' (D5) and 'develop a science of releases' (S7). However, members attributed somewhat different significance to 'the baseline of experience' in agriculture.

For example, one member wanted the committee to 'develop a detailed [safety] checklist for the lead crops', rather than duplicate the list each time a GMO release is proposed; thus, a study of the unmodified organism would help to 'clear each crop for gm' (D3), independently of the particular inserted gene. In a similar comment, 'Risks can be assessed pretty closely from experiences with other organisms, with similar organisms' (S7). More sceptical about such predictions, another (S8) advocated studying agricultural ecology, rather than take the complacent view of the 1986 OECD report. In that vein, some members cited a special problem with oilseed rape (S1,S10), which already shows weedy characteristics, as well as sugarbeet (T2), whose cultivation already encounters problems from weedbeet, which may interbreed with it.

The case of the potato highlighted various concerns about a familiar crop. One member had challenged an applicant's reassurance that the potato isn't frost-hardy, and questioned whether all parts of Britain get frost every winter; for him, such uncertainties might become a problem when small-scale releases go large-scale (S1). Another member (S9) raised the prospect of global warming, whereby declining frost may allow the survival of GMOs that are presently assumed to die over winter. Some (S1,S5,S10) felt that the potato, already a minor weed in agriculture, could become a more serious one, especially if transgenic potatoes gain frost resistance, though there was no sign of such R&D.

In summary, the goal of improved predictions remained problematic, given views about an inherent ecological complexity, as well as some worrying characteristics of 'familiar' crops.

2.1.3 'Draw parallels with novel organisms' (column 4)

There was wide agreement upon taking genetic novelty, especially genetic recombinations across species, as the main cause for concern and criterion for adjudicating whether an organism was a GMO. The emphasis on genetic novelty, more than the gm process as such, has guided safety regulation of gray areas such as organisms derived from protoplast cell fusion. Members have considered the probability of the particular genetic alteration happening naturally, or its feasibility via an earlier technique; and the criterion is applied to cytoplasmic DNA, such as in organelles, as well as nuclear DNA. Thus the regulation should 'include interspecies but not intraspecies cell fusion' (T2), and should include 'any cell fusion that couldn't otherwise be achieved directly' (S1). As others said, gm is not just about particular techniques but about crossing species boundaries (S9,S11).

Again, emphasizing genetic novelty, there was wide agreement with the administrative decision to regulate GMO releases together with non-indigenous organisms, in order to 'assess similar risks of 'novel organisms' (S5,S8,S4,D3,T2,D6,C1,C3). By widening ACRE's remit to encompass all novel organisms, the regulation would be 'logically consistent' (T2). However, that apparent agreement contains a tension regarding where to draw parallels between GMOs and 'novel' organisms (D3). With a GMO, 'we are dealing with what is in effect a non-indigenous species' (S11). In that vein, we should study invasions by 'alien genotypes', for their relevance to GMOs; drawing that parallel, some members emphasized unpredictable effects of a single-gene alteration in an otherwise familiar organism (S8), even in familiar crops (S1).

Others accepted the parallel for administrative purposes but doubted its substantive validity for risk assessment. They expressed confidence about the predictability of the GMOs which they could foresee being released (T2,C1). Field tests would help to 'prove that the probability of the unexpected from gm is low' (D2), 'to confirm the predictability of GMOs' (D1).

Some acknowledged some unpredictability for transgenic crops but foresaw no hazardous effects, perceiving crops as threatened by the environment rather than vice versa (e.g. C1). For example, 'It is often harder to maintain something in the environment than to envisage something becoming rampant'(S7), especially a crop outside of cultivation. 'As long as it's crop plants, with a very long history of safe use, I see no major problems' (S5).

CBI nominees in particular accepted some burden of evidence: 'try to find any problem for each new gm variety' (C1); 'try to prove there isn't a problem' (C3); and even 'prove that the gm crop is risk free' (C2). By comparing the behaviour of all novel organisms, they could demonstrate the predictability (C1), or even prove the safety (C3), of well-known crops which have single-gene alterations. As one stated (C1), 'history will show that they are predictable and safe', particularly in the case of long-standing non-indigenous crops, such as potato;

vulnerable to a hostile climate, 'they are unable to jump the fence', and they lack weedy relatives.

Amidst those perceptual differences, members agreed on trying 'to demonstrate the safety of GMOs', whose proponents would bear considerable burden of evidence. For some, to 'reduce the uncertainties' meant to 'identify bands of well-understood categories', ordinally ranking organisms according to risk levels. In this way, the regulation could 'take more care with contentious organisms' (S7), and 'direct the greater concern at the greater hazard' (C2,D3); the latter was referring to contained use of plant pathogens for the gm process, as well as 'real horrors' such as gm insects, fish, and rumen-living bacteria.

2.1.4 Trace gene flow (column 5)

It was widely recognized that unintended gene flow presented an important uncertainty for Britain's indigenous crops, e.g., flow from transgenic oilseed rape to other Brassicas, and from sugar beet to weedbeet or seabeet. One member argued (S10) that past gene flow has probably altered populations of wild oilseed rape and weedbeet; containment measures on GMO releases had hitherto postponed these safety issues for the inserted genes. Some (S1,S10) thought that gm on the Desiree potato warranted more scrutiny because it produces seeds and thus greater potential gene flow. Another concern was gene flow from forage crops, which persist in natural environments [though no such GMOs were created until 1992].

Members attributed different significance to unintended transfer of any inserted gene. Some stressed the importance of tracing gene flow, through geographical spread and/or hybridization (C2, S5, D3, D5). By learning where or how far the introduced gene goes, the assessment can know what difference the gm could make, and what ecological difference the resulting GMO might eventually make, e.g. by giving weeds a competitive advantage (C2).

Although isolation distances were important to know for small-scale trials, they would be less relevant for large-scale releases (S10), where gene escape cannot be controlled or monitored. Some members, with otherwise divergent views (C1,S1,S8,S9,S10), agreed that 'a release is forever', and that the genes will probably go wherever you don't want them to go. Therefore what matters is 'realized risk', the ultimate ecological effects of any unintended gene flow.

That is, the ultimate question was, 'So what?' Consequently, one member (S1) preferred simply that no one release a GMO which might do harm if it, or its inserted gene, were to disperse long distances. Others (S8,C1) hoped to find a satisfactory answer to the 'So what?' question by inducing hybrids and studying their viability, e.g. a cross between oilseed rape and other Brassicas (cf. section 1.3 on Prosamo).

2.1.5 'Judge acceptable outcomes' (columns 6-8):

Most members acknowledged the necessity of making value judgements, if only because of scientific uncertainty, though they were more reluctant to discuss judgements about acceptability. Some acknowledged that even better scientific information would not eliminate the need for making value judgements, especially about acceptable outcomes (D4,S1,S8,S1,T2): 'By its very nature, risk assessment is a subjective process, regarding what you value, though you can codify the subjectiveness by putting it in a rational order' (S11).

One member (D6), who regarded GMOs as suspected pollutants, wanted more research to identify 'any deviation from the normal baseline of the environment', so as to assess what to count as harm. To avoid relying on blind ignorance, the government should match biotechnology funding with research in microbial ecology in particular: 'it will take years to accumulate the information for a sensible risk assessment' (S10). Likewise emphasizing ecological uncertainties, others (S9,S11) suggested that any environmental perturbation could result in harm, in unforeseen ways.

The case of oilseed rape occupied a gray area between likely and acceptable harm. One ecologist (S1) preferred that there be no releases of gm oilseed rape, as the cultivated version already shows weedy characteristics and has weedy relatives. Others portrayed that problem as merely contingent: 'We see oilseed rape growing along roadsides, but only where man has come along and disrupted the plant community; you don't see it in "natural", undisturbed environments' (S5). Another somewhat undermined that reassurance by saying, 'The whole of the UK is a highly disrupted ecosystem; in managing it, man sometimes makes mistakes' (C1); yet he expressed confidence about safely managing the environment by learning from mistakes.

The acceptability of undesirable effects also depended upon the corrective power of human intervention. For example, if a herbicide-resistance gene transfers from a crop to a weed, it would have no selective advantage for persistence; if necessary, it could be controlled by using a different herbicide (S12,C1,C4). Some members regarded such an unintentional transfer as acceptable only for herbicides not yet being used in Britain. For example, one (S8) seemed untroubled by using Basta-resistant genes in GMO trial releases, which might spread such resistance. Another member (S6) specifically opposed risking the spread of resistance to any existing weed control agent; such loss of efficacy would indirectly be environmental harm. For more fundamental reasons, 'It would be difficult to reach any consensus on whether more herbicide resistance in the countryside would matter; it depends on how you value these things'; he defined unintended gene flow as 'general environmental pollution' (S1).

What should be the status of farmland in environmental protection? Some members tended to exclude it conceptually from environmental regulation, as when confidently expecting to remedy any herbicide-resistant weeds invading agriculture (see also Chapter 9, section 2.3). Some more cautious members likewise regarded herbicide-resistant weeds in agriculture as an

acceptable effect, though for different reasons: 'Crop ecosystems are so artificial anyway; what happens in them doesn't matter' (S9). Similarly, 'Agriculture uses a factory system; we want to make sure it doesn't damage the rest of the environment' (S11). In contrast, others defined 'the environment' to include farmland (S1,S8), or even defined weeds as plant pests (D2). One emphasized connections between agriculture and the wider environment, in the sense that even the latter is semi-managed and thus vulnerable to changes in the former (e.g. D6).

The case of a viral insecticide also highlighted the question of acceptable harm, even to target pests. One member advocated more extensive testing of the virus' host specificity (see also Chapter 7, section 4.2). Another (S11) sought greater consideration of the overall ecological role played by any targeted pest, though he acknowledged that its assessed 'value' might depend upon its aesthetic showiness, as perceived by the public. As the former sardonically noted (S1), conservationists are relatively less keen on preserving tapeworms and viruses than butterflies.

2.1.6 Judge benefits? (column 9)

Although interviewees were not asked their view of benefits from GMO releases, diverse members foresaw some benefit for society as a potential which safety regulation could enhance (eg C4,C2,S1,S8,D9,R2,R1). Some expressed doubts about the net benefits of certain gm products, such as herbicide-resistant crops (S4,S6,S1). One had wider doubts: 'On a rational level, you could say that the whole thing [GMO release] is so dangerous that we shouldn't do it; we don't need more agribusiness' (S1).

Many members saw the judgement of acceptable risk as linked to benefits, but in different ways. Some (S8,S6) suggested a negative linkage for any 'trivial release', lacking expected benefits in either scientific information or social benefits. Such a proposed release hardly warranted taking any environmental risk (S6) and had to be judged more stringently: 'The main benefit we look for is the advance of scientific knowledge' (S7). These members sought a significant knowledge-benefit as a trade-off with risk, even if a minor or hypothetical risk; on such implicit grounds, ACRE sometimes asked the applicant to reconsider the experimental design. According to one member (S9), every ACRE discussion involves at least some implicit risk-benefit judgement, for example, in assessing the most appropriate form of containment measures; however, discretion over such measures wouldn't make much difference in expense for the small-scale releases so far permitted, all of which ACRE had regarded as fundamentally safe.

Two members (D9, D2) wanted the committee to consider the scientific or ultimate social value of a release; this was in order to balance risk with benefits, particularly if the risks as such were ambiguous -- not clearly acceptable or unacceptable (D2). Another (D3) spoke about making certain that any risks fall into a low band, such as mere weediness, so that they

can be acceptably balanced with product benefits; he argued that risks taken 'on behalf of the community' should be made explicit in advance, in case of unforeseen consequences. Thus regulators could 'reach a consensus not so restrictive as to prevent GMO releases' (D3).

Although sceptical of industry's reassurances about unintended effects, one ecologist (S8) wanted ACRE to 'consider environmental benefits such as reduced herbicide usage, closer targeting, etc.', though not economic effects. A yet more complex version was, 'Balance benefits with publicly perceived risks' (D9), where both parts of the risk-benefit analysis might take public perception as a reference point. Another complained that the committee in effect was already influenced by expected benefits: 'Many members assume there is a positive benefit, so one has to come up with [identify] an environmental hazard to balance that, in order to recommend against a release' (S10).

Some members (T2,S1,S9) did not want the committee to consider benefits at all, as its proper role is to avoid environmental harm. As one defiantly said (S1), 'We only assess risks, rather than balance risks against benefits; that's what industry doesn't like about the committee.' However, this account was contradicted by others who acknowledged the implicit role of risk-benefit judgements.

2.1.7 Assess acceptable risk and/or 'realized risk'

Members differed over how to judge 'acceptable risk'. They variously defined it as 'almost no risk' (T2), 'no more risk than the unmodified organism (S5)', 'no perceptible risk'(T2), 'no unreasonable risk' (C1), etc. One (S7) described the issue as 'where to draw the line on the numerical value' of acceptable risk. Another even foresaw increased knowledge allowing the risk assessment to reduce the probability of harm to 10^{-12} and thus more easily to decide its acceptability (C3). By contrast, some ecologists ridiculed any attempt at quantitative risk assessment; another advocated 'keeping releases within publicly acceptable bounds, rather than use quantitative risk assessment (S6)'.

Amidst such disagreements, some members emphasized the 'so what?' question; this meant 'assess realized risk', the ultimate tangible consequences of unintended effects. Although some advisors mentioned unacceptable effects, the semi-rhetorical 'so what?' question tended to marginalize intangible harm or complexities, and to emphasize remediable harm, e.g. herbicide-resistant weeds.

Starting from different environmental values, advisors held different criteria for adequately answering the 'how likely?' question. For example, they could cite 'no evidence of harm' to vindicate the safety of the crops already tested. Or, alternatively, they could seek additional evidence of safety, to accommodate more complex ecological and agronomic models.

Such views can be depicted by reversing the direction of the arrows on the cognitive map -- from 'assess realized risk', back downwards towards investigating whichever uncertainty might produce an unacceptable outcome. In effect, this reverses the stereotypical sequence of

risk-assessment steps (see Table 8.1, 'Evaluating Uncertainties in Risk Assessment', column on ACRE members).

2.2 Genhaz proposal

The Royal Commission on Environmental Pollution took a leading role in formulating a rationale for precautionary regulation: 'This should allow safety issues to become part of the development of the technology rather than having to be introduced following problems' (RCEP, 1989: 36). For 'risk identification techniques', its 13th report mentioned Genhaz as a potential method for anticipating the unforeseen from GMO releases. If adequately devised, such a procedure 'could contribute to the reduction of risk and to the reassurance of the public' (ibid.: 42).

The Genhaz procedure was based upon 'Hazop', the 'Hazard and Operability' method already used for anticipating hazards in the chemical industry. According to the RCEP, 'The technique is based upon the assumption that incidents arise not because of a lack of knowledge or experience, but because of the complexity of designs, needing systematic but imaginative analysis to uncover the hazards' (ibid.). Hazop expresses that complexity through a series of 'guidewords' -- more, less, other than, etc. -- which help to identify potential deviations from operating intentions, their cause, possible consequences, and preventive measures.

How, then, did Britain's regulatory advisors initially regard the Genhaz idea? Many noted that it would encourage imaginative lateral thinking, even wild extrapolations, though they had diverse expectations for what such an exercise could achieve. One member (S8) doubted that scientists had an adequate theoretical basis for assessing all the hypothetical 'bizarre scenarios' that Genhaz would generate. A more hopeful though modest view was that Genhaz would help identify weaknesses in risk assessment, and so clarify what additional data were needed (D1), or at least establish a standard checklist of points for all proposed releases (T2). More optimistically, Genhaz was even expected to help 'quantify real risks for each proposed release' (member D9).

Giving more sceptical responses, some members feared that Genhaz would encourage over-confidence: 'I am wary of models because you feed in the information that you have available; Genhaz is likely to give you the answers that the model was designed to get' (S5). Moreover, another member commented sardonically (S2),

> Hazop would have said that the Flixborough plant was safe, because there was a piece of information that we didn't know about; according to Hazop, Chernobyl and Three Mile Island should not have happened. If your knowledge of the ecosystem is complete, then Genhaz analysis is fine.

By the time the RCEP (1991) issued a report specifically on Genhaz, its advocates had overcome some of the reservations expressed above. Genhaz had been tried out on a hypothetical GMO release by a group at the IPSR under Professor Richard Flavell, who afterwards spoke favourably of it, despite earlier scepticism. The RCEP's Genhaz report was also welcomed by Professor John Beringer, chair of ACRE. Another ACRE member (S1), previously wary of any overconfidence derived from Genhaz, now had a more modest reservation: 'Genhaz has showed how little we know about biological populations in the wild. If Genhaz turns out to be a cost-effective way of controlling risks, it will be adopted.'

How were some earlier reservations overcome? A key problem for Genhaz proponents was how to extend Hazop from chemical to biological complexity. According to a RCEP member, Charles Suckling, many biologists initially doubted that this procedure from the chemical industry, with its linear flow diagrams, could encompass the complexity of biological systems; indeed, they feared that Genhaz would stultify biological thinking. A principal problem was how to express the design intention of a GMO release, while using Hazop-type guidewords to imagine all possible deviations. Such an adaptation of Hazop was developed partly by the IPSR exercise, with suggestions from Keith Powell of ICI, where Charles Suckling himself was formerly General Manager of Research and Technology (interview 29 August 1991).

In the published version of Genhaz, each proposed GMO release is to be systematically analysed in terms of the recipient organism, the genetic construct (vector) and transgenic product designed for release. Characteristics of those three components are considered through a series of stages, from making the GMO, though to release and finally 'clean-up'. At each stage the assessment applies a list of guidewords, expanded from Hazop to encompass biological systems; any possible deviation is taken to challenge the supposed safety of the release (RCEP, 1991). In that way, the Genhaz schema requires asking whether the spatial and temporal limits of a release would be knowable or controllable.

There was another significant adaptation of Hazop: the latter starts by considering realistic causes of deviations from the design intention, while Genhaz starts by considering the consequences of any deviations. This starting point helps to emphasize causal links among chains of consequences in the natural environment. The report suggests that a Genhaz team first generates possible consequences, then assesses them to decide which are acceptable, and then seeks realistic causes for any unacceptable consequences. 'The outcome is essentially the same as it would have been under the Hazop protocol but the emphasis on the various steps is slightly different' (RCEP, 1991: 11-12).

Why did Genhaz shift the emphasis of the Hazop steps?

> As we were entering a new field, we felt we might come up with some novel consequences, in a way that is not very likely when you are looking at a chemical plant... If you come up with a consequence that is very serious, then you might look at the deviation in a rather different way than if the consequences seemed trivial. (Charles Suckling, interview 29 August 1991)

In other words, the relative acceptability of a hypothetical consequence could influence the extent of precaution taken to identify and avert its possible causes; the acceptability judgement could even influence how one defines a plausibly 'realistic' cause (see Table 8.1, column on Genhaz). In that sense, the report oversimplified the question of whether 'the outcome is essentially the same' in Genhaz as in Hazop. The Genhaz order of steps lends more weight to acceptability judgements, which of course could work either way, making the burden of evidence either more or less stringent, accordingly, and prioritizing some uncertainties over others.

The 'audit trail', proposed for all Genhaz exercises, would make such value judgements more explicit and thus publicly accessible (RCEP, 1991: 34). In all these ways, Genhaz highlighted the primacy of environmental value judgements. It remained to be seen whether or how this greater transparency would be received by the regulatory system.

Table 8.1: **EVALUATING UNCERTAINTY IN RISK ASSESSMENT**

Stereotypical sequence	**ACRE members (1990-91)**	**RCEP report (1991)**
risk evaluation	('realized risk') so what?	unacceptable consequences
↑	↓	↑ ↓
risk estimation	how likely?	Hazop Genhaz
↑	↓	↑ ↓
risk identification	what if?	plausible causes

3.0 CONCLUSION: STEPWISE DILEMMAS

The British government claimed to base its precautionary approach upon 'sound science', yet the latter term acquired paradoxical meanings. At issue was how best to assign and then relax the burden of evidence for safety. At least implicitly, the criteria for such evidence depended upon environmental value judgements -- regarding the likelihood, acceptability or desirability of potential effects.

In preparing to relax controls, Britain's regulatory system sought to reduce uncertainty about risk, yet the experimental results often sharpened methodological conflict about how to define and investigate the relevant uncertainty. This experience paralleled other regulatory systems, which have likewise encountered difficulty in overcoming political disputes through additional scientific research (Collingridge and Reeve, 1986: 51-60; Salter, 1988: 166, 199-201). For this case of precautionary regulation, morever, the procedure could plausibly consider an even wider range of 'what if?' scenarios.

Scientists from different disciplines emphasized different kinds of past experience as a guide for assessing GMO releases, even for generating new evidence of safety. For microbial releases in particular, some scientists wanted research to ascertain the normal ecological baseline, so that monitoring efforts could detect any perturbation and thus anticipate unidentified hazards. Others, especially laboratory scientists, justified limiting risk assessment to identifiable hazards, especially their testable components.

The same new evidence could elicit contrary interpretations for risk assessment. As Krimsky (1991: 151) notes, geneticists and ecologists embed facts in a different model of causality, so new facts do not necessarily bridge the disciplinary divide. Indeed, new knowledge opened up more areas of scientific uncertainty for risk-assessment research, such as microbial gene transfer.

Interpretation of new test data depended, to some extent, upon disciplinary views about ecological stability -- for example, whether ecological niches are restricted by environment or by genetic novelty. Accordingly, scientists justified different methodological approaches for biosafety research -- regarding, for example, how (or even whether) to monitor microbial populations for perturbations; how to test transgenic plants for pleiotropic effects; how to simulate a plausible selection pressure which might impart a competitive advantage to GMOs or to their weedy relatives; and how to set experimental criteria for identifying 'permissive hosts' of a viral insecticide (see Chapter 7, section 4).

Biosafety research was mainly testing the null hypothesis, i.e. the claim that genetic modification would have no unintended effect. At issue was the range and type of conditions which would warrant generalizing from evidence of 'no untoward effect' from a GMO release. Such preliminary evidence was cited as enhancing predictability, though its interpretation depended upon one's cause-effect model of potential harm.

In various ways, biosafety research deferred to industry's R&D priorities. It depended upon market-led innovation for resources (e.g. Prosamo funding, transgenic seeds, detection techniques); and it defined hypothetical risk as testable uncertainties of specific organisms. Biosafety research tested whichever uncertainties it could credibly and reproducibly control, such as gene flow and competitive biological advantage; the research deferred other uncertainties, such as the significance of herbicide-resistance genes in various environments.

As in risk assessment more generally, the research converted fundamental ignorance into 'marginal' imprecisions, which could then be progressively reduced with additional data (O'Riordan and Wynne, 1987: 393). Yet some advisors held doubts about what could be learned from testing properties of an organism in a carefully controlled environment. The more the experimental design contained the transgenic material, the less opportunity for unintended effects to occur, so the less could be learned from a trial release. Moreover, they anticipated agronomic practices as sources of harm, not simply as environmental variations, as in the prevalent naturalistic model of risk.

Despite obtaining additional scientific knowledge, the regulatory system faced implicit ethical judgements on the acceptability of undesirable effects. Advisors disagreed over how to evaluate hypothetical outcomes, such as enhanced weediness from herbicide-resistant crops. Asking themselves 'so what?', they gave qualitatively different answers -- for example, in defining agriculture as inside or outside 'the environment'; in defining weeds; in conceptualizing unintended gene flow as 'genetic pollution'; and in foreseeing remedies for any agricultural disruption. These answers, in turn, influenced the perceived importance of resolving ecological uncertainties prior to relaxing controls.

For regulatory advisors, environmental values did not simply fill a gap left by scientific uncertainty; rather, advisors emphasized different ranges, types and consequences of uncertainty (Levidow, 1994a). Such a logical sequence, from acceptability judgements to relevant fact-finding, was formalized by the Genhaz proposal for improving risk-identification procedures. This resonated with advisors' view that the 'so what?' question ultimately takes

priority over the 'how likely' question. These pervasive environmental value judgements, in effect, reversed the stereotypical sequence of risk-assessment steps (see Table 8.1).

Genhaz also proposed to make such judgements more publicly accessible. This proposal acknowledged that any fact-finding priority required some cognitive argument for its relevance. As in other risk controversies, 'the production or mobilization of belief becomes a central source for the social enforcement of validity claims' (Beck, 1992a: 166-68).

Given this prime role for acceptability judgements, which expressed different cognitive frameworks, precautionary regulation held some potential for democratizing risk assessment, even for influencing innovation. By requesting more complex evidence of safety, the regulatory procedure would better accommodate safety concerns, and/or it would effectively discourage particular types of biotechnology R&D. Conversely, by portraying risk assessment as 'objective', the procedure would define the uncertainty more narrowly, privilege the existing technical expertise, and so more readily relax controls.

In such ways, the regulatory procedure was serving to define safety and legitimate innovation. In so far as the procedure imposed a burden of evidence for safety, it undermined the 'rational' stereotype of risk-assessment steps. A precautionary 'sound science' remained a contradiction in terms.

Chapter 9
ROUTES TO MARKET APPROVAL

While the regulators were judging the safety of proposed trial releases, they were expected ultimately to set criteria for approving GMOs as commercial products. As the final 'step' of the stepwise procedure, market approval was also an explicit aim of GMO regulation. However, process-based legislation had deferred some contentious issues: for example, whether socio-economic criteria would supplement safety criteria; how the latter would be standardized; and how (or even whether) GMOs would enter sectoral product-based regulation.

How, then, did regulatory actors anticipate GMOs reaching market approval? How did they attempt to influence the regulatory procedure and criteria? How did the state authorities set the terms for eventually treating GMOs as normal products?

This chapter analyses conflicts over the appropriate route to market approval. In particular, it describes:

* how the European Community accommodated industry's proposals for 'rational' regulation (section 1);
* how Britain's regulatory actors foresaw the shift to market approval, according to different notions of 'the product' (section 2);
* how these conflicts bear upon prospects for normalizing GMOs (section 3).

1.0 EUROPEAN COMMUNITY: Limiting Precaution

When DGXI was drafting the Deliberative Release Directive 90/220, its 'rational' status was disputed within the European Commission (see Chapter 4, section 3.2). After the Directive was enacted in March 1990, a similar dispute erupted publicly between DGXI versus industry. However, industry lobbyists aimed strategically at limiting the precautionary content of process-based regulation, while still using its framework to legitimize the step-by-step relaxation of controls.

1.1 New industry alliance

In the mid-1980s, Europe's embryonic biotechnology industry accepted the need for an EC Directive regulating GMO releases. In particular, such a proposal was endorsed by the European Biotechnology Coordination Group shortly after it was founded in 1985 (Shackley et al., 1992). Subsequently the EBCG played little further role, perhaps because it attempted to represent the broadest possible consensus within the industry (*Ebis*, July 1991: 5; cf. Cantley, 1992: 24).

A more active umbrella group was the Green Industry Biotechnology Platform (GIBiP), whose name denoted plant breeding, rather than a political colour. Its booklets served as a lobbying tool within European Community debates on biotechnology regulation. Specifically it argued against imposing 'a moratorium on the commercial development of plant biotechnology until the completion of exhaustive risk investigation programmes'; this argument was implicitly directed against a proposal from the European Parliament's Environment Committee. GIBiP also argued that 'safety, quality and efficacy (assessed scientifically) must be the only criteria' for regulatory approval (GIBiP, 1989: 6); this argument was implicitly directed against proposals for a Fourth Hurdle, which would add a criterion of socio-economic need. Yet it acknowledged that, 'As the concept of risk is purely theoretical, decisions about risk and safety inevitably involve value judgements' (ibid.).

GIBiP accepted process-based regulation of GMO trial releases but opposed extending that basis to the market approval stage (GIBiP, 1990: 56). In this respect, its position roughly coincided with an early draft of the Deliberate Release Directive (CEC, 1988: 7-8). However, the latter was subsequently amended so as to require a 'similar' risk assessment in any product directive intended to supplant 90/220 Part C for market approval of a GMO product (see Chapter 4, section 3.1; Hodgson, 1992). GIBiP successfully lobbied EC officials to oppose some other proposed amendments, though it could not prevent the strengthening of Part C (interview, 4 January 1991). After the Directive was enacted, GIBiP (1990: 56) sought a way to shift market approval of GMO products to sectoral legislation: 'After it has been proven that genetic modification has introduced no extra risks as compared with existing commercial products, existing directives for product approval in appropriate market sectors should be applied.'

A more aggressive response came from the chemical industry organization, CEFIC, which set up the Senior Advisory Group on Biotechnology (SAGB) in July 1989. SAGB represented major agrichemical and pharmaceutical multinationals which were investing heavily in biotechnology. A GIBiP official distanced himself from SAGB when he remarked,

> SAGB came into existence through frustration that GIBiP was not interacting at the right level. SAGB is a much more senior group; rather than research staff, it consists of the heads of major European companies, who aim to go right to the top in the European Commission (GIBiP interview, 4 Jan 1991).

SAGB was formed too late to influence the Directive, which had reached its nearly final form by early 1989, though not enacted until March 1990 (see Chapter 4, section 3.1). Subsequently the Group attacked process-based regulation as such. Referring obliquely to the Directive, a SAGB (1990) booklet criticized 'a tendency to think of "biotechnology" as fundamentally different from other technologies and therefore requiring special rules'. SAGB argued that more favourable public policy in the USA and Japan was helping Europe's major competitors in biotechnology.

Advocating product-based regulation on the US model, SAGB called upon the EC to 'apply existing, non-discriminatory approaches for safety in research and industrial processes'. This would mean, for example, assessing organisms according to 'the inherent characteristics of the product'; such approaches must draw upon 'professional competence of the highest standard'. Opposing a Fourth Hurdle, it proposed that regulation 'should assess only safety, quality and efficacy for man and the environment, on the basis of objective scientific criteria' (SAGB, 1990). A related press release attacked the EC for 'political hostility' to the European biotechnology industry; SAGB claimed that over-regulation was driving its members out of Europe to the USA and Japan (Dickson, 1990a).

In response DGXI's Director General, Jan Brinkhorst, defended the Deliberate Release Directive. He justified taking the recombinant DNA process as the administrative basis for regulation: although the risk assessment must consider product characteristics as well, 'there is no denying the special safety problems associated with GMOs'. Despite his overt disagreement with US policy, Brinkhorst further argued that the Directive would generate no substantive difference in biotechnology safety regulation between Europe and the USA (Dickson, 1990b). With that rejoinder, DGXI implied that some universal regulatory science could link the US and EC approaches. By contrast, SAGB echoed the US government's 'risk-based' language to justify regulating GMOs only within existing product legislation, as the only rational framework for expert objective assessment.

In practical terms, industry could not directly undo the Directive but could limit its precautionary content. In so doing, SAGB's intervention attempted to shift the balance of power: among Directorates-General within the European Commission, between the Commission and the Parliament, and between political forces beyond those institutions.

Industry pressure took the form of restricting the type of expertise and range of ecological uncertainty deemed relevant for regulatory decisions.

One British industrialist, criticizing the extension of the Directive's Part C to all GMO products, now regretted having earlier accepted process-based legislation. He had done so, given that 'industry were not able to convince people in Europe how illogical it was to single out products of a particular process for discriminatory regulation'. Industry now had to 'limit the damage', in particular to 'curtail the power of DGXI and add scientific competency' (interview, 22 March 1991).

After intensive lobbying, industry's attempt at damage limitation achieved a symbolic success. In April 1991 the European Commission published the Bangemann report, entitled 'Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology within the Community' (CEC, 1991). Co-ordinated by DGIII, the Industry Directorate-General, it echoed many arguments from its industry precursor (SAGB, 1990), as well as from its US counterpart (BWG/Quayle, 1991).

The Bangemann report defended high environmental standards as opportunities for the biotechnology industry to develop more precise, effective and non-polluting products; implicitly this passage appealed to industry's self-interest in ecological modernisation (see Chapter 4, section 1.1). Towards strengthening the European biotechnology industry, the report confirmed that regulation would follow a single procedure of assessment and authorisation for GMO products. At the same time, it supported a 'complementary' relation between horizontal and vertical regulation, i.e., between process-based and product-based regulation, respectively. The report also relegated any Fourth Hurdle to 'exceptional cases': after all, regulatory 'decisions have to be based upon objective assessments'. The document drew sharp distinctions among the following: environmental risk assessment, value-laden issues, socio-economic impacts, and other matters (CEC, 1991).

Thus the Commission affirmed SAGB's key distinction between 'objective' assessment of product safety and merely subjective views on other aspects. Also, the term 'complementary' implied an early shift to product legislation, though a DGXII official privately described this wording as a 'massive fudge'. Industry gave the report a guarded welcome, as the wording remained 'open to many interpretations' (Hodgson, 1991). By contrast, Green MEPs criticized the report for fulfilling an industry 'wish-list' (Hill, 1991).

In the same period, the Commission established the new Biotechnology Co-ordinating Committee, which was expected to ensure that forthcoming Directives complied with the

policy of the Bangemann report (Hodgson, 1991). The BCC was nominally intended to 'develop a coherent Community policy in biotechnology' (*Ebis*, May 1991: 3), though it was also designed to shift the internal balance of power. In preparing the Bangemann report, just as in establishing the BCC, 'a DGI&DGIII&DGXII alliance prevailed over DGVI&DGXI, though one doesn't write these things down', according to a DGXII official. After all, 'The BCC was set up under growing pressure from some parliamentarians and very much from big industry and the industry ministries; now we can take our arguments to this tribunal' (DGXII interview, 18 July 1991). Clearly, DGXI was to be a defendant at the tribunal.

These political changes coincided with diminished prospects for organized resistance to biotechnology. The late 1980s had seen the height of environmentalists' influence in Germany and the European Parliament; until then, industry had feared the prospect of even more stringent regulation than the Directive, such as a virtual ban. However, after the 1989 elections the Green MEPs became a less effective opposition; and by 1991 'there was no real tangible pressure now on the biotech industry' (Envt Cttee interview, 17 July 1991). To some extent, process-based regulation may have helped to relieve such pressure.

As DGXI's Director General, Jan Brinkhorst, sardonically commented,

> When industry was afraid it was going to be banned, it came to us and said, 'Please pass a law to stop them from banning things [GMO releases].' Now that there's no danger of that, they are saying we don't really need the law at all (quoted in Balter, 1991).

Although there was no prospect of discarding Directive 90/220, industry did attempt to limit its precautionary effect, while using the Directive's procedure for normalizing biotechnology.

In this dispute, SAGB's stance was encouraged and deployed by DGXII from within the European Commission. As a DGXII official retrospectively described his warning signals to industry in 1988, 'Industry was not yet fully alert to the damage that the Directive would do to their interests; that [realization] came the following year' (interview, 18 July 1991). Far from acting as industry's agent in the Commission, DGXII saw itself as educating both industry and the Commission about their true interests in developing 'rational' regulation, and so minimizing regulatory obstacles to biotechnological progress (cf. Cantley, 1992).

Thus industry's belated lobbying could take advantage of conflicts within the European Commission. Here the putatively 'objective' status of safety regulation became a rhetorical weapon for narrowing the range of uncertainty deemed relevant for regulating biotechnology. Value conflicts took the form of disputing technical criteria; these were manifest in industry attempts to avoid a Fourth Hurdle and to narrow the risk-assessment criteria, as described in following sections.

1.1.1 Avoiding a Fourth Hurdle

The Fourth Hurdle was a proposal to subject biotechnology products to a regulatory criterion of socio-economic need. The additional criterion would strengthen the discretionary power of DGVI, the Agriculture Directorate-General, which was advocating the proposal within the Commission. DGXII had persuaded the Commission to oppose any systematic Fourth Hurdle for biotechnology (CEC, 1991: 8).

A Fourth Hurdle was originally mooted for the special case of the growth hormone BST (or BGH), designed to increase cows' milk production. BST encountered organized opposition from wide range of organizations, especially small-scale farmers and animal welfare groups. DGVI repeatedly blocked market approval of BST by extending the 'evaluation period' for safety assessment; the delay was really an implicit Fourth Hurdle on ethical and/or economic grounds (e.g. Nathan, 1992). From an industry standpoint, DGVI was undermining the authority of its own advisory committee, which had found no safety grounds to warrant blocking approval of BST; its manufacturers accused DGVI of opposing any product which enhanced productivity or efficiency (Vandaele, 1992).

Given that a Fourth Hurdle was operating informally, Ken Collins MEP (1990) had proposed formalizing it for such special cases as yield-promoting veterinary pharmaceuticals. Thus the licensing system could coherently accommodate all policy considerations, rather than rely upon scientific justifications alone. Collins portrayed a selective Fourth Hurdle as protecting industry's interests, by avoiding lengthy political scrutiny of every new product.

Industry opposed Collins' proposal as a dangerous precedent which undermined rational regulation. At least privately, some companies regretted that BST had become a test case for public acceptance of biotechnology, but the industry feared that any formal Fourth Hurdle might be extended to all of biotechnology. In response, industry reiterated the three criteria used routinely for assessing drugs -- safety, quality and efficacy; these now acquired a rhetorical significance as universal objective parameters, in contrast to a merely 'subjective' fourth criterion (CEC, 1991: 8).

In this vein, the language of scientific rationality became central to the dispute, as reported in a British television programme. Dieter Brauer of the German firm Hoechst warned against imposing additional criteria 'which have emotional backgrounds, which are not based on logical and scientific backgrounds'. ICI's Peter Doyle feared 'a move away from a predictable, science-based regulatory framework'. Similarly, his ICI colleague Ed Dart speculated, 'If for

some irrational reason Europe opts not to follow this technology...' Throughout the programme, industry speakers expressed confidence in assessing products as unambiguously 'safe' and in predicting benefits; they emphasized the socio-economic 'risks' of obstructing product development. By contrast to industry, Ken Collins MEP described the present assessment procedure as a 'system of irrational non-decision making', incapable of making 'rational decisions' about risks and benefits (BBC, 1991).

In all those ways, protagonists put forward opposed versions of rationality -- either claiming an objectively scientific expertise, or proposing to make value judgements explicit rather than conceal them behind technical safety criteria. Thus, although BST itself was not a GMO, the Fourth Hurdle debate took on a wider importance in reaffirming a stereotypical scientific rationality as the proper basis for regulating biotechnology in general.

1.1.2 Narrowing risk assessment

For GMO releases, deregulatory moves took the form of narrowing the range of scientific uncertainty deemed relevant to risk assessment. Regarding Directive 90/220, in dispute were technical Annexes which specified the definitions of a GMO and the risk-assessment criteria; the latter went beyond those which would otherwise apply to biopesticides, plants, etc. As the technical specifications now had full legal status, they could be changed only through special procedures involving the environmental ministries of member states (EEC, 1990: 21, Articles 20-21).

Partly for that reason, DGXII had opposed granting Directive-level status to the Annexes. In retrospect, DGXII acknowledged that the 1990 Directive had been 'a political requirement at a certain moment in time, and scientifically justifiable as a response to uncertainty, but in need of frequent review as flexibly as possible'. It later proposed that DGXI delegate some of the technical details 'to a standards body like CEN [Comite Europeen de Normalisation], which would be controlled by industry', and which might justifiably alter the risk-assessment criteria 'as an adaptation to technical progress'. Derogating GMO products to specific product legislation would facilitate such adaptation (DGXII interview, 18 July 1991). By the same token, DGXI opposed delegating technical details to CEN or to separate product legislation superseding Directive 90/220: 'What industry really wants is... to edit out any additional assessment' of GMOs, as compared to non-GMOs (DGXI interview, 18 July 1991).

A long-standing body, CEN had responsibility for setting Europe-wide product standards. In March 1990 it established a Technical Committee on Biotechnology, TC233, whose chair was Brian Ager, also Director of the SAGB (*Ebis*, November 1990: 6). CEN soon set up working

groups, with an official from Roussel-Uclaf chairing the group on agricultural and environmental applications (*Ebis*, March 1991: 15-16).

Not only was the CEN subcommittee 'controlled by industry', as DGXII had noted, but it was headed by prominent lobbyists for deregulating biotechnology. CEN's possible role in risk assessment had been left open by the Bangemann report (CEC, 1991: 14). Although CEN could not change the Annexes of Directive 90/220, its advice could influence how they were adapted in any further directives superseding Directive 90/220.

1.2 Pesticide directive

There was no industry-wide consensus, much less Commission support, for abandoning the Deliberate Release Directive 90/220. In practice, SAGB and DGXII prioritized weakening Part C, which all of industry regarded as a problem (e.g. GIBiP, 1990; see Chapter 4, section 3.2). They attempted to supersede Part C with vertical product directives, sooner rather than later.

After the Bangemann report had ambiguously affirmed a 'complementary' relation between horizontal and vertical legislation (CEC, 1991), the first test case came with the draft Directive on Plant Protection Products, colloquially known as the pesticide directive. At issue was whether GMO biopesticides would still have to undergo market approval under the Deliberate Release Directive 90/220 Part C, depending upon whether that procedure was superseded by the pesticides directive. Industry protested that GMO biopesticides might have to satisfy both both types of directive; such 'dual regulation' would impose increased regulatory costs and uncertainty, thus discouraging European investment in biotechnology (CBC, 1990: 35).

1.2.1 Bypassing precaution

The draft pesticide directive declared that its procedures were 'not appropriate' for environmental risk assessment of GMOs (CEC, 1989: 4); the wording left open how and when GMO pesticides would be included. For example, some MEPs suspected that pesticide regulation would allow GMOs to bypass Directive 90/220, so they sought to strengthen the draft pesticide directive. In February 1991 the Parliament approved a 'compromise amendment', which strengthened the 'not appropriate' to read 'not adequate', clarifying that additional criteria were needed for assessing GMO biopesticides; it also specified that such products must first obtain 'a clearance for release' under Directive 90/220 (EP, 1991a). With that proposed wording, the Environment Committee wanted to ensure that the additional risk

assessment would be defined by 90/220, not by some other formula (Envt Cttee interview, 17 July 1991).

The Commission accepted that amendment in March 1991, but a leaked document later suggested that the Commission was devising a substitute amendment. The latter would incorporate a procedure for an environmental risk assessment analogous to the one in 90/220, within two years of adoption. In May the European Parliament issued a resolution in protest 'about this potential breach of undertakings made by the Commission to the Parliament' (EP, 1991b). Few MEPs had any understanding of the safety issues involved; they protested mainly on procedural grounds: i.e., that the Commission was reneging on a previous agreement with the Parliament. The resolution was initiated by Green MEPs, who also raised the substantive issue, but they could not interest other MEPs in protesting on environmental safety grounds (Envt Cttee interview, 17 July 1991).

DGXII, a leading advocate of the two-year timetable, argued as follows: The existing expertise in product regulation is the most appropriate base for 'the learning process'; that expertise might rightly judge the risk-assessment criteria of 90/220 to be scientifically unwarranted for some products. GMO biopesticides, for example, should not be classified as GMOs: 'A pesticide is a pesticide. The pesticide authorities should, if necessary, buy themselves or teach themselves biotechnology... These people should take over' from the environmental authorities (DGXII interview, 18 July 1991).

By contrast, DGXI drew a less reassuring analogy to regulatory practices in agriculture ministries. Precisely because biopesticides have posed few problems, pesticide regulation has focused upon environmental effects of 'residues' from chemical pesticides. Such expertise was hardly appropriate for self-reproducing biopesticides, much less for GMO biopesticides. Moreover, 'the assessors are more likely to concern themselves with efficacy than with safety'; agriculture ministries hadn't the capacity or inclination to extend the Directive's risk-assessment criteria to the market approval stage (DGXI interview, 18 July 1991).

DGXI's stance received public support from Green MEPs, who mounted similar arguments in order to generate public protest by NGOs. Staff issued a briefing document which attacked the new amendment as deregulation, for the following reasons: It would 'kill horizontal regulation for the marketing of [pesticidal] GMOs', rather than fulfill the 'complementary' relation announced in the Bangemann report. The two-year timetable would remove GMOs from the Deliberate Release Directive even before the environment ministries had accumulated much expertise through the experience of trial releases, whose knowledge would then be lost; their role would be replaced by agriculture ministries, whose expertise lay in

assessing synthetic chemical pesticides. Contrary to industry's claims about dual regulation being 'inefficient', product-based regulation 'would require a proliferation of different committees for each GMO product category....' Moreover, 'It is not scientifically sound' to presume product safety on the basis of small-scale trials (Bullard, 1991). In Britain the Genetics Forum (1991) made similar arguments in a letter to the government.

Implicitly in dispute here was how to interpret the significance of genetic novelty and how to assign the burden of evidence. Although traditional biopesticides already underwent safety regulation, the Greens' document neglected to explain why that knowledge base was inadequate for GMO biopesticides. Classifying GMOs as inherently novel rather than as familiar organisms, their 'efficiency' argument presumed that some new type of knowledge was needed. In this way, the Greens implicitly challenged the stereotypical meaning of 'sound science'.

Within the Commission, DGXI strongly opposed the two-year timetable for the pesticides directive to supersede 90/220 Part C, though to no avail, and it felt unable to dissent publicly from the Commission's new policy (DGXI interview, 22 May 1992). The lead agency for the pesticide directive, DGVI, favoured a longer transition to vertical regulation, i.e. five years, as did DGXI and the Parliament. Within the Commission, DGVI was supporting DGXI, in return for DGXI supporting DGVI on a proposed Fourth Hurdle for BST. However, it became clear that the five-year timetable had no support in the Council of Agriculture Ministers, apart from Denmark. To avoid defeat there, DGVI conceded to the Commission and Council majority by accepting a two-year transition (DGXII interview, 18 July 1991; Envt Cttee interview, 17 July 1991).

Finally in July 1991 the Council of Ministers approved an amended pesticides directive, which mandated adding risk-assessment criteria specifically for GMOs within two years (EEC, 1991: 4). Once implemented, the pesticides directive would include GMO biopesticides within the standard licensing procedure of a DGVI expert committee, representing the national authorities which already regulated agrichemicals (Mackenzie, 1991). These were mainly agriculture ministries, which held responsibility for both promoting and regulating agricultural products, and which were relatively less open to public consultation.

For such reasons, among others, the Greens warned that DGVI's Brussels committee would 'bypass the expertise and concerns of the national environment ministries' (ibid.). In Britain environmentalists were apprehensive about the pesticide directive superseding Directive 90/220 Part C: probably ACRE would still provide safety advice on a GMO biopesticide at the

market approval stage, but MAFF rather than the DoE would ultimately decide whether to act on the advice (Green Alliance interview, 30 October 1991).

Once industry had won the dispute over the pesticide directive, further demands followed. It now criticized the broad risk-assessment criteria in Directive 90/220 as scientifically unwarranted and as regulatory discrimination against GMO biopesticides. Such arguments came from an industry speaker at a major conference on biotechnology regulation, held on 23-24 June 1992 in The Hague. Representing European pesticide companies, Eva Sorensen argued,

> If initial tests show no hazard, then they don't require [warrant] further testing.... The environmental risk assessment needs to evaluate whether the genetic change will pose a risk to the environment. It should not request unnecessary information on the GMO, such as its metabolic role in the environment [a reference to 90/220 Annexe II]. The extra requirement puts a burden upon scientists and regulators; it prevents explaining the real prospects to the public.

This argument retrospectively clarified industry's reasons for having turned against process-based regulation. Now it explicitly intended to edit out any additional assessment for GMO products (as DGXI had privately claimed). In complaining about the administrative burden, industry was attempting to minimize the precautionary content and hasten the symbolic normalization of GMOs.

What might this mean for the precautionary content of 90/220? Even at the R&D stage, covered by Part B, the testing of ecological uncertainties would depend partly upon whatever data requirements were anticipated at the commercial product stage. If releasers expected that DGVI's procedure could bypass the precautionary intent of Part C, then they would have less incentive to design trial releases for collecting any safety data beyond those required for non-GMOs. Thus the procedural and technical features of product-based regulation favoured reliance upon traditional expertise, anticipating only those hazards already documented.

1.2.2 Whose democracy?

How did the amended pesticide directive result from the EC's democratic procedures? When DGXI attempted to keep GMO biopesticides within Directive 90/220, European industry portrayed that stance as undemocratic, self-serving and irrational. According to a SAGB representative, the Council of Agriculture Ministers had wanted the pesticides directive to include GMOs, but the Environment Directorate DGXI had them excluded from the Commission's draft proposal:

> Regrettably, the Commission worked behind the scenes, and we still have [the prospect of] dual regulation. We don't have a democratic system operating in Europe... DGXI has to be willing to negotiate. A few dictators around the world have said 'No, no.'

> Saddam Hussein has got his come-uppance; we'll see what happens in the future (interview, 22 March 1991).

In July 1991, when the Commission adopted industry's proposal for the pesticide directive, presumably this was the moral equivalent of Operation Desert Storm, re-imposing the democratic rule of law.

By contrast, Greens MEPs had argued for prolonging process-based regulation, especially because 'the creation of new forms of life presents our ailing planet with a unique challenge'. As the manoeuvres around the pesticide directive illustrated, 'industry is more powerful than the only democratically elected institution at a European level' (Bullard, 1991). Thus the Greens identified industry as a dual threat to the environment and to democracy.

The meaning of European democracy depends upon whether one's main reference point is the Council of Ministers or the European Parliament -- and therefore who had bypassed whom. Directive 90/220 gave an initial role to environment ministries, partly accommodating environmentalists' concerns. However, Part C allowed for product-based regulation, whose procedure would favour the agricultural policy of national governments.

Here it is instructive to recall that Directive 90/220 had its legal origins in Article base 100a, for completing the EC internal market. When such a market seemed threatened by organized opposition to GMO releases and regulatory disharmonies, a political opportunity opened for a precautionary approach. Yet the original market rationale ultimately strengthened the national ministries responsible for approving and promoting agricultural products.

Some officials welcomed such a shift as 'the withering away' of Part C (e.g. DGXII interview, 18 July 1991; HSE interview, 26 September 1991). It also meant a withering role for the European Parliament, DGXI and the environment ministries; such bodies had little scope for influencing the pesticide directive. Much less could environmentalist groups mount a public campaign, once the value conflicts took the form of technical criteria, long before any relevant products might have gained public attention.

1.2.3 Whose competitiveness?

The pesticide directive had marked a victory for the rhetorical imperative of international competitiveness. Industry's warnings about disinvestment helped to persuade government, as reflected in the Bangemann report (CEC, 1991). As one industrialist described his successful lobbying on regulatory policy, 'Now at last [Jacques] Delors and senior members of the [British] cabinet have realized that the industrial base of Europe is in serious jeopardy' (interview, 22 March 1991).

Lobbying to hasten product-based regulation, industry and DGXII emphasized GMOs' familiarity, their presumed benefits, and the economic costs of over-regulation. However, this latter claim exaggerated the importance of regulatory costs; in reality such costs had little bearing upon strategic R&D decision-making in large biotechnology firms, such as those represented by their lobbying organization, the SAGB (Chataway and Tait, 1993).

In the late 1980s, moreover, few GMO biopesticides were undergoing trial releases in EC countries anyway; Europe had far fewer microbial than plant GMO releases, as compared to the USA (OECD, 1990a: 113). Although several EC-based companies were developing GMO biopesticides, most were conducting their trial releases elsewhere, mainly in the USA, where they anticipated finding a larger market anyway, given the greater problem of plant pests there than in Europe. For example, the Danish-based Novo Nordisk was linked with the US-based Entotech (Cutler, 1991); likewise Royal Dutch Shell with a small US firm (Mycogen Corporation, 1989: 14). Thus EC regulation could hardly drive out an investment which had already gone to the USA for other reasons.

Why, then, was 'dual regulation' such a problem? Whenever a company obtained commercial product approval from the USA's Environmental Protection Agency, the product might then face more stringent testing requirements for importing the product into Europe. This was why EC regulation would make an important difference, according to a spokesperson for European pesticide companies (GIFAP interview, 24 June 1992).

Thus European industry was urging a deregulatory move which would facilitate US exports to Europe (Levidow, 1994b). If EC biotech companies were not already multinationals, then they were developing trans-Atlantic joint ventures, thereby following a more general industrial pattern (Ramsay, 1992: 29; Assouline, 1989; Petrella, 1989). In general, regulatory standards have assisted precisely this international integration of capital, rather than any geographically-based competition (Picciotto, 1991). As a further irony, the biotechnology industry was urging the EC to imitate US 'risk-based regulation', yet this framework was proving contentious in the USA, where only the USDA had so far issued any regulations (see chapter 4, section 2). In sum, EC biotechnology regulation was deferring to a rhetorical rationality which concealed its own political agenda.

2.0 BRITAIN: 'Regulating the Product'

During the EC-level disputes over how GMOs might obtain market approval, there was little public debate or press commentary in Britain (except, e.g. BBC, 1991). By 1992 the market approval stage had been reached by only one GMO product involving a live release; this was a bakers' yeast, whose approval met a brief flurry of newspaper articles which expressed resentment at inadequate public consultation (analysed by Kemp, 1992). No other GMO had advanced beyond the stage of small-scale field trials.

Nevertheless, within Britain's regulatory system, routes to market approval were already being debated, long before products had reached this stage. The debate entailed diverse concepts of a GMO 'product'. This section analyses, in turn: industry's scenarios; regulatory advisors' scenarios; and the special case of herbicide-resistant crops.

2.1 Industry scenarios

SAGB was attacking the EC's entire regulatory framework, but British industry remained somewhat ambivalent towards abandoning process-based regulation. Industrialists did prefer a shift to product-based regulation, but they located such a shift within quite different strategies. These differences can be seen by comparing excerpts from individual cognitive maps; below, the dash (--) denotes 'in order to'.

At one extreme, a DTI official (individual code I5) regarded the process-based regulation as entirely misguided, even at the R&D stage, because it confirmed rather than allayed irrational fears about GMOs. Therefore, 'Put GMOs into product regulations -- avoid the view that GMOs are inherently risky -- people's fear recedes -- get rational regulation.' By invoking scientific rationality as both a guiding principle and goal, his formula coincided with DGXII's early warning to industry about the political hazards of process-based regulation.

One industrialist (I1) preferred ideally to 'hive off the R&D stage to the relevant product areas -- avoid an unwarranted discrimination against GMOs -- avoid increased regulatory burdens on industry'. Yet he reluctantly accepted the political necessity of process-based regulation at the R&D stage: 'Adopt satisfactory product legislation, and exempt GMO products from Part C of the Deliberate Release Directive -- base regulation on the intrinsic risk of the final product.'

In a similar vein, another industrialist (I6) recognized the flexibility in the 1990 Environmental Protection Act as it applied to the market stage: 'Government keeps the fuzziness of the Act, rather than develop process-based regulations -- UK implements the Act

on a product basis, rather than adopt overly stringent regulation -- innovation is hastened, rather than delayed.' At the same time, he acknowledged some political risks of that scenario: 'Ideally the research phase would be regulated on a process basis, but the development phase would be regulated as an existing category of regulated products, e.g. pesticides. Of course a product-based approach risks increased regulation of earlier (non-GMO) products, but we hope that sensible people won't do so.' That is, regulators might take GMO regulation as an occasion to reconsider inadequately regulated hazards of wider product categories. (For such proposals, see section 2.2.)

Another industrialist (I3) felt confident that regulators would remain 'sensible'. According to his scenario, 'Structure regulation on the basis of good science all the time, rather than a PR basis -- apply the same regulation to identical products, rather than different regulation to a gm product -- gm products go through only one form of approval.' Meanwhile, in parallel, 'Get a regulatory continuum from the first release onwards, rather than an overlap of regulatory authority -- build up an information base in stages -- require no new data at the product [market] stage -- the GMO product gets ultimate clearance as it pops out the top.'

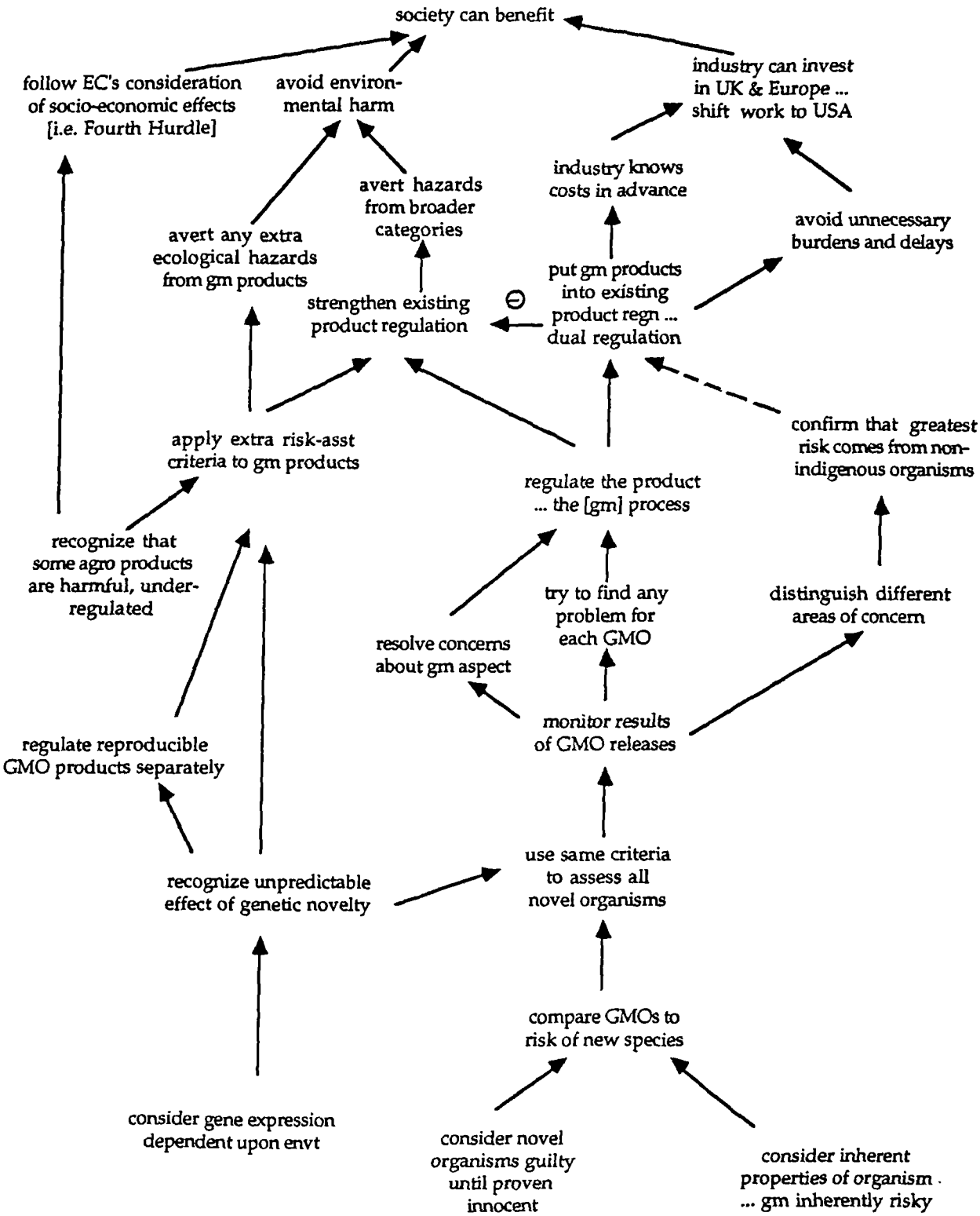
Industrialists looked to the regulatory procedure for predictably normalizing transgenic plants as they 'pop out the top'. For example (I7), 'Know what genes you have changed with gm, rather than random changes from traditional breeding -- know what changes to look for -- establish that gm is safer than traditional breeding.' Although some biotechnologists had made similar statements as first principles, here they were stated as hypotheses for testing: regulatory experience would vindicate the genetic modification process as precise and therefore safe. Process-based regulation could even make itself obsolete, according to one ambitious scenario (I1): 'Experimental results are held together centrally -- develop data on safety of gm process -- prove the novel techniques are safe.'

In sum, although industrialists reluctantly accepted process-based regulation of GMOs at the R&D stage, they wanted regulators to regard the organisms from the start as prospective products, not the results of a problematic process. 'Regulate the product' expressed both a guiding principle and desired shift to product-based regulation, warranted by objectively testable properties. Next, let us compare Britain's regulatory advisors to industry's notion of 'sensible people'.

2.2 Advisors' scenarios

The regulatory officials in the ACRE Secretariat brought different concepts of GMOs to bear upon the proceedings (as noted earlier in Chapter 6). The DoE asserted a scientific rationale for process-based regulation, particularly through an analogy to non-indigenous organisms.

Map 9.1: COMMERCIAL PRODUCT APPROVAL
Regulatory advisors' composite map



By contrast, an HSE official shared the prevalent industry view: 'There is not a great deal of scientific logic in the process-based regulation; probably the regulation will remain process-based for research, but there will [and should] be a rapid shift to product legislation' for market approval (interview, 26 September 1991).

ACRE members held diverse views on that anticipated shift, as depicted in the Cognitive Map 9.1. Divergent views concerned 'products' in at least two senses of the word: how to conceptualize GMOs' characteristics, as shown roughly in the bottom half; and how to regulate products at the market stage, as shown in the top half. Scenarios for straightforwardly normalizing GMOs appear on the right-hand side, while more cautious views appear on the left-hand side. The map shows a superficial convergence at two main concepts, where each turns out to have different meanings for different advisors. (This map overlaps somewhat with the bottom of Map 8.1, in order to demonstrate links between those value judgements and routes to market approval; see Chapter 8, section 2.1.2.)

* *'Assess all novel organisms'*

Near the bottom of Map 9.1 is the first convergence: 'Compare GMOs to the risk of introducing a new species', so that regulators can 'Use the same criteria to assess all novel organisms', be they genetically modified or non-indigenous (S8,T2,C1,C3). Advisors regarded this as a more scientifically sound basis than regulating GMOs alone (as described in Chapter 6, section 2), though for quite different reasons.

Some advisors accepted that dual remit as a way to avoid stigmatizing GMOs, while credibly disproving the hypothetical analogy to non-indigenous organisms, especially for single-gene changes in well-known crops. For example, in the lower right of the map, 'Consider the inherent properties of the organism, rather than consider GMOs as inherently risky' (D4,C1,C3); this expresses confidence in GMOs' predictability. 'Distinguish different areas of concern' (C1) means to obtain experimental results which show that 'GMOs pose no special or unexpected hazards' (S7,C1), and thus 'confirm that the greatest risk comes from [newly introduced] non-indigenous organisms' (C1).

Other advisors, however, emphasized an ecological complexity which small-scale field trials might not adequately anticipate. They wanted the regulation to 'consider gene expression dependent upon environment', and so 'recognize the unpredictable effect of genetic novelty' (S8,S2,S1). Anticipating unpredictable effects, moreover, two advisors (S2,S4) wanted to 'regulate reproducible gm products separately', even at the commercial product stage.

Some advisors spoke as if the genetic modification process were on trial, though not mainly for the reasons given by ecologists. 'Resolve concerns about the genetic modification aspect' (D2) meant, for example, verifying the stability of the new genetic combination and safely using plant pest vectors. Even for broader safety criteria, laboratory tests and small-scale field trials could enable us to 'conclude that the probability of the unexpected from genetic modification is low'. Although others were less confident, they too spoke in terms of vindicating the technology: 'If the technology is proven safe, then the constraints should be relaxed to the point of being no hindrance' (S8). Thus, within a formal case-by-case approach for assessing individual GMOs, advisors acknowledged a pervasive subtext of 'process' stigma and uncertainty, to be overcome through testing.

* *'Regulate the product, not the process'*

From the first convergence, the composite map continues upwards: 'monitor results of releases -- try to find any problem for each GMO -- 'regulate the product, not the process' (D4,S8,D2,C1,S1), which provides the second main convergence. Nominally this meant regulating each GMO 'on the basis of its intrinsic properties, rather than on the process by which it was produced' (e.g. D4,C1,C3). However, advisors expressed differences about how those 'intrinsic' properties can be adequately known, even if one knows the precise genetic changes, and how their benign character can be verified at the commercial product stage.

The upper right-hand part of the map depicts a confident view of safety and predictability (though does not depict all the concepts mentioned here). Monitoring results would soon warrant allowing some GMOs to 'short circuit the risk assessment' and to enter a 'fast-track'. Regulators could resolve questions about large-scale trial releases, and finally put some GMO products into the existing product regulations, wherever available (C2,C1,C3,D4), rather than face 'dual regulation'. In this way (C1), industry could know its regulatory costs in advance, rather than undergo unpredictably higher costs and marketing delays; industry would then have the incentive to invest in the UK and Europe, rather than shift gm work to the USA and elsewhere.

The upper left-hand part of the map shows more cautious meanings of 'regulate the product, not the process.' In addition to the two advisors (S2,S4) who advocated separate regulation for GMO products, some expressed reluctance about simply putting GMOs into existing product regulations.

Emphasizing ecological uncertainties, some advisors favoured subjecting GMO products to extra risk-assessment criteria at the commercial stage, in order to avert any extra ecological

hazards. For example, existing product regulations would be adequate 'only if there is no special hazard'; in any case, it should 'build in an extra check for genetic stability', and 'broaden the risk assessment to take into account the larger scale' (S7). Another advisor (D3) was sceptical that the civil servants presently regulating plant products would adequately take into account the gm aspects. Some advisors proposed greater changes to current product regulation. 'If a transgenic plant contains an insect toxin, then regulate it as a pesticide' (T2), unlike non-gm plants. And if the GMO is intended for export, then 'assess effects beyond the UK' (D2); in particular, 'assess potential hybrids of transgenic plants worldwide' (S5).

Some advisors acknowledged the limits of safety testing. Rather than pretend omniscience about all eventualities, ACRE's chairman suggested that farmers monitor the behaviour of any novel products that they use, whether a GMO or not (e.g. Beringer et al, 1992: 139). Stated another: 'Small-scale trials will make us more confident than if we hadn't done them, but my main concern is that the really interesting environmental problems won't show up until commercial release' (S1); he preferred that biotech R&D simply avoid releasing problematic organisms, such as oilseed rape and the AcNPV baculovirus.

Some advisors emphasized institutional uncertainties which could influence environmental effects; from that standpoint, some saw GMO regulation as an opportunity to strengthen existing product regulations, by assessing products in their agronomic and/or socio-economic context. In general, 'consider agronomic practice in scale-up' (S9). Likewise, 'There is more to worry about at the commercial stage; don't expect that everyone behaves as expected' (S1). For example, 'Consider effects on herbicide usage' (S7,S9), and do not assume that crop spraying will always remain within the target field (S1). 'Anticipate GMOs being marketed aggressively, and consider their wider impact on current farming practices' (D1). There was some concern about exporting GMOs to Third World countries which might have less stringent regulation (S10,T2).

Moreover, 'recognize that some agricultural products are environmentally harmful and under-regulated' (left-hand column). For example, 'regulate all biopesticides' so as to 'avoid spreading resistance to them, especially among wild populations' (D1). Starting from concerns which predated GMOs, this advisor treated GMO regulation as an occasion for seeking more stringent regulation of broader product categories.

Looking beyond environmental consequences as such, two advisors (S4,D3) wanted the assessment to consider socio-economic effects, such as nutrition and Third World exports (cf. Hobbelink, 1991: 93; cf. Walgate, 1990: 57); these advisors regarded a Fourth Hurdle as necessary, in order to gain public acceptance for biotechnology. More modestly, some (e.g.

T2,S9) wanted adequate information disclosure on prospective products, so that public debate could lead industry R&D in an environment-friendly direction. CBI nominees (C1,C2) wanted to 'let the market decide' social need, rather than introduce any Fourth Hurdle.

A potential dilemma arose from biotechnologists' claims that GMOs are just as safe as the products of traditional breeding. In that context, 'be cautious about statements comparing GMOs and non-GMOs', lest such statements lead to increased regulation of traditional breeding (as some advisors advocated above). Through accumulated testing, we can 'overcome discrimination against GMOs, rather than regulate traditional plants as well' (C1). As shown near the centre of the map, there is a negative link to the proposed strengthening of product regulation.

Several advisors felt that risk assessment could not afford to depend upon the particular manner of using a product, because restrictions on product use would be unfeasible at the commercial stage: 'If it needs special controls at that stage, then we have really lost it' (S1). Safety tests would have to 'prove that the product is risk free', so that commercial use would 'require no special handling of the product, rather than trust the farmer to make no mistakes' (C2). However, that apparent agreement involved disagreements about the criteria for regarding product safety as independent of human behaviour.

The ostensibly common goal, 'society can benefit', served to justify different priorities. Given various scenarios about potentially harmful effects, some advisors foresaw additional regulation as necessary so that GMO products could 'avoid environmental harm', as shown in the upper-left hand side of the composite map. For others, especially the CBI nominees, industry must 'avoid unnecessary regulatory burdens and delays', as shown in the upper right-hand side.

In summary: The consensual slogan -- 'regulate the product, not the process' -- concealed different concepts of the 'product' as predictable and/or benign. Advisors disagreed on how to define the risk-generating system: e.g. as a testable property of a product and/or as all its concomitant practices, including indirect effects. There were related tensions around vindicating 'the technology', as if it were reducible to the genetic modification technique. Advisors' views indicated that a precautionary approach might pose difficulties for normalizing GMO products -- indeed, even for equating normality with safety.

2.3 Herbicide-resistant crops

The prospect of herbicide-resistant crops most clearly evoked different concepts of product risk (see also Chapter 7, section 3). Hypothetical hazards had special urgency for oilseed rape and sugar beet: as particularly lucrative crops, they also happened to have indigenous weedy relatives, with which they might interbreed. As one advisor had suggested, unintended effects 'can be put in a rational order', as follows.

First, could a herbicide-resistance gene impart a selective advantage to a weed? Some industrialists and biosafety researchers offered a reassurance: 'For resistance to a particular herbicide, transgenic plants would be at a selective advantage only if the herbicide was used in natural plant habitats' (Dale, 1991). Others regarded this reassurance as naive, given that crop-spraying often strays outside cultivated areas, even apart from the possibility of pleiotropic effects.

Second, if herbicide-resistant weeds became a nuisance to agriculture, then should this effect be regarded as environmental damage? Some ACRE members had suggested not, when arguing that farmers could switch to another herbicide, and that such a nuisance was 'only a problem for agriculture', as ACRE's chairman stated at a public conference in June 1990. On the contrary, insisted some other members, 'The environment includes agricultural fields' (Williamson, 1992: 3), as implied by Britain's statutory definition of environmental harm (EPA, 1990: 116).

Third, what if herbicided-resistant weeds arose indirectly, from the sheer selection pressure of changed herbicide usage? This scenario apparently lay beyond the remit of process-based GMO regulation, though it was discussed by regulatory advisors, as exemplifying the warnings about a genetic and/or chemical treadmill. In response, one research manager (C4) considered biotechnology R&D as adequate to 'solve the technical problems of homogeneous monoculture with technical means'. Others expressed unease at agribusiness generating the need for yet more technological solutions (e.g. S1). Another advisor (S4) resented the prospect of herbicide-resistant crops being mass-marketed: 'This makes me uncomfortable because genetic modification isn't about avoiding pesticides; it's just making them a little less hazardous. I'm not very happy about that. And the committee wouldn't look at [assess] that.'

Indeed, the herbicide-crop link strained regulatory boundaries. Existing pesticide legislation required manufacturers to make a new application to MAFF for any change in the terms of approval, such as extending a herbicide's use to additional crops; this change would be assessed by MAFF's own Advisory Committee on Pesticides. Few ACRE members favoured broadening their remit to consider the herbicide implications, but some doubted that MAFF

would adequately handle these, much less the complex link between crops and herbicide usage. As one ACRE member said (S9), 'The agronomic implications of the herbicide/seed combination is a value judgement which ACRE is trying not to make, as it lies outside our genetic [modification] remit; the issue is slipping between ACRE and MAFF.'

Industry advocated separating the 'science-based' safety assessment of the crop and the herbicide. According to a CBI nominee (C1), environmentalist groups were pursuing an illegitimate 'linkage' between GMOs and herbicides by attempting to treat them together: 'It is illogical because it is assuming that the two are linked... Herbicide usage, or misuse, or lack of use, is considered by the pesticides committee, and its safety is verified. The two things are separate.' And relative environmental benefits or preferences were an 'ethical question', not a safety issue (interview 22 March 1991; note the rhetorical resonance with the USA's rejection of a proposed 'linkage' among issues in the Gulf conflict.)

In response to these arguments, a MAFF official prepared a discussion document (Bainton, 1991; cf. Bainton,1993). Recasting the issue, it reduced environmental problems to separate considerations about the gene, crop and herbicide. Indeed, 'herbicide-resistant crops do not form a uniform group with similar characteristics'. By denying systemic hazards, it relegated risk assessment to separate risk factors for specific cases: 'risk' as a testable property of things.

The MAFF document briefly mentioned commercial pressures, but solely as if they provided an incentive for farmers to reduce herbicide usage: 'the assessment of the value of the benefits is for the market to decide'. Like industry, MAFF portrayed market relations as a free choice of individual consumers to buy products already approved for safety. The document ignored competitive pressures upon companies to market particular gene-crop combinations and upon farmers to buy them. Although it acknowledged the potential for sheer selection pressure to generate herbicide-resistant weeds, it suggested no way to prevent or even anticipate that outcome, conceptually delinked from market relations. Moreover, as the Greenpeace (1991c) reply noted, MAFF made 'no attempt to consider whether there were other approaches to the problem of weeds which might carry less risk'.

Thus MAFF's analytical reductionism, and ACRE's alloted role within it, abstracted risk factors from a wider risk-generating system. In this way, the regulatory system prepared to displace issues of commercial pressures perpetuating herbicide usage. Such issues were conceptually fragmented into a technical risk assessment of unintended effects, and a free consumer choice of desired effects.

3.0 CONCLUSIONS: NORMALIZING GMO PRODUCTS

Long before GMO products were proposed for commercial use, the terms for their market approval were being debated and foreclosed, in ways which highlighted different concepts of a biotechnology 'product'. After the EC Deliberate Release Directive was enacted, agrochemical multinationals attacked process-based legislation as irrational; they claimed that it lacked any scientific basis, hindered the competitiveness of the European biotechnology industry, and stigmatized the genetic modification process. From within the European Commission, DGXII encouraged industry demands for a policy shift towards product-based regulation; in effect, such a shift would minimize the precautionary content of the EC Directive, while still using its framework to legitimize moves towards market approval.

In particular, industry lobbying efforts gained a significant step towards removing GMO biopesticides from process-based regulation; once implemented, a new pesticides directive would shift risk management to those national authorities which had previously regulated agrochemicals. In this conflict, victory went to the side which portrayed risk assessment as an objective scientific matter of assessing 'inherent product characteristics'. Complementing this portrayal, industry subsequently proposed to delete the broader risk-assessment criteria for GMO biopesticides.

This political pressure was indeed motivated by market imperatives, though in quite different ways than were officially claimed. In practice the market competition was among trans-Atlantic multinationals or joint ventures. The deregulatory moves were less about enhancing 'European' biotechnology, than about facilitating US-based exports into the EC and the international integration of EC-based firms. Such changes would also privilege the established scientific expertise, and perhaps minimize popular influence over regulatory policy. (Compare this with industry's anxiety about excessive public participation, in Chapter 6, section 3.)

Similarly, as a major study of chemicals regulation concluded, 'Evidence of an emerging international consensus can strengthen the hand of regulators who are engaged in difficult domestic proceedings... bureaucratic policy making in Brussels can be used by national governments to widen their already substantial advantages over the legislature' (Brickman et al., 1985: 294, 67). In the case of GMO biopesticides, moreover, national agriculture ministries strengthened their advantage over environment ministries, as well as over the European Parliament, even though the Single European Act supposedly strengthened the Parliament vis a vis the Commission and the Council.

During these EC-wide disputes, industry was urging government to 'regulate the product, not the [gm] process', as in the US government slogan; however, the concept of 'product' had problematic meanings. In Britain's regulatory system, advisors preferred to judge product safety without presuming any special conditions of use. In this way, risk assessment could avoid naively assuming that commercial use will strictly follow safety rules. However, by seeking an unconditional version of safety, the assessment would have to consider a wider range of ecological and agronomic uncertainties, hardly amenable to standardized testing. Thus market approval entailed a practical dilemma: how to achieve social legitimacy by specifying testable uncertainties of a GMO product.

Although regulatory advisors accepted the need to 'regulate the product', they interpreted 'product characteristics' in divergent ways. Industry in particular sought a standard regulatory procedure for testing inherent properties of organisms. Industrialists expected the procedure to vindicate the genetic modification process as safe, to clear GMOs of suspected hazards, and thus to normalize GMO products.

By contrast, some regulatory advisors sought more wide-ranging studies to anticipate ecological complexities and product uses. They foresaw commercial pressures and agronomic practices causing environmental harm, which might arise from using some non-GMOs as well, especially in the context of intensive monoculture. Some hazards apparently lay beyond the remit of safety regulation: for example, herbicide-resistant crops influencing herbicide usage, or herbicides generating resistant weeds, or biopesticides generating resistant insects. For industrialized agriculture, as in other industrial systems, the context *constitutes* the hazards (Wynne, 1992: 284).

In response to such concerns, some advisors (and many environmentalists) favoured subjecting biotechnology products to a 'Fourth Hurdle', i.e. socio-economic and/or ethical criteria. For them, herbicide-resistant crops in particular exemplified how commercial pressures become embedded in R&D priorities and harmful agricultural practices. In response, the regulatory system justified assessing such crops separately from herbicide usage, thus denying their mutual linkage within R&D and agricultural practice; thus issues of commercial control could be displaced into technical risk assessment.

The wider debate on a proposed Fourth Hurdle had a double-edged role. On the one hand, it highlighted potential harm which lay beyond safety regulation. On the other hand, the state and industry rhetorically distinguished the merely subjective Fourth Hurdle from a putatively 'objective' risk assessment. Moreover, the latter portrayal became a self-fulfilling claim, as industry attempted to narrow the range of uncertainty deemed relevant to risk assessment.

In summary, by demanding moves toward product-based regulation, industry was pursuing several aims: to obtain a short-cut normalization of GMOs, to restrict the range of relevant ecological uncertainty, to limit the precautionary content, and to minimize the potential for public involvement. In this way, industry might obtain more predictable safety standards and thus protect its prerogative to direct innovation. Yet it thereby jeopardized the social legitimacy which market approval could provide for GMO products.

This dilemma arose from an endemic regulatory tension. Although industry arguments about competitiveness were misleading, the deregulatory pressure did arise from market imperatives, which had made the EC Directive possible in the first place. After all, both the regulators and regulated were engaged in a common project: to establish the political conditions for an international market to treat GMOs as normal products. Even within the precautionary framework, the very concept of 'safety' tended to internalize market constraints -- by abstracting 'risk' from the context of intensive monoculture, and by standardizing testable uncertainties of prospective commodities. Thus, in disputing the terms for market approval, regulatory actors were playing out a pervasive tension between commercialization and social legitimacy.

Chapter 10

Conclusions: CONTESTED RATIONALITY

This study began with research questions about the system developed for regulating GMO releases. Drawing upon earlier chapters, this one discusses the following questions:

* How does GMO regulation construct some type of rationality? (section 1)
* How might further research test or strengthen the argument of this thesis? (section 2).

1.0 CONSTRUCTING A PROCEDURAL RATIONALITY

In the thesis I argue that GMO regulation was managing a tension between social legitimacy and commercialization. This internal contradiction helps to explain the pervasive regulatory dilemmas: how to acknowledge the stigma associated with GMOs, in a way which can overcome it; how to justify risk-management rules in terms of a hypothetical risk identification; how to define safety criteria which can depoliticize 'uncertainty' about risk; and how to make safety judgements unconditional, i.e., independent of human behaviour. The thesis extends earlier theoretical insights on such dilemmas, regarding how regulators defend their own cognitive framework (Beck, 1992a: 167-69) and how safety judgements bound the risk-generating system (Wynne, 1982: 172).

In so doing, the thesis recasts theories of safety regulation as a distinct rationality. According to such theories, technological-risk controversy should be analysed as a recurring conflict between safety regulation versus other rationalities. In the case of GMO regulation, such conflict did indeed arise -- between regulators, industry and environmentalist groups -- yet it also arose within the regulatory procedure itself.

Thus I argue that the regulatory procedure mediated between internal poles of tension which various theories attribute to distinct rationalities. In particular, the regulatory framework derived its context, and even its technical content, from the need to overcome potential threats to a market; such a feature should not be attributed to a distinct 'individualist' rationality (as do Schwarz and Thompson, 1990). Also, as precautionary measures went beyond technically measurable parameters, or even beyond identifiable hazards, these measures conveyed symbolic meanings of environmental control; such

features should not be attributed to a distinct 'cultural' rationality (as do Krimsky and Plough, 1988).

In analysing the internal tensions of a procedural-technical rationality, the thesis builds upon theories of how safety regulation constructs stereotypical objective/subjective boundaries. The argument is elaborated below by linking the original research questions to the literature survey (Chapter 1, sections 1.4, 2.0), and then by discussing 'the precautionary principle'. The questions were:

* How does the regulatory system handle diverse accounts of the risk problem? How does this treat some 'perceived risks' as if they might be real? (subsection 1.1).
* How is a risk-management regime devised and justified? What is the significance of 'national regulatory styles'? (subsection 1.2)
* How does the regulatory procedure attempt to reduce uncertainty about risk? How does this effort depoliticize scientific uncertainty? (subsection 1.3)
* What is the precautionary content, and why? (subsection 1.4)

1.1 Defining the risk problem

From an early stage of R&D, biotechnologists faced political challenges to their avowed project of further industrializing agriculture. Opponents cast the 'risks' as a cultural danger, expressed in both ethical and ecological terms. They foresaw biotechnology aggravating the hazards of intensive monoculture: GMOs threatened to cause instabilities which would mean greater agricultural dependence upon laboratory expertise and commercial interests.

By contrast, industry celebrated biotechnology as a reprogrammed, precisely controlled nature which would safely supersede the limits of chemical-intensive agriculture and thus realize nature's cornucopian potential. 'Environment-friendly' products would protect a fragile agriculture from environmental threats. Through a rhetorical greening of biotechnology, industry naturalized the project of investing nature with metaphors of computers and commerce (see Chapters 3, 4 and 9).

In challenging biotechnology as a mode of control, critics appealed to environmental images which express divergent 'myths of nature' (Schwarz and Thompson, 1990: 3-4, 62-68). Some depicted GMOs as potential pollutants, running out of control and thus threatening a fragile Nature, which could tolerate only 'trial without error'; some also attacked biotechnology as a sinister control over nature and society. Although some industrialists acknowledged that biotechnological progress might entail some 'trial and error', they presumed that any mishap would be minor or remediable (see Chapters 3, 8 and 9).

Each account of the problem had its own inner link between risk and benefit. On one side, society was 'at risk' from biotechnology, which imposed a sinister control, transgressed natural boundaries, created new pollutants, and/or excluded beneficial alternatives. On the other side, society was at risk from failing to reap the indispensible benefits of biotechnology, whose environment-friendly products offered a benign mode of controlling environmental threats to agriculture.

Despite the cornucopian rhetoric of biotechnologists, their practice and strategic aims were more complex (than the distinct rationalities theorized by Schwarz & Thompson, 1990: 66-67). Industrialists sought an official safety imprimatur which could overcome political threats to biotechnology R&D and to an eventual market. Recognizing this need, regulators proposed safety procedures as essential means of protecting biotechnology as well as the environment (see Chapters 4 and 5).

GMO regulation analytically separated 'risk' from benefit; it cut across the stances of both biotechnologists and their opponents. Safety regulation took for granted socio-environmental benefits from biotechnology, by offering to protect its wealth-creating potential. At the same time, safety regulation attempted to anticipate any physically measurable, direct harm from GMOs or their inserted genes; regulation proceeded as if some hypothetical hazards were unacceptable, while defining them in naturalistic ways, abstracted from the risk-generating system of intensive monoculture (Chapters 4, 5 and 8; see also below, section 1.2).

The step-by-step principle provided a means for Britain's regulators to postpone distinguishing between 'real versus perceived risks', and thus to legitimize early trial releases. By confining the genetically modified material, initial precautions went beyond identifiable hazards and so accommodated diverse risk perceptions. Regulatory advisors could reach agreement on the conditions for each small-scale field trial, while symbolically containing perceived risks. This often meant selecting initial releases for public acceptability, and/or designing them to demonstrate that GMOs were being kept under safe control (see Maps 6.8, 7.1).

However, such measures could not always contain fears of biotechnology as an ominous control. In a low-key local protest in North Cornwall, some residents responded to the small-scale field trial of a herbicide-resistant crop as a commercial and territorial invasion; they perceived the particular release as a 'step' towards undesirable agricultural practices, as well as a short-term potential for harm. In the case of a viral insecticide which was proposed for trial release, regulatory advisors cited plausible hazards which went beyond the scientific uncertainties testable in a laboratory; some safety questions were apparently intended to discourage the applicant's genetic redesign of the virus for eventual commercial use (see Chapter 7).

In both those difficult cases, and perhaps more generally, pollution imagery informed a precautionary approach: hypothetical hazards had to be 'perceived' before they could be translated into scientific terms, incorporated into safety measures, and/or empirically tested. Formally, regulators assessed the safety of present 'step' only, but sometimes this became difficult to separate from the commercial forces which were driving it. At the same time, an R&D trajectory could be rendered more acceptable through a dual 'advance of knowledge', whereby enhanced efficacy provided the resources and incentive to test safety as well.

In all these ways, Britain's stepwise procedure can be understood as a cultural form, a shared symbolic framework for acknowledging and potentially overcoming the perceived abnormality of GMOs. Thus it would be misleading to theorize GMO regulation as a 'technical rationality' which considers only measurable parameters, as distinct from a 'cultural rationality' (as do Krimsky and Plough, 1988: 108, 306). At the same time, those authors rightly attribute local US protests to a feared loss of environmental control (ibid.), in a way similar to the concerns expressed by Cornwall residents; in these local protests, NIMBY and NIABY features merged. Both episodes illustrate how new technological developments generate 'rational anxieties' which environmental regulation displaces rather than addresses (Grove-White, 1991: 439-40).

The above features warrant extending one philosopher's argument: that risk controversy cannot be resolved until 'people stop trying to distinguish real risk from perceived risk'; and that such controversy obstructs social negotiation on technological progress (Shrader-Frechette, 1991: 85-87). Certainly, GMO risk management rendered small-scale field trials more acceptable, as their design effectively suspended the distinction between 'real/perceived risk'.

However, such a distinction could not be abandoned but only deferred, perhaps until the stage of market approval. Moreover, some critical responses did not readily distinguish a trial release from the commercial aims and institutional forces which it embodied; in effect, safety sceptics were disputing the boundary of the risk-generating system. Such a dispute over 'real' risk became the only available means of socially negotiating a contentious form of technological 'progress' (notwithstanding Shrader-Frechette, ibid).

In sum, the stepwise procedure initially suspended the stereotypical distinction between 'real/perceived risk'. In making authoritative safety judgements on each step, the procedure took for granted the benign R&D agenda of industrializing agriculture, of further reconstructing nature as a commodity. By ensuring and demonstrating that GMOs would not run out of control, it displaced issues of socio-agronomic control -- though not

always successfully. By symbolically containing these concerns, safety regulation mediated a tension between social legitimacy and commercialization.

1.2 Justifying risk management

In establishing a risk-management regime for GMO releases, it was difficult to justify formal rules in terms of a prior risk identification for hypothetical hazards. Nevertheless a scientific rationale was devised to justify a regulatory system which served political-administrative needs. These systems (in the USA, EC and Britain) can be analysed as fulfilling several roles: e.g. providing a cognitive framework, handling the stigma associated with GMOs, and managing political conflicts.

Given the national differences in political protest and regulatory responses, an international consensus remained elusive. Although regulators nominally accepted the 1986 OECD proposal to follow a stepwise relaxation of containment, there were sharp disagreements on its proper legal and scientific basis. In this regard, the 'product versus process' debate concerned how to classify GMOs for regulatory purposes.

The US government adopted a product-based regulatory system, also called a 'risk-based' approach, which gave several meanings to the term 'product'. An implicit aim was to portray GMOs as otherwise normal products, i.e., to avoid stigmatizing them by association with the genetic modification process. Through new administrative rules, the government classified GMOs according to their ultimate product use and assigned them to Federal agencies accordingly, under existing product legislation; this legal status narrowed the types of hypothetical hazards for which agencies could demand safety data. The rules also compelled each agency to justify any 'additional' regulation of a GMO release in terms of specific product characteristics which would warrant such scrutiny; yet the government had difficulty finding a practicable, consensual way to specify such grounds for a risk-management procedure.

Indeed, in the name of keeping the rules 'rational', the US government inadvertently made regulatory science appear even more political. Its administrative rules pre-empted risk-assessment issues, by presuming that the available knowledge was adequate to predict the significance of genetic novelty, and by imposing cost-benefit criteria upon any 'additional' regulatory procedure. Consequently the new rules provoked public controversy, highlighting conceptual differences among the Federal agencies, as well as among other protagonists, especially environmentalist and industry groups (see Chapter 4). USDA regulators even acknowledged that their safety criteria might not adequately reassure the public about 'perceived risks' at the market approval stage (see Chapter 7, section 1).

In the USA, GMO regulation extended features of the characteristic 'adversarial' style: interested parties had much opportunity to challenge risk-management rules, while official appeals to a scientific basis intensified political conflict. US regulators were left with the burden of evidence for imposing any 'additional' regulation upon GMO releases. For the Environmental Protection Agency in particular, executive-level constraints hindered the attempt at negotiating scientific criteria through its advisory committee. Biotechnology regulation could not readily stabilize a 'science policy', as chemicals regulators had recently done (Jasanoff, 1990).

In contrast to the USA, the EC adopted a process-based regulatory system, which arose from the imperative of overcoming national regulatory differences. Some officials called this 'uncertainty-based' regulation, thus acknowledging indeterminate cause-effect models of potential harm. Although the 1990 EC Deliberate Release Directive was called 'preventive', it went beyond preventing documented hazards. The Directive had several precautionary features: it subjected all GMO releases to broad risk-assessment criteria; applicants held the burden of evidence for demonstrating safety, with respect to hypothetical hazards.

Shortly regulators encountered attempts at limiting the precautionary effect of the Directive. Agrochemical multinationals attacked process-based legislation as irrational, on grounds that it lacked any scientific basis and hindered the competitiveness of the European biotechnology industry. Their lobbying efforts gained a significant step towards removing GMO biopesticides from process-based regulation; once implemented, this would shift risk management to those national authorities which had previously regulated agrochemicals. In this episode, victory went to the side which portrayed risk assessment as an objective scientific matter, assessing only 'inherent product characteristics'. Complementing this portrayal, industry attempted to narrow the range of ecological uncertainties relevant to risk-assessment, and so gain a short-cut normalization of GMOs (see Chapters 4 and 9).

The advocates of product-based regulation were more complex and varied than their rhetoric might suggest. DGXII had no direct responsibility for safety regulation, unlike the biotechnologists whose research it was funding, and unlike the agrochemical multinationals which comprised the SAGB. Although these firms challenged the conceptual basis of the process-based Directive, their regulatory officials also participated in developing its framework, at least in Britain, thus using it to legitimize R&D trial releases. Indeed, leading industrialists in Britain accepted the political necessity of adopting process-based legislation there, if only for obtaining an official safety imprimatur.

As the EC framework pushed Britain to go beyond the HSE's voluntary controls, the DoE took the opportunity to formalize a precautionary rationale for process-based legislation. When the British government incorporated the EC Directive into a new law, the DoE gained industry support for a statutory licensing system but met criticism for its precautionary legal language; this conflict symptomatized the dilemma of how to legislate credibly for hypothetical hazards. At the same time, by rejecting proposals for a Public Biotechnology Commission, the government confirmed that the environmental regulation would narrowly define the risk-generating system, by excluding effects on and from agricultural practices (see Chapter 5).

Britain's new advisory committee, ACRE, complemented the statutory control of hypothetical hazards, by establishing a consensual risk-management regime prior to any agreed risk-assessment methods. As a scientific basis for the committee's existence, regulators cited the genetic novelty of GMOs, by analogy to non-indigenous organisms; industry pragmatically accepted this cognitive framework as a basis for ACRE, despite having dismissed such an analogy earlier. Placed under an HSE/DoE Joint Secretariat, ACRE could discreetly negotiate the different safety perspectives of those two (and other) departments, combine human health and environmental considerations, and signal the DoE's greater role in biotechnology regulation (see Chapter 6).

In establishing its broad-based committee, the British government implicitly acknowledged the social negotiation of regulatory science, while attempting to keep it within confidential procedures. In deciding ACRE's membership, the government stretched the 'specialist' category to encompass an informal public-interest representation; the latter members personified the tensions of translating 'risk' as cultural danger into 'risk' as manageable, testable uncertainties. ACRE's composition also embodied the tension between easing market approval versus gaining social legitimacy -- a tension which was manifest even within the same member (see Chapters 3 and 6, including the cognitive maps). With a broadly-based confidential procedure, Britain's consultative regulatory style was extended from other hazards to GMO releases. ACRE's composition in particular exemplified 'responsible co-optation', which serves to protect the neutral image of regulatory science, while gaining public deference to expert committees (cf. Vogel, 1986: 51-52; Brickman et al., 1985: 310; Jasanoff, 1986: 66).

Having surveyed the regulatory frameworks in the USA, EC and Britain, this thesis supports the theoretical claim that cognitive differences 'render policy making possible', by virtue of attaching symbolic meanings to issues (Schwarz & Thompson, 1990: 68). Such analysis contradicts a recent lament that 'rational' risk-management institutions have been difficult to design, supposedly because risk debate 'has become heavily politicized around different cosmologies or worldviews' (Royal Society, 1992: 153) -- as if risk management could exist outside of a cognitive framework. As Britain's case illustrates, a

hypothetical biological analogy served as a pragmatic compromise, which many participants provisionally accepted as a framework for demonstrating safety and thus for eventually allowing process-based regulation to 'wither away' (see Chapter 9).

As this thesis also argues, each risk-management regime had an implicit political aim which found a scientific rationale. The British government cited the ecologists' analogy between GMOs and exotic organisms; this helped to justify an administrative compromise, suitable for negotiating specific cases, in the British 'consultative' style. The US government devised special risk-management rules for GMOs, yet used linguistic euphemisms to avoid stigmatizing them; this stance provoked public debate about the detailed scientific criteria, and so reproduced the US 'adversarial' style. From these national cases, we can slightly rephrase the following aphorism: 'what matters most in risk management is the process, not the outcome' (Jasanoff, 1986: 81); or rather, the most important outcome is social legitimacy, in turn dependent upon the regulatory mode of public representation.

This thesis also emphasizes difficulties in establishing and justifying a hierarchal, expert-based authority. Such authority has been theorized as fundamental to a procedural rationality -- which is 'more concerned with the proprieties of who does what than in evaluating the outcome', if there is one (Schwarz & Thompson, 1990: 7). For GMO releases, British and EC industry sought a formal hierarchy -- i.e., a licensing system which could validate each risk assessment, specify the conditions of each release, and exclude those who might discredit biotechnology. At the same time, some industrialists sought to undermine the process-based framework for such an authority, and to narrow the range risk-assessment criteria, particularly for the stage of market approval. This indicates a tension between commercialization and social legitimacy -- within a procedural rationality, not simply between distinct rationalities.

1.3 De/politicizing uncertainty?

For GMO releases, the early scientific debates featured antagonistic accounts of the relevant uncertainty (see Chapters 1, 3 and 4). Biotechnologists celebrated their genetic techniques as a benign precise control; they acknowledged (at most) an uncertainty about product efficacy and about remediable damage to agriculture -- which they perceived as fundamentally threatened by the environment, rather than vice versa. Their account was challenged by ecologists who depicted scenarios of GMOs perturbing an ecological balance and/or aggravating familiar agricultural problems.

Biotechnology critics emphasized such accounts of scientific uncertainty, and its unacceptable consequences, when they turned GMOs into an environmental issue. They portrayed biotechnology as a cultural danger, in both ecological and ethical terms: GMOs

as nature out of control, and/or nature under sinister control. These warnings had a rhetorical continuity with other protests, whereby activists articulated the scientific indeterminacies in ways which raised issues of environmental control (Grove-White, 1991: 439, 441). By casting GMOs as a 'risk' problem, biotechnology activists posed a political threat, in turn cited by regulators when proposing new risk-management procedures.

Britain's precautionary legislation presumed the unacceptability of hypothetical harm from GMO releases. Although the government justified its policy by invoking 'sound science', GMO regulation reversed the earlier meaning of the term. In regulating hazardous chemicals and pollution, for example, 'sound science' had served to defer or weaken preventive measures, whose proponents were left holding the burden of evidence for demonstrating harm (Boehmer-Christiansen, 1992: 22).

By contrast, process-based GMO regulation demanded evidence of safety. As an implicit ethics, this requirement was justified by the uncertain potential for 'irreversible' harm, as cited in the EC Directive and British policy documents (see Chapters 4 and 5). Within this risk-management framework, Britain's regulators could generally accommodate diverse criteria for evidence of safety, and so legitimize the initial 'step' of small-scale field trials (see Chapter 7).

However, prospective conflict arose over the scientific basis for routinizing those small-scale trials or for relaxing controls. As in the earlier debate, scientific arguments expressed cognitive differences over how genetic novelty might affect ecological relationships; accordingly, they emphasized different kinds of past experience as a guide for reducing uncertainty about GMO releases. For microbial releases in particular, ecologists advocated research to ascertain the normal ecological baseline, so that monitoring efforts could detect any perturbation and thus anticipate unidentified hazards. Others, especially laboratory scientists, justified limiting risk assessment to identifiable hazards, especially their testable components (see Chapter 8).

In various ways, GMO risk research tended to test whichever uncertainties it could credibly and reproducibly control, such as gene flow and selective biological advantage of crops; in testing the host range of a viral insecticide, the research took for granted a reassuring model of viral epizootics (see Chapters 7 and 8). As in risk assessment more generally, biosafety research converted fundamental ignorance into 'marginal' imprecisions, which could then be progressively reduced with additional data (O'Riordan and Wynne, 1987: 393). Yet some advisors held doubts about what could be learned from testing properties of an organism in a carefully controlled environment.

Moreover, additional knowledge sharpened methodological disputes about how to obtain relevant and adequate evidence for relaxing controls. The same new evidence could elicit contrary interpretations -- for example, regarding whether ecological niches are limited by genetic variation or mainly by environmental variables. Geneticists and ecologists embed facts in a different model of causality, so new facts do not necessarily bridge the disciplinary divide, as noted by Krimsky (1991: 151).

In GMO regulation, new knowledge opened up further areas of uncertainty for biosafety research. Much research was testing the null hypothesis, i.e. the assumption that genetic modification would create no unintended effects. At issue was the range and type of experimental conditions which would warrant vindicating this hypothesis.

For GMO releases, risk assessment could plausibly consider an even wider range of 'what if?' cause-effect models, whose perceived importance depended upon environmental value judgements. Even for identifiable hazards from plants, regulatory advisors differed over how best to generate and interpret relevant evidence (see Map 8.1). This dilemma parallels other regulatory experiences, where more scientific knowledge has often intensified methodological disputes (Collingridge and Reeve, 1986: 51-60; Salter, 1988: 166, 199-201).

Thus the regulatory system still faced judgements on the acceptability of undesirable effects (see Chapter 8). Advisors disagreed over how to evaluate hypothetical outcomes, such as enhanced weediness from a transgenic crop. Asking themselves 'so what?', they answered that question in divergent ways. They differed, for example, in defining agriculture as inside or outside 'the environment'; in defining weeds; in conceptualizing unintended gene flow as 'genetic pollution'; and in foreseeing remedies for any agricultural disruption.

The regulatory procedure tended to undermine the stereotypical sequence of risk-assessment steps, i.e. from risk identification to risk evaluation. In practice, 'so what?' took priority over 'what if?'; such a logical sequence, from value judgements to fact-finding, was formally proposed by the Genhaz procedure for improving risk-identification methods. That is, Genhaz acknowledged that acceptability judgements on a hypothetical outcome would influence efforts to ascertain whether such an outcome has a realistic cause (see Table 8.1).

Starting from different accounts of uncertainty, regulatory advisors differed on how additional testing could eventually warrant market approval of a GMO product. Most advisors nominally said, 'Regulate the product, not the process', but they gave the slogan quite different meanings (see Map 9.1). Some advisors, especially from industry, sought to codify safety tests; the resulting knowledge would vindicate the genetic modification

process as safe, make the regulatory requirements predictable, and normalize GMOs as benign products. In the case of GMO biopesticides, industry lobbyists even attempted to narrow the original risk-assessment criteria of process-based regulation.

By contrast, other regulatory advisors expressed environmental concerns which went beyond readily testable uncertainties; some also foresaw biotechnology products encouraging agricultural practices which might indirectly cause harm. As they intuitively recognized, the context of industrialized agriculture *constitutes* the hazards, as in other industrial systems (cf. Wynne, 1992: 284). In proposing that socio-economic criteria should supplement safety criteria, even some regulatory advisors questioned the context of intensive monoculture, such as inner links between herbicide-resistant crops and chemical usage. However, government protected GMO products from any Fourth Hurdle; regulation would go no further than separately assessing the various products, e.g. crops and chemicals. Thus the regulatory procedure would delink products from each other and from the broader risk-generating system (see Chapter 9).

What did this mean for reducing uncertainty about potential harm? On the one hand, risk-management rules provoked overt controversy over their scientific rationale, particularly regarding the significance of genetic novelty. Regulators had to defend the cognitive framework which underlay their administrative rules, both for the US product-based or the EC process-based systems (see Chapter 4, 5 and 9). This feature illustrates how 'the mobilization of belief becomes a central source for the social enforcement of validity claims' (Beck, 1992a: 167-69); indeed, such mobilization politicized the official account of uncertainty from GMOs.

On the other hand, regulators adopted naturalistic accounts of the risk problem -- e.g. via a biological analogy between GMOs and plant pests (USDA) or exotic organisms (UK); this provided a common symbolic framework for translating a broad cause-effect indeterminacy into technical terms. By grounding the 'technical' upon a naturalistic account, the regulatory system could depoliticize its own problem-definition (cf. Schwarz and Thompson, 1990: 139). In so doing, it marginalized other accounts of the risk problem, e.g. GMOs as a sinister control, as intensive monoculture, as herbicide-crop links, etc.

GMO regulation illustrates the more general role of uncertainty in risk controversies. Each protagonist emphasizes the potential consequences of a perceived 'uncertainty'. This key term serves as a strategic argument for whatever is essential to know in advance, rather than as the reason for disagreement (Campbell, 1985).

As this thesis argues, value conflicts made uncertainty more important, rather than vice versa. That is, the uncertainty is always value-laden; it becomes 'politicized' only in the

sense that the values become publicly contentious. (See for example Schwarz and Thompson, 1990: 159-62; Grove-White, 1991: 442). This role for uncertainty contradicts some theoretical models, e.g. whereby scientific uncertainty allows greater opportunity for contending values to fill a 'gap' between science and policy. (See Nelkin, 1979: 16; Majone, 1989: 40; Jasanoff, 1986: v, 10; Jasanoff, 1993: 125).

On the contrary, as this thesis argues, 'uncertainty' was constitutive, not merely contextual; the regulatory debate became constituted by contending accounts of the relevant scientific uncertainty (Levidow, 1994a). By promoting some account of the unknown, or of the unknowable, each actor was promoting a type of policy -- rather than filling an *a priori* 'gap'. Amidst these arguments, the regulatory procedure was undergoing pressures to narrow the range of uncertainty.

By emphasizing and identifying testable properties of products, GMO regulation prepared safety standards for eventually treating GMOs as normal commodities, even though this incurred the political risk of jeopardizing their social legitimacy. Thus, in 'reducing uncertainty', regulators faced a contradiction between commercializing and legitimizing biotechnology.

1.4 Precaution: defining safety and innovation

This thesis argues that both the potential and limits of precaution derived from the project of normalizing GMOs as benign products. This meant specifying testable ecological uncertainties, rooted in some naturalistic analogy, in turn abstracted from issues of socio-agronomic control. Precautionary efforts remained dependent upon biotechnologists' co-operation, in providing resources and integrating safety criteria into innovation (as in earlier cases of safety standard-setting, e.g. Salter, 1988: 169).

As the previous section argued, precautionary efforts probed new types of uncertainties. GMO regulation sought different kinds of facts, rather than simply relaxing or shifting the burden of evidence within the same empirical framework (cf. Wynne, 1993). Thus, when discussing the precautionary principle, it was misguided for a major report to ask 'how far public policy should run ahead of clear scientific findings' (Royal Society, 1992: 155) -- which assumes that policy is otherwise based upon 'clear findings'. By asking 'how far?', rather than 'which way?', the report took for granted a linear scale of uncertainty and safety, as if this were pre-given by '*the* precautionary principle'.

In subjecting GMO releases to 'additional' regulation, whether precautionary or preventive, it was difficult to justify risk-management rules in scientific terms (see Chapters 4 and 5). This difficulty arose partly from the precautionary character of GMO regulation, which was established prior to any evidence of harm from GMO releases.

However, the risk-management rules in turn responded to an incipient legitimation crisis for the biotechnological project of industrializing agriculture. Although GMO regulation may have undermined the 'rational' stereotype of risk assessment, it also constructed a procedural rationality which made biotechnology R&D politically possible.

When the regulatory system translated 'risk' as cultural danger into 'risk' as expert management, it necessarily made environmental value judgements on acceptable effects. As regulatory advisors acknowledged, such judgements pervaded the entire regulatory procedure, e.g. when establishing risk-management rules, when setting criteria for evidence of safety, and even when directing biosafety research on hypothetical hazards (see Table 8.1).

Given these pervasive judgements, and the underlying legitimacy problem, GMO regulation bore some potential for wider public involvement. In this vein, some advisors advocated more extensive public disclosure of release applications, partly as a means of encouraging 'green' pressure upon R&D agendas (see Map 6.9). In particular, some emphasized environmental concerns which could discourage types of R&D, e.g. on a viral insecticide, on weedy crops, on herbicide resistance, etc. (see Chapters 7, 8). This democratic potential was countered, in effect, by asserting the 'objective' status of risk assessment, while narrowing the range of scientific uncertainties deemed relevant for anticipating harm (see Chapter 9).

Such tendencies illustrate the double-edged character of safety regulation. Risk assessments can serve as implicit ethical statements, even as 'an unwanted means' of democratizing technoscientific progress (Beck, 1992a: 28). Yet such a potential was hardly realized for GMO regulation in early 1990s Britain, where the more cautious advisors and environmentalist pressure groups lacked tangible backing from public protest (see Chapters 3, 7, 9).

Such tensions were again manifest in attempts to influence rules for market approval of a GMO product; at this stage, uncertainties about the larger scale were compounded by those of agronomic practices. On the one hand, regulators and innovators sought a risk assessment which could certify product safety, independently of any conditions of use. As they intuitively realized, risk assessment would lack credibility if it made assumptions about human behaviour, for either small-scale releases or product use (cf. Wynne, 1989, 1992).

On the other hand, an unconditional product approval would require anticipating a wider range of systemic uncertainties. Yet it was difficult to test these, short of literally simulating hazards. For herbicide-resistant crops in particular, the regulatory procedure

would treat the herbicide and GMO as separate matters, and so deny the linkage which had generated public suspicion (see Chapter 9).

Thus the market approval stage highlights a dilemma. Namely, a safety judgement could be definitive only by contextualizing the potential effects within the biotechnological agenda of industrializing agriculture. Yet it could be authoritative only by pretending that such an issue did not exist, i.e. by abstracting potential harm from intensive monoculture (cf. Wynne, 1982: 172).

Bureaucratic language often flattens such contradictions into a potential dysfunction, e.g., as a problem of over- or under-regulation. For example, diverse commentators have advocated a judicious 'balance', between allowing technological innovation versus ensuring safety (Ravetz, 1989: 72; Environment Minister, in CBC, 1990: 17). The 'balance' cliche portrays regulation as adjusting a metaphorical pivot along some ordinal scale, or as if operating a zero-sum game between two things: 'innovation versus regulation'.

On the contrary, precautionary regulation was *defining* safety and innovative progress, in the mutual design of safety tests and organisms to be tested. At stake was how safety procedures might legitimize and/or influence the direction of biotechnological progress.

2.0 RELEVANCE AND LIMITS OF THIS STUDY

This thesis offers a way of interpreting disputes over the 'rational' status of GMO regulation; it identifies sources of the practical dilemmas which faced the various participants. The analysis may help regulators to understand the social conflicts which they are managing via the terms of technical risk. It may also help biotechnology critics to resist the regulatory strategies for marginalizing their accounts of the risk problem. (Indeed, the thesis resulted partly from discussing early drafts of papers and chapters with several key actors, whose comments are acknowledged elsewhere.)

This final section acknowledges some limits of the study:
* possible ways of counterposing alternatives to my interpretation (section 2.1); and
* questions for further research, on both past and future developments (section 2.2).

3.1 Alternative interpretations

As a way of testing my thesis, this section poses alternative interpretations; for each challenge, I offer a counter-argument and suggest a line of further research.

* Although market imperatives (unsurprisingly) influenced safety regulation, weren't these really antagonistic forces? If they appeared as an *internal* tension, rather than as an external tension, perhaps this is only because I take some actors' comments too much at face value.

In reply: True, I could have interpreted the research material in terms of distinct rationalities, by treating some comments as 'stolen rhetoric' (Schwarz and Thompson, 1990: 73). Perhaps regulatory officials were opportunistic when, for example, they appealed to industry's self-interest in protecting a future biotechnology market; likewise when industry officials devised precautions to anticipate hypothetical hazards. From the present study, we cannot know the full intentions behind their arguments.

Nevertheless there is much evidence of practices consistent with the rhetoric. Regulatory procedures and criteria did accommodate market imperatives. Meanwhile academic scientists were recruited to conduct biosafety research, and industrialists did take precautionary measures. In particular, ICI Seeds continued to devise and assess such measures in a cautious manner, even while its officials were publicly criticizing the regulatory framework as 'irrational'; strangely, it is the latter which most seems to be stolen rhetoric.

The study was not designed to test cultural theory, which fundamentally concerns how individuals attach themselves to organizations, so as to pursue preferred 'ways of life'; an ethnographic study would be needed to investigate such features. Nevertheless I could have more closely researched the internal development of the new regulatory agencies (the biotechnology units of HSE, DoE and DGXI), as well as their mutual interactions. Such a study could have clarified how each institution constructs an 'expert-based hierarchy', defines the breadth of its competence, and perhaps internalizes commercial pressures. Similarly, one could study how seed companies develop expertise for safety regulation of products which never before underwent risk assessment.

* Although the regulatory procedure (unsurprisingly) bore symbolic meanings, weren't these just incidental to the procedure? If a technical-procedural rationality appears 'cultural', perhaps it is because I exaggerate the *explanatory* importance of the symbolic meanings.

True, I could have explained safety precautions in strictly scientific terms, especially given the vague ecological 'uncertainty' which initially justified such measures. However, according to the actors themselves, they did carefully construct precautions in order to accommodate and transform risk perception; regulatory pressures were informed by pollution analogies. Therefore it is valid to interpret symbolic meanings as integral to

designing early GMO releases; such meanings made it possible to develop a safety science, which might later justify relaxing some controls.

In my study, the symbolic aspects might have been clarified by systematically tracing the step-by-step principle for some types of GMOs. In particular, I could have closely studied a series of GMO release applications and queried interviewees in detail about the changing experimental design. However, this research method would have required a second round of interviews, given that I generally met the interviewee before requesting any copies of release applications, so as to gain their confidence first (see Chapter 2, section 3). Moreover, such pointed questions might have produced a defensive response, unlike the open-ended interview questions which I did ask them.

* Although the regulatory procedure (unsurprisingly) encountered conflict over the range of relevant uncertainty, doesn't the latter nevertheless explain the dispute? If the uncertainty *appears* as a resource rather than as an explanatory cause, perhaps this is only because I abstain from characterizing the 'real scientific uncertainty' (e.g. Jasanoff, 1986: 75; cf. Nelkin, 1985: 17).

True, I could have interpreted scientific uncertainty as an explanatory cause: i.e., that it provided greater opportunity for actors to promote different values by emphasizing different accounts of the unknown. However, such an explanatory model would take too literally the apparent disagreement over worst-case scenarios from GMO releases. As related evidence suggests, such scenarios express different environmental values -- regarding acceptable tangible effects of GMOs, and even regarding modes of environmental control. Such links provide a richer analysis of social meanings and motives, apart from whether one accepts a realist account of the 'uncertainty'.

3.2 Further research questions

This final sub-section suggests further research questions, which all concern how GMO regulation defines safety.

* Innovation and regulation

If the safety regulation makes it politically possible to pursue biotechnological innovation, then (how) does it influence the ultimate content of innovation? Does the regulatory procedure *always* downplay whatever uncertainties defy meaningful testing? Does the regulation simply normalize some GMOs first and others later? Or alternatively, does it reshape product design?

* Biosafety research and standards

As biosafety research provides funding for molecular ecology, how are GMOs designed so as to explore their own risks? How do the research tools define the uncertainties to be investigated? What explains the funding priorities? (How) does the research influence safety and product standards? Even if a particular uncertainty is clarified, (how) is the knowledge cited for clarifying safety?

* Democracy in risk assessment

If a precautionary approach offers greater potential for wider public involvement, then why wasn't this potential realized? If the risk assessment entailed pervasive value judgements, then why were these successfully kept within confidential procedures? As R&D brings GMOs to the stage of market approval, will agronomic uncertainties provide another opportunity for public involvement? Or alternatively, will these generate even less public interest than did the hypothetical catastrophe from R&D trial releases?

* Regulatory styles

As some types of GMO releases become routinized, (how) will this affect national regulatory styles? In Britain, what did it mean to shift Ministerial responsibility from the HSE (Dept of Employment) to the DoE? Why was this shift delayed until 1993? Since Britain started providing details on each proposed release in 1993, could this access affect the official boundary between regulatory insiders/outsiders? How will NGOs take up the new opportunity to challenge regulatory value judgements? In post-1993 USA, how might the Clinton administration facilitate a 'science policy', i.e. negotiating regulatory science within expert committees? What would this mean for the US 'adversarial' style?

Such questions warrant further research, for which this thesis provides a theoretical and empirical basis.

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