IDS Working Paper 147

Science, policy and regulation: challenges for agricultural biotechnology in developing countries

Ian Scoones[1]

January 2002

INSTITUTE OF DEVELOPMENT STUDIES
Brighton, Sussex BN1 9RE
ENGLAND

[1] Background literature searches for this paper were carried out by Dominic Glover and James Keeley.

ISBN 1 85864 403 8

Summary

What is the relationship between science, policy and regulation in the context of debates about the future of agricultural biotechnology? This paper explores the real world of policy-making and regulation surrounding agricultural biotechnology. The starting point is a view of policy-making which is non-linear, incremental, contested and negotiated. This involves a critical examination of the competing discourses and narratives which frame the debate, the forms of practice that make up day-to-day actions in policy and regulatory arenas, the underlying political, economic and social interests which are both influential and excluded, and the complex and often changing networks of actors involved. The paper first outlines some of the particular challenges for biotechnology policy and regulation. The following section explores notions of 'sound science' and 'precaution' in the context of risk assessment before examining the application of science in biotechnology policy and regulation through a series of examples. These show how regulatory science sets an interpretative frame for the establishment and implementation of regulations. Highlighting the social and political commitments of such scientific knowledge, the notion of an abstract, objective 'sound science' as the foundation for regulatory decision-making can be opened up to questioning. Finally, particular issues for developing countries are raised, with the conclusion outlining some of the challenges for regulatory policy.

Contents

Preface

Agricultural biotechnology and policy processes in developing countries Working paper series

Policy processes surrounding new agricultural biotechnologies today involve a wide and growing range of actors, including scientists, government officials, international organisations, local and transnational companies, and farmers' organisations among others. Policy processes occur at different scales, ranging from local negotiations around agricultural technology priorities to global debates surrounding property rights, biosafety regulation and biodiversity protection. Given the rapid pace of technological change and the fast-moving international regulatory environment, developing effective national policy processes is a major challenge. Yet relatively little work has been focused on understanding how particular national and local contexts influence policy processes. Similarly, at the international level, the globalisation of the biotechnology industry has not been matched by the internationalisation of effective regulation. Overall, there has been a lack of critical attention to the way in which the policy processes connecting local, national and international levels can be enhanced so that emerging policies and regulations support the livelihood needs of poor people in the developing world.

This Working Paper series emerges from a series of three interlinked projects which together address these issues. They involve collaboration between IDS and the Foundation for International Environmental Law and Development (FIELD) in the UK and partners in China (Center for Chinese Agricultural Policy (CCAP)), India (Centre for the Study of Developing Societies, Delhi; Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS), Delhi; National Law School, Bangalore), Kenya (African Centre for Technology Studies, Nairobi) and Zimbabwe.

Three key questions guide the research programme:

- What influences the dynamics of policy making in different local and national contexts, and with what implications for the rural poor?
- What role can mechanisms of international governance play in supporting the national efforts of developing countries to address food security concerns?
- How can policy processes become more inclusive and responsive to poor people's perspectives? What methods, processes and procedures are required to 'democratise' biotechnology?

The work is funded by the UK Department for International Development (DfID) ('Biotechnology and the Policy Process in Developing Countries' and 'Globalisation and the International Governance of Modern Biotechnology') and the Rockefeller Foundation ('Democratising Biotechnology').

This paper is a product of the 'Biotechnology and the Policy Process in Developing Countries' project. Other papers in the Biotechnology and Policy Processes series are:

IDS WP145, *Agricultural biotechnology and food security: exploring the debate*, Ian Scoones
IDS WP146, *Biotechnology and the politics of regulation*, Peter Newell

More details of these projects and downloadable versions of all papers in this series and other project outputs can be found at: www.ids.ac.uk/ids/env/biotechpubs.html. For further information please contact: k.hawkins@ids.ac.uk

1 Introduction

What is the relationship between science, policy and regulation in the context of debates about the future of agricultural biotechnology? One view would suggest a simple linear connection where science engages in independent enquiry, where clear choices are offered to policy-makers, who are in turn informed by political and social priorities, and then a regulatory policy framework emerges, and is implemented according to a set of specified rules on the basis of 'sound science'. As anyone involved in policy and regulatory debates on biotechnology – or any other issue for that matter – will agree, this neat linear schema is far from an accurate depiction of what actually happens. Yet, very often, either implicitly or explicitly, such a linear view of the policy process is assumed, and deviations from it seen to be aberrations rather than the norm.

This paper explores the real world of policy-making, suggesting issues for investigation when examining policy and regulatory processes surrounding agricultural biotechnology in developing countries. The analytical starting point is a view of policy-making, which is non-linear, incremental, contested and negotiated. This involves a critical examination of the competing discourses and narratives which frame the debate, the forms of practice that make up day-to-day actions in policy and regulatory arenas, the underlying political, economic and social interests which are both influential and excluded, and the complex and often changing networks of actors involved (cf. Jasanoff and Wynne 1998; Keeley and Scoones 1999).

Such a perspective, it is argued, allows a more nuanced insight into how particular policies and regulatory frameworks actually emerge and the ways particular perspectives come to dominate and others are excluded. No neat relationship between science, policy and regulation is found. Rather than seeing science as a separate, isolated and independent activity informing policy from a distance, much biotechnology science is seen to be very much part of the policy and regulatory process. For example, direct connections through funding relationships, political or commercial pressures, personal links, publishing networks, involvement in scientific advisory committees combine with more indirect routes through which the framing of debates is influenced by scientific discourse and practice.

A form of trans-science is observed therefore (Weinberg 1972), where co-production processes involving the 'mutual construction' of knowledge (Shackley and Wynne 1995) between science and policy arenas are ongoing. A rigorous dissection of this relationship in the field of biotechnology development points to a more realistic and honest appreciation of the role of science; one that does not dismiss the role of scientific expertise, but contextualises it in a broader understanding of the social and political commitments which the engagement of science with regulatory policy necessarily implies.

The paper is organised as follows. The first section outlines some of the challenges for biotechnology policy and regulation. The next section looks at different contexts for biotechnology science and the framing of the policy debate. The following section explores in more depth notions of 'sound science' and 'precaution' in the context of risk assessment before the next section examines applications of science in biotechnology policy and regulation through a series of examples. Issues for developing countries are, in turn, raised and a

series of questions are posed. Finally, the conclusion outlines some of the challenges for regulatory policy suggested by the issues raised in the paper.

2 Challenges for biotechnology policy and regulation in developing countries

There are two broad areas where scientific advice is important in the development of agricultural biotechnology policy and regulation. The first relates to what might be broadly defined as 'technology assessment' – choices about the role of new technologies in the wider system, and the relative benefits and costs of opting for a particular technological pathway. Such assessments require looking at the range of future options, and the potential benefits and risks of each. Questions of opportunity costs and option foreclosure, for example, are important, as are wider questions of development strategy. Approaches of technology foresight, scenario development, environmental assessment and social cost benefit appraisal are all routes by which such decisions can be made. In respect of agricultural biotechnology such choices may be part of broader rural development and agricultural strategies, as well as more specific priority setting within research and development systems. Clearly scientific advice is important in such processes, and very often key to the making of decisions. Yet choices of technology pathways are bound up with wider commitments, part of a broader realm of economic, social, cultural and political debates, and so require the interaction of different perspectives in the decision process. It is this interaction, this paper argues, which is key in understanding how science engages with policy (cf. Rip 1996).

The other area where science is important in the development of policy and regulation in the field of agricultural biotechnology is around risk assessment procedures. Central to the regulatory frameworks being adopted around the world for the regulation of biotechnology developments (particularly concerning transgenics) are standardised approaches to assessing potential risks to human health and the environment. A variety of different risk assessment frameworks have become central to regulatory policies (for example the important contrast between product and process based approaches; cf. Bennett *et al.* 1986; Tait and Levidow 1992; see below). What is common across these is the claim that 'sound science' should inform the decision. In order for this to happen different procedures are put in place, ranging from scientific data requirements for submissions to laboratory and greenhouse safety and containment procedures, field trial protocols, regulatory review committees, scientific advisory panels, inspection guidelines and so on. The institutionalisation of these procedures and practices within scientific institutions and regulatory bureaucracies is an important process by which the relationship between science and regulatory policy becomes established.

The challenges posed by the new biotechnologies suggest some important contrasts with earlier technological 'revolutions' in the agricultural sector. Most countries have invested at various times in strategic planning for rural development, technology assessment, R and D priority setting and risk assessments. These

have taken various forms from state led five-year planning to national technology missions to research institution reviews of funding priorities to cost/benefit and risk assessments of different options. The breadth, scope and inclusiveness of such processes have of course varied, but nevertheless past experiences exist from which current initiatives inevitably draw.

However, in contrast to the earlier 'Green Revolution' for example, two features stand out which make the challenges of the new biotechnology applications distinct. First, the range of uncertainties involved in assessing the consequences of the new biotechnologies is perhaps greater than ever. These include fundamental scientific uncertainties about the potential environmental and health risks of such technologies, as well as wider uncertainties about the likely impact of the introduction of such technologies on agricultural systems and rural livelihoods. This makes the tasks of technology assessment and risk appraisal especially difficult, requiring, this paper contends, new ways of thinking about decision-making.

Second, the range of actors involved in the development of the new agricultural biotechnologies is far wider than before, making the negotiation of regulatory policy frameworks an especially challenging task. Such actors are not all located within one country with one jurisdiction and public policy process. Instead, such policy players are spread around the world, connected through large multinational companies, NGO lobby groups and through international convention and protocol processes. With major commercial interests involved in the development of the technologies, and huge financial and other incentives to see the products of expensive R and D endeavours approved, the pressure on the regulatory bureaucracy is potentially massive (Barben 1998). Combined with this there exists, in some parts of the world, increasingly vocal and effective public lobbying around biotechnology issues, making it vital to respond to such concerns if broader public acceptance and legitimacy of new regulatory policy is to be assured.

Thus the challenge for emerging policy and regulatory mechanisms is both to develop approaches that deal with questions of uncertainty head on, and to balance the range of interests and perspectives in transparent ways, resulting in regulatory approaches which have wide legitimacy and the possibility of enforcement. The degree to which current regulatory policies achieve these goals in three countries – China, India and Zimbabwe – is explored briefly below. Before turning to such specific cases, however, the following section examines the way biotechnology science helps frame the debate in the first place.

3 Framing the debate: the role of biotechnology science

The 'gene revolution' is seen as a science led revolution, driven largely by the relatively recent advances in molecular genetics and biology. In contrast to the 'green revolution' where it was conventional crop breeding through hybridisation that offered the advances, today it is laboratory technicians, rather than field based scientists who are at the centre of the endeavours. Genetic engineering is assumed to be precise, accurate, rapid and effective, in contrast to the rather haphazard and painstakingly slow process of conventional

breeding. Thus in most reflections on the nature of biotechnology science, metaphors associated with complex, integrated biological and crop systems give way to those associated with precise, controlled engineering solutions.

The history of biotechnology science is revealing. The 'life sciences' emerged as a cutting edge area of biology particularly following breakthroughs in recombinant rDNA techniques in the 1970s. The new biological sciences were increasingly seen in the hierarchy of the discipline as superior to the more mundane field based challenges of experimental biology and ecology. Having cast off the shadow of its earlier origins in the field of eugenics, the new life sciences were able to promise new hopes of revolutionising conventional industries from brewing to pharmaceuticals to farming (Bud 1993; Gottweis 1998). Through the latter part of the twentieth century, biotechnology was seen as a potential saviour of modern industrial economies, as well as a solution to more global ills, ranging from the energy crisis to world hunger (Bud 1993). Throughout these debates the boundaries between engineering and biology were continually contested, debates which were in turn reflected in approaches to regulation (Bud 1991).

The science of biotechnology is thus carried out in labs, in settings far from field conditions. Test tubes, pipettes, centrifuges, culture jars and containment cabinets or greenhouses are the tools of the trade. These are the means through which scientific representation occurs; and in turn particular understandings of genetic and molecular processes emerges through such modes of experimentation and organisation of scientific activity (Knorr-Cetina 1981; 1999). What is key is to understand the fundamental link between representing and intervening, as these representations in turn are the basis of intervention in such areas as regulation and policy (cf. Hacking 1983).

Particular types of scientific practice are created, and reinforced by the cultures of science developed in different sub-disciplines. The dominant approach to genetics and molecular biology is that captured by the metaphor of engineering – precise manipulation of the genetic code and the transfer of genes in an ordered manner. The focus is on the genes, the stretches of rDNA and the mechanisms of transfer, rather than the 'ecology of the genome' or the consequences of interactive epistatic (where one gene can modify the expression of another gene that is not an allele of the first) or pleiotropic effects (where a single gene produces an effect on more than one trait), cascade impacts of gene insertion or complex genetic or molecular responses at the level of the whole genome. The assumption is somehow that this is more like building a bridge or a car using innovative methods, rather than manipulating a complex genomic system.

The lab setting removes the practice of science from the conditions under which the new innovations are expected to perform. Because of risk considerations early testing in field conditions are clearly inappropriate. The focus of the life scientists is therefore in getting the required response through careful genetic manipulation in highly regulated conditions in the lab or greenhouse. But newly engineered crops must

perform in real farming settings, and the poor understanding of these sometimes means that the gaps in performance between lab, greenhouse, field trial and commercial planting can be very large.[2]

Of course the disjuncture between research conditions and field realities is not new – indeed one of the criticisms of the Green Revolution crop breeding approaches was that potential yield gains were not realised in farm conditions. But there are perhaps wider questions of scientific culture and style, which separate the new molecular biology from farm settings. While the match between lab engineering and industrial agriculture may be clearer, the contrast with the complex agricultural systems of much of the developing world is stark. The technologists' ideal of the 'magic bullet' solution created through sophisticated science helps frame a debate where the emphasis is on the engineered solution, rather than the broader and inevitably more complex problem.

3.1 Contexts for scientific practice

The laboratory science of genetic engineering is governed by some important contexts, which further influence the nature of the debate. Scientists do not work in isolation, somehow separated from the messy world of research funding and politics. Again the contrast with the Green Revolution era is apparent. In the 1960s the major efforts in crop breeding were the result of public and philanthropic funding which created the international agricultural research centres and the CGIAR system. It was on the field research stations of CIMMYT and IRRI in Mexico and the Philippines or in the publicly funded national agricultural research systems, academies and universities of China and India, for example, that the major breakthroughs in crop breeding occurred during this period (Lipton and Longhurst 1989; Perkins 1997). Of course, such scientists were not immune to broader contexts, and the influence of the funding agencies and political imperatives, but today the context for much life science research is very different.

The huge investment costs in developing new biotechnologies – in labs, equipment, costly reagents, skilled staff and so on – mean major funding pressures. For the public sector (both national and international) where the squeeze on funding has been felt for many years, the opportunities for long term research of this sort (particularly for the more sophisticated genetic manipulation techniques) are limited without significant injections of support. With growing commercial interest in biotechnologies in the private sector through the 1980s and 1990s, an obvious source for additional support has been joint work with commercial companies (Krimsky *et al.* 1998; McMillan *et al.* 2000). Such patterns are increasingly apparent in the developing world. For example, in India a joint venture with Monsanto was initiated at the Indian Institute of Science, and the CGIAR system has been exploring ways of levering private finance to support its work (Thornstrom 1999; Byerlee and Fischer 2001). Many scientists argue that such collaborations do not affect the quality of the

[2] This applies to both transgenic products and more low-tech tissue culture technologies, where there are major challenges to the effective delivery of disease free planting material to farmers, for instance (Tripp 2000).

science, and this is simply a pragmatic response to a funding crisis and ensuring that biotechnology science for public good ends can continue.

However, others point out the pressures that such linkages impose. The pressure to deliver marketable products that can gain a return within the lifetime of a patent are enormous, given the huge upfront investments that private companies have made. The practices of commercial science are far from the leisurely pursuit of more knowledge under unconstrained conditions, but firmly linked into commercial targets and objectives. The blurring of public and private science – science for knowledge advancement and science for commercial gain – has many important ramifications for the contexts for scientific endeavour and, in turn, how scientists must engage with the policy and regulatory process. It is no surprise that industry players argue for a speedy, uniform, harmonised and product based form of regulation, governed by strict adherence to intellectual property rights, which, they argue, both provides appropriate protection against potential risks to the public and environment, but also protects their commercial interests and investments. Without such efficient, unambiguous regulatory frameworks, they argue, the opportunities of biotechnology will be lost.

In contrast again to the Green Revolution era, the physical location of scientific endeavours is far more diffuse. While the earlier technological revolution could be argued to have a global character, emerging as it did from an international response to the problems of food deficits, chronic hunger and recurrent famines in the developing world, the location of the science was decidedly local. Even though the early CGIAR centres created infrastructures that isolated them in many ways from their local surroundings, creating well-funded enclaves of international science in the developing world, they had to interact at some level at least with national agricultural systems and local conditions.

But today, the life science industry is truly global, with laboratories scattered across the world, linked through major companies whose forms of integration – both horizontal to other sectors (pharmaceutical, financial, chemical) and vertical (from seed production to marketing, processing and consumption) – mean that the science of genetic engineering is not a separate activity, but one linked to a range of other activities across locations, north and south. Thus the performance of scientists is often linked to wider transnational economic concerns, and they are necessarily locked into a wider political economy of the food-agricultural-chemical industry (Bonanno *et al.* 1994; Buttel 1999).

3.2 Regulatory and policy science

As a potentially highly lucrative commercial activity and an area which public sector agencies regard as a priority, scientists necessarily get engaged in wider debates about policy and regulation. Scientists – and particularly biotechnology scientists – are not just boffins in white coats isolated from the world of policy and politics. Perhaps more than many other areas, given the range of scientific uncertainties associated with the new technologies, scientists are regularly called on to provide advice in the policy arena (Salter 1994; Irwin *et al.* 1997).

Advisory committees, commissions of enquiry and consultancies all provide fora where scientists become directly involved in framing the policy debate. Jasanoff (1990: 237) observes: 'Protected by the umbrella of expertise, advisory committee members in fact are free to serve in widely divergent professional capacities: as technical consultants, as educators, as peer reviewers, as policy advocates, as mediators, and even as judges'.

The authority of scientific advice is central, and scientists are asked to pronounce on key issues of potential returns, risks and so on. As Jasanoff notes (1990: 236): 'When the boundary holds, both regulators and the public accept the experts' designation as controlling, and the recommendations of advisory committees, whatever their actual content, are invested with unshakeable authority'. However: 'When the stakes are high enough, no committee of experts, however credentialed, can muster enough authority to end a dispute on scientific grounds' (Jasanoff 1990: 234).

Thus the forms that risk assessment guidelines take, and the decisions that emerge from regulatory committees and panels is significantly influenced by such advice. In this hybrid world between science and policy the networks of actors involved are of course key. Overlapping layers exist, ranging from professional groupings and associations, editorial/peer review networks around particular publications, communities of researchers created by particular funding agencies, links created by overlapping membership of different advisory groups and so on. Such networks may stretch across many continents, linked by email lists, international conferences and peer reviewed journals. The way such networks emerge – through processes of enrolment and enlistment (cf. Latour 1987) – and how they coalesce around particular types of knowledge claim or policy position provides important insights into the way science and policy interact. The history of such actor networks, discourse coalitions, epistemic communities (cf. Callon and Latour 1992; Hajer 1995; Haas 1992)[3] can be traced, with particular individuals – sometimes branded 'policy entrepreneurs' (Kingdon 1984) – identified and particular moments in scientific and policy debates highlighted when 'policy spaces' (Grindle and Thomas 1991) open up. Thus, for example, in the context of the agricultural biotechnology debate in developing countries a number of contrasting perspectives on the potentials for the new 'gene revolution' for feeding the world exist, ranging from techno-optimists to those with a more sceptical view, each associated with a network of policy players – including scientists, industry officials, NGO activists and others – and often particularly vocal advocates (see Scoones 2002).

In this hybrid world between science and policy where regulatory decisions are made and policies developed, there is a need to both encourage communication between actors, as well as maintain the authority of expertise. Through the creation of 'boundary objects' groups are both separated and linked. Such 'boundary work' (Gieryn 1995) involves: 'The attribution of selected characteristics to the institution of science (i.e. to its

[3] It is beyond the scope of this paper to explore the differences between these different disciplinary/theoretical traditions for looking at actors and networks in policy processes, but see Keeley and Scoones (1999) for a discussion.

practitioners, methods, stock of knowledge, values and work organisation) for purposes of constructing a social boundary that distinguishes some intellectual activity as non-science' (Gieryn 1993: 782).

For example, a 'gene' means different things to scientists (and indeed different types of scientists) and to 'lay' politicians and publics. However there is enough understanding to allow a discussion to proceed, but one where particular types of scientific expertise continues to be called upon (Gottweis 1998). In a similar way, boundary terms such as 'familiarity', 'novelty' or 'substantial equivalence' become central to the debate about regulation, with their meanings and authorities developed by science, but their interpretation and application negotiated in the policy and regulatory sphere (see below). By creating and upholding a social and cultural boundary, though, regulatory processes can proceed on the basis of uncontested scientific authority.

Scientific models may be critical in such boundary work. Stable predictions and standardised approaches may create 'anchoring devices' (van der Sluijs *et al.* 1998). Despite considerable uncertainties embedded in the layered assumptions of the models, a generalised consensus can be generated for the purposes of engaging in a policy debate. Disputes can occur at the margins, but the dominant framings and assumptions remain stable and not fundamentally questioned. Thus for example the experimental routines central to the assessments of biotechnology applications often require a model that equates in vitro testing with real ecosystem complexity (Gottweis 1998). Similarly, the reliance on generic safety models for the risk assessment of new biotechnology products assumes forms of 'equivalence' and 'familiarity', which are informed by scientific arguments and framings (see below).

The way such boundary work is played out depends on the context. Different national or regional regulatory cultures or styles have been identified, with significant contrasts observed.[4] The US system is described as technical, adversarial and legalistic, with important roles for scientists and lawyers on advisory committees and panels. (Jasanoff 1990). Yet, in contrast to the UK, where discretionary, discreet, informally negotiated processes dominate, the regulatory style is characterised by a degree of openness and transparency. Without the legalistic imperatives of the US regulatory system, few legally binding rules and procedures exist in the UK (although this may be changing with increasing EU influence. Scientists thus engage in different ways under different regulatory regimes. In the US, for example, there is a high demand for precise, unconditional advice, while in the UK scientific advice may be more informal and less binding. Because of this, van Zwanenberg and Millstone (2000: 274) argue that: 'there are few incentives to ensure that UK regulators do not conduct sloppy uncritical or opportunistic assessments of toxicological evidence'.

[4] For example, Jasanoff (1995) contrasts the UK with Germany and the US and Dunlop (2000), Wright (1994) and Levidow (1999), Levidow and Carr (2000a) and Carr and Levidow (2000) contrast the US with Europe, while Levidow and Carr (1999), Levidow *et al.* (2000) and Majone (1997) and Renn (1995) look across the EU.

4 Sound science, precaution and risk assessment

For these reasons, then, contexts really do matter – the framing of the science debate, the culture of scientific and regulatory institutions, and the funding sources and pressures all inevitably have an effect on policy outcomes. 'Sound science' – the basis for much policy and regulatory decision-making – must therefore be located within its political, economic and social context (Grove-White 1999). So how sound is 'sound science' in practice? By examining the contexts and practices of science and its relationship to regulation and policy, some questions must be asked as to the place of science in policy and regulatory decisions. How are debates framed? How are risks and uncertainties dealt with? What is the relationship between scientific 'facts' and broader questions of norms, ethics and values?

A formal definition of risk would focus on the probability times the magnitude of the hazard. Yet, as is widely acknowledged in the risk assessment literature, risk has many dimensions – severity, immediacy, spatial and temporal distribution, reversibility are among many possible dimensions (Stirling 1998). A single measurement of risk is therefore unlikely. This is certainly the case in the context of biotechnology assessment – health, environmental and livelihood risks may be direct, indirect, cumulative or synergistic (Rissler and Mellon 1996; Benbrook 2000). Yet conventional risk assessment approaches are often ill-equipped to deal with multiple criteria and incommensurability, where scientific uncertainties, indeterminacy and ignorance prevail.

With limited budgets, staff and skill shortages and short-time frames, policy and regulatory decisions often focus on the obvious and apparently tractable elements of a decision problem. In order for scientific and economic appraisal to move ahead therefore a narrowing of scope seems almost inevitable. The consequence, of course, is that more complex criteria are left out of the equation, uncertainties are 'black boxed', and areas of ignorance avoided (Sahl and Bernstein 1995). Standard risk assessment procedures are usually based on the assessment of a limited number of criteria where technical assessments are seen to be sufficient (Krimsky and Golding 1992). While risk perceptions are seen to be important (e.g. Slovic 1997; Simmons and Walker 1999), the task for agencies commissioning risk assessment exercises is to develop a strategy for 'risk communication' or 'risk management' which seek to assuage any public fears (and 'misperceptions') and manage the risk environment based on technical criteria (Royal Society 1992).

Responsibilities for policy and regulatory choices are therefore divided up, with environmental and health appraisal seen as the domain of scientific assessment, while ethical and moral considerations are allocated to other areas of professional expertise and social and economic issues are deemed best dealt with by consumer choice and market response (Levidow and Tait 1992; Carr and Levidow 1997; Levidow and Carr 1996; 2000). Thus formal risk assessment is deemed to be a delimited, technical exercise, one where inputs from objective science are seen to be crucial. With the separation of technical from political, moral or ethical dimensions this, in turn, allows for a demarcated role for technical expertise which is seen to be independent and objective.

4.1 Taking uncertainty seriously: 'sound science' and precaution

However, such a narrow, technical approach to risk assessment has been widely criticised over many years (e.g. Royal Society 1992; Douglas 1985; Krimsky and Golding 1992; Wynne 1992; Renn 1997). Recently, particularly in the European context, such debate has been focused on interpretations of the 'precautionary principle'. In environmental debates the precautionary principle has been evident since early concerns with sustainability (1972 onwards, see OECD 1993), and came to particular prominence in the Rio Declaration of 1992. In the context of the biotechnology debate, a precautionary stance is stated in the Biosafety Protocol, and in many policy positions of national governments. For example in the EU, the precautionary principle is applied: 'Where preliminary objective scientific evaluation indicates there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen' (Cantley 2000).

However, the precautionary principle is highly contested, and is linked to a range of principles and concepts with multiple interpretations (von Schomberg 1998; O'Riordan and Cameron 1994). For some it simply provides a normative decision criterion which must be applied once risk assessment based on 'sound science' has been carried out, and as a result is not appropriately in the realm of regulation, but more part of political decision-making. For others it urges a wider examination of questions of uncertainty, indeterminacy and ignorance and a fundamentally different approach to regulatory appraisal and assessment, which goes beyond a narrow, technical approach and recasts and redefines the role of science in more fundamental ways.

For Stirling *et al.* (1999), taking precaution seriously requires a broader definition of science; 'one that recognises broad framing, incommensurability, multidimensionality, acknowledges ignorance etc.'. If such features are incorporated into our understanding of 'sound science' then, they argue, 'precautionary approaches become *more* scientific than a narrow risk approach' (Stirling *et al.* 1999). They argue that:

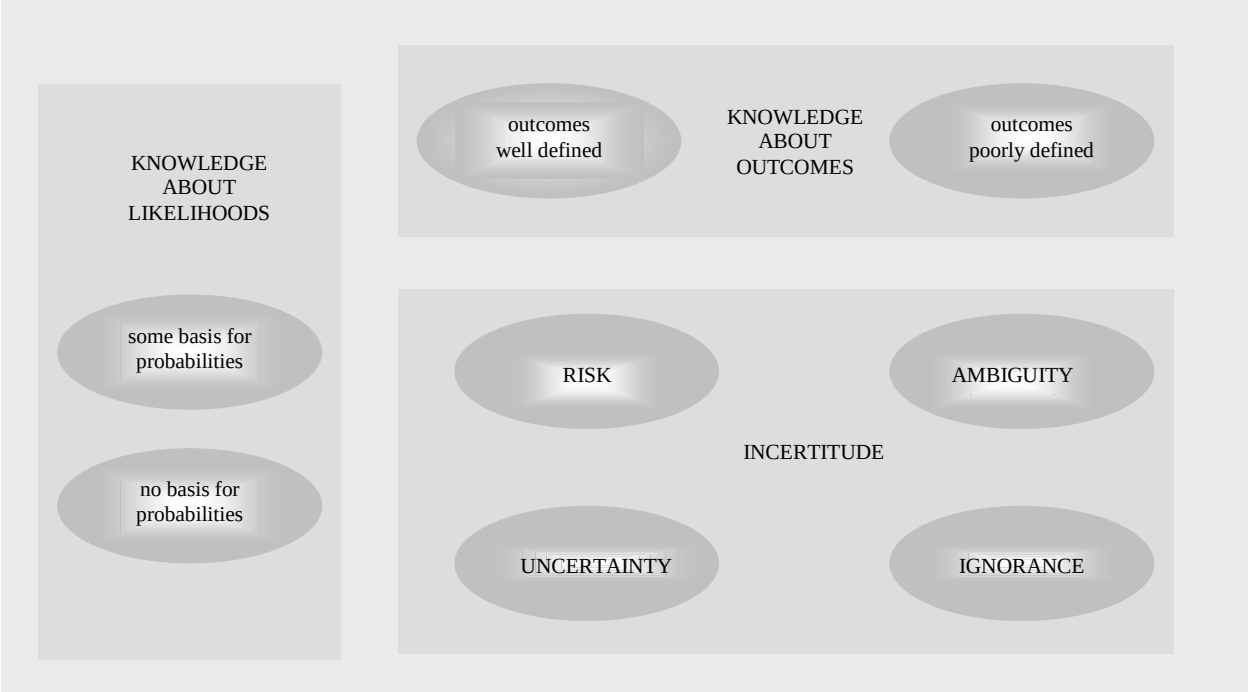
> The importance of factors such as divergent contexts and interests, plural values and rationalities, intractable uncertainties and ignorance, the implications of social learning and under-determining character of science… all militate against the definition of a single monolithic stance for thinking about regulatory options for the management of risk.
>
> (Stirling *et al.* 1999: 35)

In the context of biotechnology debates this is potentially highly significant, as policy and regulatory decisions are characterised by incertitude, where knowledge about likelihoods and outcomes is limited or absent. Thus various forms of uncertainty and ignorance are prevalent (cf. Figure 4.1).

These may derive from physical/biological characteristics of genetic modification processes where consequences are unknown or, potentially, unknowable, as well as uncertainties surrounding economic/social effects, moral and ethical values and political consequences. Given the level of incertitude the chances of developing a simple metric for decision-making for regulatory policy are effectively zero. If a precautionary

stance is to be adopted which recognises the potential for surprise, unforeseen consequences and the potentials for complex effects, then an approach, which makes explicit the areas of uncertainty and ignorance, is clearly required. This need not be seen, as some have argued, a simple excuse for the rejection of new innovations or protectionism by the back door, but one that accepts that not all costs or benefits can be known in advance, even in probabilistic terms.

Figure 4.1: Risk, ambiguity and ignorance (from Stirling *et al.* 1999)



Thus, it is argued, risk assessment must take on a different character, one that examines the broader context and framing of the decision issue, tackles the issue of incommensurability head on, and makes explicit the areas of uncertainty and ignorance in the development of policy and regulatory solutions. Under such a scenario the distinction between broader technology assessment and specific risk assessment becomes blurred, as the range of implications of new technologies must be taken into account – from wider issues of the diversity, flexibility and resilience of technological pathways in particular social, economic and political contexts (cf. Stirling *et al.* 1999) to the more narrow concerns of the risks of particular technological products or processes.

Some would argue that such an approach would inevitably result in policy and regulatory chaos. Without the rigorous application of 'sound science' as arbiter of the technical domain of decision-making and the conflation of technical and socio-economic questions, the whole process has the potential to become both confusing and arbitrary, and so open to manipulation by special interest groups. The counter to this position,

though, is that such an approach can potentially add more rigour, and with a more sophisticated, integrative form of science (e.g. post-normal science Funtowicz and Ravetz 1992), more trustworthy, reliable decisions will emerge.

Ranges of approaches have been developed which are aimed at providing tools for dealing with such integrative, complex decision-making. These range from quantitative approaches which help to examine the range of criteria important in decision-making (e.g. multi-criteria analysis – Stirling and Mayer 1999) to scenario approaches which systematically analyse future options according to a range of criteria to more participative, deliberative approaches (e.g. citizen juries, consensus conferences etc.) which allow rigorous analysis in open debate among a range of actors (Durant 1999; Fischer 1999; Kass 2000; Holmes and Scoones 2000).

What is common to these approaches to integrative science is that they recognise the plural nature of views and positions on technology choice from the start; they accept that uncertainty and ignorance are inevitable; and they introduce rigour, not by narrowing the scope to tractable issues amenable to simple technical methods, but through processes of triangulation, deliberation and reflexive review. If an effective 'audit trail' is established for such approaches, they can also be argued to be transparent and open approaches to developing policy and decision-making, where decisions can be fine-tuned, challenged and adapted. In addition, such approaches, because of their inclusive nature – both of the issues addressed and the participants involved – can help to engender trust and legitimacy in the policy and regulatory process; issues that are clearly key if controversial technological innovations, such as biotechnology, are to gain wide acceptance.

Existing expert institutions, bound as they are to a particular style and practice of technical scientific advice, are generally ill-equipped to deal with such an approach to integrative decision-making (Fischer 2000). Indeed calls for incorporating participation into existing institutional settings may be problematic, if the frame of debate is already set within a narrow risk-benefit scenario which assumes a priori that a particular vision of agriculture and food production is inevitable (Levidow *et al.* 1998). The focus, as already discussed, has been for the separation of the technical element of decision-making with the policy and regulatory choices cast often in very narrow, delimited terms, with other issues – often of major concern to publics – deemed off limits (Levidow and Carr 2000; Jasanoff 2000a). By broadening the scope of the policy and regulatory process in the light of concerns raised by debates about precaution provides a significant challenge to conventional processes for regulatory policy development. Instead of focussing on a narrow set of decisions, the challenge is to develop a process of 'embedded social learning', which is, at one time, inclusive, transparent, rigorous and integrative.

Thus policy and regulatory choices emerge from a process of negotiation around a range of often highly context specific technical, economic, social, political, moral and ethical issues among a range of different actors. This does not mean to say that conventional scientific expertise does not have its place, but it must put

alongside a range of other forms of expertise. It also does not mean such decision processes are not rigorous – or based on a form of integrative 'sound science'. Indeed there is a good case to be made that such processes are more rigorous than more narrowly defined ones. With existing expert institutions ill-equipped to respond to such issues, a major challenge is to explore the potentials of new 'reflexive institutions' (Fischer 2000) which can convene such processes of regulatory policy decision-making.

4.2 Regulatory harmony or inevitable divergence?

One aim of the narrow form of technically based risk assessment is to develop simple and standardised procedures resulting in uniform and harmonised policies and regulations. Thus, for example, risk assessment approaches for biotechnology around the world are modelled on a particular formula derived from the US or Europe and often promoted by international agencies (see below) (Levidow *et al.* 1996; 1998). Michael Osborne of the OECD, one of the promoters of standardised regulatory approaches, comments:

> This harmonisation process provides significant savings for countries by avoiding duplication of scientific trials and creating mutually acceptable best practices among regulators. It also ensures that scientifically reliable consensus based and transparent information is available to policy makers when international frictions develop over GMOs.
>
> (Osborne 1999)

Very often though embedded in such regulatory approaches are assumptions, drawing from science in various though often contested ways, which encourage a standardisation of approach. Thus, the idea of 'substantial equivalence' or the seeing GM introductions as analogues of the introduction of exotic species (see below) encourage the translation of standardised approaches across diverse contexts.

There are immense pressures to promote such standardised approaches. Standardisation is seen as compatible with simple administrative and bureaucratic procedures. With limited capacity to implement and enforce regulatory processes, simple approaches are inevitably welcomed by regulatory bureaucracies under financial, staffing and time pressures. Standardisation is also seen to reduce the opportunities for arbitrary regulatory discretion. If standard procedures exist, then these can be monitored and evaluated, and regulators have less opportunity to be swayed in a particular direction by interested parties.

Standardised regulatory procedures, with limited ambiguity and strict protocols, also, it is argued, encourage investment in technology. With uncertainty surrounding regulatory policy making, investors may shy away from the necessary up-front investments in technologies if there is a chance of no payback following regulatory approval. Finally, there are pressures for standardisation emerging from the attempts to develop global trade regimes under the WTO. Free trade, it is argued, must not be hampered by the application of what might be seen as protectionist regulatory policies based on standards and procedures that are not universally agreed.

Yet the logic for standardisation and harmonisation can be questioned on a number of counts. If standardisation means forcing science to offer universalised solutions while ignoring areas of uncertainty and ignorance then we have to doubt the value of such approaches. The experience of the BSE crisis in Britain (and now more broadly in Europe) provides some pertinent lessons, as the failure to recognise uncertainties resulted in major economic and health costs, and a more general undermining of confidence in agricultural and food safety policy processes. In addition, assuming that regulatory bureaucracies operate without discretion, even within standardised guidelines and procedures, runs against the empirical evidence. Many studies of regulation in practice show how scientific evidence and advice is used in a discretionary manner by regulators, particularly at the level of informal negotiations on the ground by 'street-level bureaucrats' (Lipsky 1979). Discretionary choices arising from necessary ambiguity and complexity are almost inevitable, but the key is to ensure that discretionary actions are transparent and open to interrogation.

The investment and trade implications present more complex issues of how to integrate context specific, negotiated regulatory and policy frameworks with the emerging global imperatives for harmonised regimes. We have to be aware of the political and economic context of the deployment of science in globalised contexts. The current danger is that, with the pressures to conform to the emergent globalised market system, science is employed only at one level to generate standardised procedures and processes which serve a particular form of global capitalism and particular regional industrial and political interests. Instead, the type of integrative science for complex decision-making discussed above has a role to play at all levels, from the local to the global. This presents many challenges for how to institutionalise forms of reflexive, integrative expertise that inform processes of multi-level governance, where 'subsidiarity' operates in a global context (Vogler and Jordan, forthcoming).

So would, as some argue, the adoption of a more open-ended policy and regulatory development process, based on learning, reflection and adaptation over time, with context specific divergence in regulatory and policy frameworks expected, result in discord and chaos? Such an approach is certainly far from being practised in the US, for example, where strict adherence to standard regulatory guidelines backed by a strong scientific advisory process, and supported by legislation is the norm. By contrast in Europe a more discretionary and precautionary stance is observed (with national variations Levidow 1994; Levidow *et al.* 1997; Gent 1999), with a range of experiments in more open, consultative approaches to expert advice being initiated in the wake of public concern about environmental and food safety issues (Kass 2000; Joss 1999). In the global arena there is much variation. In many global processes these days, there are at least rhetorical arguments for participatory involvement of different stakeholders and recognition of national divergences of regulatory requirements (e.g. in the Biosafety protocol) (Falkner 2000; Gupta 2000). However, in the increasingly dominant field of trade questions the emerging approach to regulation in the context of the WTO (not surprising given US interests and influence) is firmly based on standard, narrow, technical versions of 'sound science'.

But others argue that a recognition of uncertainties and ambiguities allows iterative negotiation, the creation of new boundaries and norms and a progressive move towards more effective regulation (Black 1998). Commenting on the Biosafety protocol Gupta (1999) argues that 'a transnational negotiated science which explicitly allows for ambiguity is likely to be the only way forward in managing biosafety'. Elsewhere she argues in a similar vein:

> The call for scientifically sound decision-making in an arena where the science itself remains heavily contested will inevitably result in ambiguity and openness to differential interpretations, rather than standardised, uniformly interpretable criteria.
>
> (Gupta 2000: 8)

So if conventional understandings of 'sound science' are increasingly contested, what implications does this have for the form and practice of regulatory and policy processes around agricultural biotechnology, particularly in the developing world? The following section picks up on this question by asking how science engages with biotechnology policy and regulation in practice in a range of different settings, and how, in particular, certain styles of science help frame and delimit the debate, fore-grounding some regulatory and policy positions and masking others.

5 Science and agricultural biotechnology policy and regulation

As already hinted at, many of the debates outlined in the previous sections resonate strongly with the emerging discussion about policy approaches for the regulation of agricultural biotechnology. So how is science deployed? What are the foci for scientific input? What are the resulting regulatory approaches?

Most current experience has been in the US and Europe where agricultural biotechnology regulation has been in development for several decades (Gottweis 1998; Wright 1994). In the EU the Directive 90/220 set an important framework which has subsequently been adopted and indeed adapted across Europe. This included a firm statement in support of the precautionary principle, but one that was firmly based on 'sound science'. In the UK for instance the 1992 and 1995 regulations established the operation of the Advisory Committee on Novel Food Products and ACRE (responsible for food safety and field trials and releases respectively). In the US, despite important federal control, a fairly diffuse and state specific elaboration of regulatory procedure and practice has been evident (Webber 1995). The US system in particular has been criticised for its reliance on scientific expertise as the basis for decisions, particularly the forcing of a 'product based approach' to regulation which was heavily backed by industry pressure. Bereano (1999) argues that: 'sound science became a mantra to obscure the exercise of partisan political power'.

Experiences in North America and Europe in particular were picked up and promoted by a variety of international agencies keen to develop regulatory approaches of wide applicability, including in the developing

world. The OECD in particular has been a major advocate of standardised, harmonised approaches based on the principles of 'sound science', and issued a range of guidelines and advice since the early 1990s (e.g. OECD 1993; 2000a-d). Various UN agencies, including UNEP, WHO and FAO have also been involved in providing advice on biosafety and environmental assessment approaches, as well as the CGIAR system (through ISNAR) and some NGOs (e.g. ACTS in Kenya) (Qaim *et al.* 2000). However it was only with the discussions surrounding the biosafety protocol when these issues became part of an international agreement which national governments signed up to. The text of the protocol was much contested, but in its final form promoted a precautionary approach, with provisions for national difference (Gupta 1999; McKenzie and Newell 2000).

In the last few years, developing countries too have been attempting to develop their own regulations and guidelines. These have largely mirrored international developments, often with consultants and legal support being provided by international agencies, or European or North American countries. Not surprisingly the texts of such regulations bear a very strong resemblance to those found elsewhere. Box 1 gives three examples from China, India and Zimbabwe.

Across these three developing country examples there are a number of common elements in the design of formal regulations. These include the categorisation of risk types (I to III or IV); the data requirements for risk assessment procedures; the distinctions between contained experimentation, field trials and commercial release; the structure of committees and their defined membership (heavily weighted towards scientific experts, with variable possibilities for others to participate); the limited scope for enforcement beyond committee inspection, monitoring and evaluation; overlapping links to other legislation (e.g. food/health, biodiversity/conservation, seed certification/import controls), and multiple ministerial responsibility (science and technology, agriculture, environment, health etc.). There are also some differences, including specific data requirements (for instance, India's requirements for more extensive data); patterns of ministerial control and responsibility; and the nature of overlapping legislation.

Such a very preliminary examination of the regulatory texts tells us only so much. In all countries, there is a strong presumption that 'sound science' will guide regulatory decision-making. Given the origins of all the regulations in US, European and international models, this is not surprising. But how does science operate in practice? What contexts mean that a particular type of scientific input finds its way into regulatory policymaking? The following section examines science in regulatory policy and how it helps both guide the establishment and set an interpretative frame for the implementation of the type of regulations discussed above.

Box 1 Regulatory contexts

In China the earliest regulations guiding the development of biotechnology were issued in 1993 by the State Science and Technology Commission. These were general in nature, and followed broadly the OECD guidelines. In 1996 the Ministry of Agriculture issued more detailed implementation guidelines which outlined the data requirements for risk assessment, the procedures to be followed prior to commercial release and the establishment committees to oversee the regulatory process.

In India the Environmental Protection Act of 1986 first outlined requirements for dealing with genetically engineered organisms, resulting in a set of rules laid out in 1989. In 1990 the Department of Biotechnology issued a series of guidelines for biosafety which were updated in 1994 and 1998. The guidelines draw on the US Department of Agriculture, Plant and Animal Health approaches, and those promoted by OECD and others. However, they depart from these in several ways, with Indian regulators arguing that they provide a stricter form of regulation than elsewhere, as they require both the incorporation of socioeconomic assessments in agronomic testing and field trials and also toxicity and allergenicity testing. A series of committees oversees the regulation of biotechnology, with the RCGM under the DBT dealing with research/small-scale trials and the GEAC under the Ministry of Environment and Forests dealing with releases. Under these national committees a series of institutional, district and state level biosafety and biotechnology coordination committees are supposed to exist, along with a Monitoring and Evaluation Committee. Biotechnology specific legislation and regulations overlap with other legislation, including the 1966 Seeds Act (under the Ministry of Agriculture) and the 1954 Prevention of Food Adulteration Act (under the Ministry of Health).

Regulatory developments are more recent in Zimbabwe, where in 2000 the Research (Biosafety) regulations (SI 20/2000) were issued. This instrument establishes a Biosafety board under the Research Act, linked to the national research council (under the President's office), and, as elsewhere, requires the establishment of institutional biosafety committees in all research locations where higher risk category activities are being carried out. Approvals are to be overseen by the Board, who can also carry out inspections to see regulations are being fulfilled. Other legislation does not cover biotechnology explicitly, although the new Environment Bill covers some relevant issues (under the Ministry of Environment, Mines and Tourism), as do various Acts dealing with seed health and certification (under the Ministry of Land and Agriculture).

Sources: UNIDO/Binas and OECD websites

5.1 Science in regulatory policy

A number of scientific disciplines necessarily become engaged in regulatory policy debates around biotechnology, each carrying with them particular models, experimental protocols and terminologies. Molecular genetics, toxicology and ecosystem ecology, for instance, each operate at different scales, with different ways of dealing with complexity, different styles of experimentation and testing, and different forms of representation of reality. This section examines five areas where ideas from different strands of science have become important in regulatory policy.

5.1.1 Precision engineering or complex genomic responses?

As discussed earlier agricultural biotechnology science is dominated by a particular type of molecular genetics, one which argues – at least in regulatory and policy contexts – that the processes employed in genetic engineering are precise and controlled, resulting in predictable and manageable effects. This 'engineering' view of science argues for a particular type of risk assessment, which focuses on a controlled and limited set of predicted effects. Thus, through the adoption of the engineering metaphor in regulatory settings, other types of molecular and genetic science which emphasise more complex, interactive and longer term genomic responses, are effectively ignored.

While acknowledged by scientists in footnotes and qualifications these have not been widely studied in explicit terms. In a thorough analysis of the recent scientific literature, Benbrook (2000) for instance analysed publications on the impacts of genetic modification, and highlights the fact that very few studies have been reported on, for instance, gene silencing, gene flow/transfers and epistatic/pleiotropic effects.[5] While the incidence of such studies published in the scientific literature is on the increase, they remain limited. Longer-term, complex, interactive effects are difficult to assess in the conventional experimental designs of molecular genetics, requiring instead a different analytical frame and experimental methodology to that normally associated with the sub-discipline.

Scientists of course recognise such complexities, but a convenient silence is maintained in more public discussions. One industry source notes however the range of uncertainties and the more haphazard, trial-and-error approach to actual scientific practice:

> The precise principles governing the expression of recombinant traits in transgenic plants are poorly understood. As a result problem solving in agricultural biotechnology relies even more heavily on physical experimentation than on conceptual modelling. Thus, although early greenhouse observations are critical the real uncertainty lies in predicting a recombinant trait's agronomic performance in elite commercial germ-plasm. This is especially true for output traits, the efficacy of which can be significantly effected by so-called genotype effects. In this context, one tends to find that 'learning by doing' is the only available process-development strategy.
>
> (McElroy 1999: 1073)

For regulators without access to the emerging scientific literature or these types of practical insights, the incentive to keep to the simple and tractable is high, making regulation easier, and so decreasing complexity and uncertainty in decision-making. With a dominant view of molecular biology and genetics holding sway, and mainstream scientists the most likely representatives on advisory committees and in hearings, there

[5] See for example reviews by Butler and Reichardt (1999); Ho *et al.* (1998); Tappeser *et al.* (1998); Hansen (2000); Clark (1999), reported by Benbrook (2000).

remain only limited, and often dismissed, challenges to the authority of such mainstream science in the regulatory and policy process.

But if such complex genomic effects are real, with implications for such longer-term and multiple cause impacts such as allergenicity, resistance and so on, then, others argue, surely they should be part of the regulatory remit, and will require different, more complex types of risk assessment (Krimsky 2000), based on the principles of scientific precaution described above.

5.1.2 Gene insertion: genes as 'magic bullets'

One of the recurrent popular images of genetic engineering is the assumed ability for biotechnologists to find and insert 'a gene' for a particular trait. For example in a release from College Station, Texas A and M University biologist Timothy Hall and colleagues explain how to combat rice water weevils they 'insert insect killing genes in the seeds of rice plants. When the plants grow, these genes produce insect killing proteins in the plant roots'.

The construction of the scientific endeavour as the search for genes for particularly valuable traits is well entrenched. Genes for vitamin enhancement, drought tolerance, nitrogen fixation and so on are always held up as the basis of the scientific quest. In recent times, for example, the focus on Vitamin A enhanced rice (or golden rice) has been at the centre of attention. Apart from the queries raised by the problems of acceptance, distribution, marketing and so on, a key issue is whether the genetic manipulation that has to occur to achieve such traits is as simple as is sometimes described.

Ernie Jaworski, who built up Monstanto's capacity in agricultural biotechnology in the 1980s, comments in relation to nitrogen fixation: 'If I could put all the genes needed to create a nitrogen fixing plant in corn, I would probably end up with a plant that resembled soya' (quoted by Hodgson 2000). As he explained, to put only the genes directly linked to fixation would be insufficient, as much of the plant's nitrogen metabolism and transport functions would have to be reengineered in order to accommodate the increased availability of nitrogenous precursors (Hodgson 2000).

In other words, the idea that simple gene insertion is all that is required is often very far from the truth, as complex traits have multiple genetic bases, and insertion of new genes may have major ramifications for the plant's biological functioning. The degree to which such complexities enter discussions in the regulatory and policy sphere is, however, very variable.

5.1.3 Familiarity in risk assessment: introduced 'exotics' as analogues for GM releases

A major area of concern in discussions about the regulation of GM products is the impacts of their release into the environment. Issues of biodiversity loss, crosses to weedy relatives, toxicity effects, patterns of pest and disease resistance all raise complex questions about the functioning of ecosystems with new introductions (e.g. Lutman 1999). Yet since, by definition, the particular product being assessed has not been released before how can regulators make predictions of impacts?

The concept of 'familiarity' thus becomes important in discussions about risk and regulation. In the same way that the chemical industry assumes that if the structure and activity of a new chemical is known, then closely related chemicals can be assumed to behave in the same way (Barrett and Abergel 2000; Regal 1999). The National Academy of Sciences in the US, for example, developed the concept of familiarity by arguing that if it can be established a priori that a new GM introduction is essentially phenotypically equivalent to a similar product, or that if the modification has only involved the introduction of a marker gene or sequence with no likely effects, then a limited form of risk assessment based on the principle of familiarity is appropriate (NAS 1989). The OECD guidelines also use the concept of familiarity to encourage the generation of standard approaches to regulation when knowledge is shown of any or all of: the crop plant, environment, the trait, previous modifications of the crop or trait, and interactions among the crop trait and the release environment (Barrett and Abergel 2000, quoting OECD 1993). As familiarity with introductions increases, it is argued, then deregulation – or at least streamlined harmonisation – can occur, allowing a more direct route to large scale releases.

As the NAS document acknowledges though, 'familiar does not necessarily mean safe', but instead risk assessment can proceed by drawing on experience from elsewhere and using analogues as predictors of future risk. Generic safety models (for non-pathogens) have much appeal both to regulators unwilling to cope with complex and site specific decisions, and industry that is always keen on simple, streamlined regulatory approaches. By the 1980s in the US such models – based on the assumption that genetically engineered introductions were likely to be 'ecological cripples' like many domesticated varieties – were the basis for biotechnology regulation, and many foresaw the prospect of deregulation in the future (Regal 1993). However, the flaws in such models were highlighted as the prospects of the deliberate release of GM self-sustaining organisms became a reality. Ecologists pointed out the limitations of the generic safety models which ignored the potentials for significant, if rare, impacts (Regal 1993).

Other regulatory models were in turn sought, this time drawing for the first time in the biotechnology regulation debate on ecological science. Over many years, ecologists had studied the introduction of exotics into wild ecosystems, with detailed documentation of effects and impacts in different settings (e.g. Williamson 1996; Paoletti and Pimental 1996). If exotic species introductions could be used as an analogue for GM releases, then a regulatory approach could be built on the basis of solid scientific insight it was thought. However, a simplistic application of the exotic species model has been criticised on a number of counts. For example, risks may be underestimated because transgenic forms engineered from native hosts may be considerably better adapted than introduced exotics and because minor genetic changes may result in major shifts in ecological and evolutionary advantage with significant consequences (Regal 1993). Therefore, although the exotic introductions model may offer a useful way of thinking about and assessing the impacts of GM introductions, it is unlikely to offer a route towards a simple generic model where a particular product can be allocated to one of a variety of predefined risk categories on the basis of 'familiarity'. Regal (1993) points

out how it is dangerous 'to assume that one is sufficiently familiar with an organism to make predictions when the familiarity is not based on a detailed understanding of the mechanisms of adaptation and the range of latent adaptive potentials of the organism' (Regal 1993). Instead, case-by-case analysis will be required during regulatory approval, involving field testing, monitoring and evaluation. This in turn poses other issues for the involvement of science.

5.1.4 Scales, boundaries and field trials

Field trials are seen as a key step in the regulatory approval process. But how should such trials be designed? Different perspectives exist, emerging from different scientific traditions. Agronomists, for example, argue that simple plot based experiments are sufficient for assessing likely effects, while ecosystems ecologists, on the other hand, argue that more elaborate designs are required because of the likelihood of complex responses at an ecosystem level (Krimsky and Wrubel 1996; Krimsky 2000). Still others argue that field trials are probably not necessary as likely impacts can be predicted from models and the extrapolation of in silico, in vitro or greenhouse responses.

Such contrasting perspectives of course present dilemmas for regulators attempting to design policies on the basis of 'sound science'. What spatial scale is appropriate for field trials? Over what time period should such tests be carried out? What boundaries are appropriate to prevent cross-pollination? Easy answers of course are not available, as major uncertainties prevail.[6] 'Field tests tell us little about commercial scale risks' (Rissler and Mellon 1996: 24) because the probability of conjunctions of rare factors occurring together increases significantly on larger scales.

Advisory committees and even courts must then seek advice from different sources on such subjects as how far pollinating bees can fly before decisions can be reached. Standard designs for field trial testing though look unlikely, given the variation in ecological setting and dynamics. This has been recognised in the Biosafety Protocol, for example, in the compromise wording which recognised that assessments must take account of the 'likely potential receiving environment' (Gupta 1999).

5.1.5 Substantial equivalence and risk assessment

The degree to which risk assessments for genetically engineered organisms should have a special status, with particular requirements additional to the conventional approaches to the release of new varieties, is the subject of intense debate. On one side there are those who argue that the processes of genetic engineering result in novel biological entities with potentially unique hazards and, for this reason, there should be special attention paid to risk assessment. By contrast, others argue that genetically engineered products are not substantially different from other equivalent crops and therefore there should be no reason for special treatment.

---

[6] See for example: Tiedje *et al.* (1989); Pimental *et al.* (1989); Larson and Knudson, (1991); Wrubel *et al.* (1992); Panetta (1993); Regal (1994); Rissler and Mellon (1996); Parker and Kareira (1996); Steinbrecher (1996); Snow and Moran (1997); Scientists Working Group on Biosafety (1998); Lu *et al.* (1999) among many others.

Process based regulation therefore emphasises the special qualities of the genetic engineering processes by which new products arise, particularly the potentials for unknown and indeed unknowable complex effects due to genetic engineering. Therefore process based approaches attribute special status in risk assessment and regulatory procedures to genetically engineered organisms. By contrast, product based regulation focuses exclusively on the final product, arguing that genetic engineering processes should be given no special status. Such product based approaches therefore emphasise chemical, toxicological, immunological, allergenicity and other testing on the same basis that other new food products are assessed (cf. Tait and Levidow 1992).

The highly contested notion of 'substantial equivalence' has been central to this debate. As a classic boundary term, substantial equivalence has been advocated as a regulatory device particularly by those scientists (and associated networks, especially in the biotechnology industry) that argue for a product based approach to regulation. Substantial equivalence was initially developed as a baseline for food safety assessment on the assumption that if a new GM product was substantially equivalent in chemical composition its 'natural' antecedent, then it could be assumed that no new health risks would arise (Millstone *et al.* 1999). The concept arose as part of attempts by international organisations (notably WHO, FAO and the OECD) to develop generally applicable and standardised guidelines for the regulation of food safety (cf. OECD 1993; 2000a-d). By collecting data on existing products, the hope has been to develop databases of consensus based scientific information on potential hazards of existing organisms to guide choices about the type of risk assessment for GM products on the basis of the substantial equivalence principle. Industry claims that comprehensive safety reviews have been carried out on transgenic crops are thus largely based on chemical compositional analyses, many published in scientific journals such as the *Journal of Agricultural Chemicals* or the *Journal of Nutrition*.[7] But some commentators are worried that:

> Such 'science-based' regulations will provide policymakers with the knowledge and predictive capabilities necessary to manage GEO hazards in any political or ecological context, thereby encouraging 'harmonised' regulations and free trade.
>
> (Barrett and Abergel 2000: 5)

Others question the degree to which the notion of substantial equivalence is based on 'sound science' at all. Quoting a Dutch research team, Millstone *et al.* (1999) argue that 'compositional analysis … as a screening method for unintended effects … of the genetic modification has its limitations … in particular regarding unknown anti-nutrients and natural toxins'. They go on to argue for the abandoning of the concept:

---

[7] See for example Monsanto's lists of Round-up ready soya safety references on www.biotechbasics.com/product_information/rrsoy_safetyref.html See for example: Nida *et al.* (1996) or Padgette *et al.* (1996).

> Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific. It is moreover anti-scientific because it was created primarily to provide an excuse for not requiring biochemical and toxicological tests. It therefore serves to discourage and inhibit potentially informative scientific research.
>
> (Millstone *et al.* 1999)

By unreasonably black-boxing uncertainties and restricting other avenues of scientific enquiry for risk assessment, the boundary term of substantial equivalence therefore upholds a particular strand of science and an associated position on regulation and gives it authority in regulatory and policy arenas, but in so doing excludes other perspectives. However, by exposing the social and political commitments of such a term, and interrogating its underlying scientific basis, a question mark is raised as to the appropriateness of the term as a basis for regulatory and policy decision-making.

5.1.6 Novelty, origins and intellectual property rights

By contrast to the focus on familiarity and equivalence in risk assessment, in the area of policy surrounding intellectual property rights and patenting the emphasis has been on novelty and innovation. As some commentators have observed it is somewhat ironic that often the same scientists and industry players argue for chemical equivalence in the area of food safety assessment and familiarity with regard to ecological impact assessment, yet stick to arguments for novelty in respect of genetic transformation in order to meet patenting criteria (Millstone *et al.* 1999).

In order to assure the granting of patents three main criteria must be established – novelty, non-obviousness and utility (Erbisch and Karim 1998). Thus proving novelty is key in this policy debate. Just as selective areas of science are deployed in debates about food safety or biodiversity impact, notions of novelty and innovation can be derived from a particular interpretation of science in showing how genetically modified products and processes are new and thus the intellectual property of the innovator. But this interpretation of novelty is contested, with those arguing against the 'patenting of life' putting the case that only marginal changes have resulted, and that patents would potentially undermine access to genetic material managed for centuries by local people as part of natural and agricultural ecosystems (Shiva 2000).

5.2 Contexts for science and regulation

Science therefore enters debates about biotechnology regulatory policy in a number of ways, often providing authority for particular terms, models and methods that in turn act as boundary objects in the interaction between science and policy. By framing discussions about regulation and policy in a particular way, such terms, models and methods often have a major impact. The range of risk assessment approaches used in biotechnology appraisal, for example, are therefore structured in particular ways, drawing on particular types of scientific evidence and excluding other sources of information. Highlighting the social and political

commitments of such scientific knowledge, the notion of an abstract, objective 'sound science' as the foundation for regulatory decision-making can be opened up to questioning. It is clear that the particular framings of risk assessment approaches – and associated terms, models and methods – have particular histories associated with particular sets of actors and networks, allied to certain interests and objectives. Making such links explicit is important – not to uncover conspiratorial dealings, but to highlight the often, inadvertent, path dependent way regulatory policies emerge, and how scientific concepts and practices are deeply intertwined with the social and political processes of policymaking. Through such an analysis a more realistic appreciation of regulatory policy processes can be gained, one that can help to point to the potentially important perspectives that have been excluded.

Much of the previous discussion has shown how contexts – scientific, social, cultural, economic and so on – are critical to understanding the interaction between science and regulatory policy. Most experiences and examples in the literature are from Europe and North America where most of the debate about regulatory policy has taken place to date. But what issues are pertinent in the developing world context? What might we learn from a comparative study of the relationship between science, policy and regulation? Most discussions of regulatory policy making and the role of science in developing country contexts has focused on the specifics of implementing existing frameworks, highlighting particularly issues of capacity for implementation,[8] but have largely failed to ask perhaps more fundamental questions about the relationships between science, regulation and policy underlying these debates.

There is a current danger that a 'transfer or regulation' process simply follows in the wake of a 'transfer of technology' process, without a more basic interrogation of what is appropriate where and why. Drawing on the preceding discussions, the following section highlights some key questions that might form the basis of a comparative understanding of science, regulation and policy. Clearly the contexts for debates about agricultural biotechnology are very different in different developing countries, with different histories, political contexts, scientific capacities and so on influencing the way the relationships between science and regulatory policies are played out.

- *Scientific cultures and practices*. What is the history of public scientific institutions? What relationships to the state and international players do they have? What peer circuits and professional networks exist? What is the organisational structure of industrial, public and other types of science? What are the day-to-day practices of biotechnology science in different types of lab or field station? Who gets involved in different types of biotechnology science, through what training paths and career tracks? What national and international organisations and networks are scientists connected to? What disciplines, interests,

[8] See for example: Komen and Persley (1993); Komen *et al.* (1995); Compeerapap (1997); Essegbey (1998); Ives and Bedford (1998); Cohen (1999); Qaim *et al.* (2000), among others.

positions and politics are reflected in the scientific establishment? How is scientific debate and contestation played out? What exists beyond the mainstream and outside the establishment?

- *Scientific capacities and funding: public, private and international.* What is the basis of national scientific infrastructure? How is this funded? What have been the trends in funding, staffing levels and disciplinary composition of scientific institutes? What is the role of private sector funding in science? How do public and private sectors – both national and international – interact? What issues of proprietary rights are raised?
- *Regulatory and policy styles.* What models for the regulation of biotechnology are adopted? What are their origins? How do such new regulations relate to longer established regulatory and legal frameworks? What mechanisms exist for establishing the authority and effectiveness of regulatory approaches? What roles do state enforcement, voluntary compliance and public accountability play? What is the role of science in regulatory processes (in advisory committees, risk assessment panels etc.)? What types of scientific advice are important? From where are they sought? How legitimate and trustworthy are regulatory and policy institutions seen by different groups in society?
- *The political economy of agriculture and food.* What 'narratives' inform policy surrounding agriculture? How is 'modern', 'industrial' agriculture seen in relation to 'subsistence', small scale farming? How is agriculture viewed in relation to other sectors and development more broadly? Is a poverty focused approach to agriculture seen as a political priority? How is the link between private and public sectors seen in agricultural service and input provision? What role does science play in agricultural development?
- *Trade, industry and technology development.* What is the emerging structure of the agricultural-food industry? How is it linked to other sectors? What commercial and political interests (national and international) are behind such developments? What regulatory policies and processes enable and limit the development of the sector, both national and international? What are the scientific and R and D strategies being deployed?
- *Political contexts for policy and regulation.* How is agricultural development viewed politically? How do changing international contexts (e.g. WTO) and national policy priorities (e.g. liberalisation) influence policy? What actors and interests are involved? Through what mechanisms do they try and get their positions taken on board? How is science deployed by different players in such debates? What boundary terms and anchoring devices are important?
- *Public engagement, dissent and debate.* What types of public engagement is there in debates about rural development, agriculture and the new biotechnologies? Is such debate 'hidden', consensual or conflictual? Where organised opposition exists, what is the basis for dissent? What is the social, political, ethnic composition of opposition movements and organisations? What links exist with international

groupings? What alternative narratives are presented? Do these constitute alternative views of science and technology development?

6 Conclusion

Debates about biotechnology regulatory policy therefore pose some fundamental questions about how science and expertise should relate to public policy and planning. Provoked by concerns about risks of environmental impact and food safety, and the core issues of uncertainty and ignorance, the debate about the future of agricultural biotechnology throws up questions about how regulation and policy should emerge.

Particularly in Europe – but perhaps more broadly too – questions are being asked about the implications of the changing relationship between expert institutions and citizens around the management of new technologies with unknown risks (Ashford 1996). Such changes could, it is argued, have profound political consequences. Rather than seeing public responses to biotechnology risks as a retreat to the primitive and a rejection of enlightenment ideals and the modernist project of development, such responses can be seen as a maturation of response (Jasanoff 2000), where multiple and new forms of modernity are constructed, responding to new technological opportunities, risks and uncertainties and constructed through new types of engagement between science, citizens and the state (Beck 1992; 1995; Lash *et al.* 1996).

Debates about biotechnology policy and regulation are being played out in many arenas, from local negotiations with local regulators, to national level policy discussions, to global fora, protocols and conventions. The relationship between science, policy and regulation is thus characterised often by increasingly diffuse and mobile networks, often only fragilely linked. The result is the playing out of debates in multiple knowledge arenas – in academia, in regulatory bureaucracies, in industry boardrooms, in the courts and so on. The negotiation of regulatory policy is thus far from straightforward, involving as it does multiple actors and multiple forms of knowledge deployed in different ways at different times (Hunt and Shackley 2000).

There is of course no single pattern, and major divergences in regulatory and policy approaches are seen between, for example, the US and Europe and between countries in the developing world. Such differences are dependent on a range of contextual factors – political, economic, scientific, bureaucratic and so on. These result in different cultures and styles of science, bureaucracy, policy, regulation, despite the homogenising forces of globalisation. Thus a diversity of discourses and practices associated with biotechnology can be observed, resulting in divergent regulatory and policy approaches.

A recognition that scientific knowledge – and the regulatory and policy decisions that flow from it – is contextual and socially and politically embedded is important. In one sense all knowledge is constructed, and is dependent on the actors and networks which uphold particular truth claims. However a 'constructivist' approach to science and policy processes does not mean a necessary resort to extreme relativism, where there

are no bases for deciding between better or worse regulations and policies. Integrative, precautionary science that acknowledges partial and plural positions and takes uncertainty and ignorance seriously can be based on criteria for rigour and trustworthiness, based on a 'critical realist' perspective. A questioning of framing assumptions, the incorporation of multiple criteria, the use of diverse methodologies, and the development of explicit approaches for reflexive interrogation of results might be regarded as more 'sound' than conventional 'sound science', based as it often is on a rather narrow remit.

Such a redefinition of 'sound science' then has some major implications for thinking about regulatory and policy approaches around biotechnology:

- First, the scope of assessment has necessarily to be expanded beyond narrow technical concerns to a range of strategic economic, socio-cultural, political, ethical and moral issues associated with choices about new technologies. Thus a continuum is created from broad technology assessment to narrower risk assessments of specific products and processes, where questions cannot be delinked and wider questions must inform and frame the more specific issues.
- Second, such a shift requires that the methods used need to be expanded beyond narrow risk assessment tools to include systematic assessment and inclusive deliberation techniques which deal with multiple criteria and uncertainty explicitly (Stirling *et al.* 1999).
- Third, this implies that criteria for rigour and trustworthiness be revised to go beyond narrow, technical quantification measures to include a range of other tests including transparency of information, triangulation of methods, wide peer assessments (including by publics), 'boundary testing' approaches and others (van Zwanenberg and Millstone 2000; Carr and Levidow 2000).
- Fourth, this in turn implies that the range of expertises involved in risk assessment and regulatory policy decision-making needs to be expanded. This is not to deny that conventional, mainstream science has an important role, but this may be usefully complemented by other disciplinary scientific perspectives, lay knowledges, and 'citizen sciences' which are currently largely excluded or marginalised (Fischer 1993; Irwin 1995).
- Fifth, if understanding risk and uncertainty requires a located, embedded and context specific assessment (cf. Irwin *et al.* 1999), then inevitably there will be divergence in emerging assessments and regulatory choices, rather than standardisation and harmonisation.
- Finally, the institutional contexts for the development of regulatory policy need to be rethought, if they are to encourage the characteristics of openness and transparency and so garner widely held authority and legitimacy for regulatory decisions. In short this requires an institutional innovation process which helps to democratise science and the regulatory decision-making, from local to global contexts (Kleinman 1998; Jasanoff 2000b).

References

Ashford, T., 1996, 'Regulating agricultural biotechnology: Reflexive modernisation and the European Union', *Policy and Politics,* Vol 24 No 2: 125–35

Barben, D., 1998, 'The making and outcomes of biotechnology regimes: towards an extended regime analysis', *Osterreichische Zeitschrift fur Politikwissenschaft,* Vol 27 No 1: 47 (16 pages)

Barrett, K. and Abergel, E., 2000, 'Breeding familiarity: environmental risk assessment for genetically engineered crops in Canada', *Science and Public Policy,* Vol 27 No 1: 2–12

Beck, U., 1992, *Risk Society: towards a new modernity*, London: Sage

—— 1995, *Ecological Politics in an Age of Risk*, Cambridge: Polity

Benbrook, C., 2000, 'Who controls and who will benefit from plant genomes?', presented at AAAS Annual Meeting on 'The Genomic Revolution in the Field, Facing the Needs of the New Millennium', February 19, Washington, D.C. www.biotech-info.net/AAASgen.html

Bennett, D.P., Glasner, J., *et al.*, 1986, *The Politics of Uncertainty: regulating recombinant DNA research in Britain,* London: Routledge and Kegan Paul

Bereano, P., 1999, *Sound science and the precautionary principle.* Centre for International Development, Harvard www.cid.harvard.edu/cidbiotech/comments/comments92.html

Black, J., 1998, 'Regulation as facilitation: negotiating the genetic revolution', *Modern Law Review,* Vol 61 No 5: 621–60

Bonanno, A. *et al.*, 1994, *From Columbus to Con-agra: the globalisation of agriculture and food*, Laurence: University of Kansas Press

Bud, R., 1991, 'Biotechnology in the 20th century', *Social Studies of Science,* Vol 21 No 3: 415–57

—— 1993, *The Uses of Life: a history of biotechnology,* Cambridge: Cambridge University Press

Butler, D. and Reichardt, T., 1999, 'Long term effect of GM crops serves up food for thought', *Nature* 398: 651

Buttel, F., 1999, 'Agricultural biotechnology: its recent evolution and implications for agrofood political economy', *Sociological Research Online,* Vol 4 No 3: U292–U309

Byerlee, D. and Fischer, K., 2001, 'Accessing modern science: policy and institutional options for agricultural biotechnology in developing countries', *IP Strategy Today 1,* www.biodevelopments.org

Callon, M. and Latour, B., 1992, 'Don't throw the baby out with the Bath School! A reply to Collins and Yearley', in A. Pickering (ed.), *Science as Practice and Culture*, Chicago: University of Chicago Press

Cantley, M., 2000, *An old biotech case study on the precautionary principle,* Centre for International Development, Harvard University, www.cid.harvard.edu/cidbiotech/comments/comments97.htm

Carr, S. and Levidow, L., 1997, 'How biotechnology regulation separates ethics from risk', *Outlook on Agriculture,* Vol 26 No 3: 145–50

—— 2000, 'Exploring the links between science, risk, uncertainty, and ethics in regulatory controversies about genetically modified crops', *Journal of Agricultural & Environmental Ethics,* Vol 12 No 1: 29–39

Clark, A., 1999, *Ten reasons why farmers should think twice before growing GM crops,* www.plant.uoguelph.ca/faculty/eclark/10reasons.htm

Cohen, J., (ed.), 1999, 'Managing agricultural biotechnology: Addressing research program needs and policy implications', *Biotechnology in Agriculture Series* 23, Wallingford: CABI

Compeerapap, J., 1997, 'The Thai debate on biotechnology and regulation', *Biotechnology and Development Monitor* 32: 13–5

Douglas, M., 1985, *Risk Acceptability According to the Social Sciences,* New York: Russell Sage Foundation

Dunlop, C., 2000, 'GMOs and regulatory styles', *Environmental Politics*, Vol 9 No 2: 149–55

Durant, J., 1999, 'Participatory technology assessment and the democratic model of the public understanding of science', *Science and Public Policy,* Vol 26 No 5

Erbisch, F.H. and Maredia, K.M., 1998, *Intellectual Property Rights in Agricultural Biotechnology*, Wallingford: CAB International

Essegbey, G., 1998, 'Developing a biosafety regime in Ghana: issues and options for policy makers', *Science, Technology and Development*, Vol 16 No 2: 32–54

Falkner, R., 2000, 'Regulating biotech trade: the Cartagena Protocol on biosafety', *International Affairs,* Vol 76 No 2: 299–315

Fischer, F., 1993, 'Citizen participation and the democratization of policy expertise', *Policy Sciences*, Vol 26: 165–87

Fischer, F., 1999, 'Technological deliberation in a democratic society: the case of participatory inquiry', *Science and Public Policy*, Vol 26 No 5

Fischer, F., 2000, *Citizens, Experts and The Environment. The Politics of Local Knowledge*, Durham: Duke University Press

Funtowicz, S. and Ravetz, J., 1992, 'Three types of risk assessment and the emergence of post normal science', in S. Krimsky and D. Golding (eds), *Social Theories of Risk*, Westport, CT: Praeger: 251–73

Gent, R.N., 1999, 'Genetically modified organisms: an analysis of the regulatory framework currently employed within the European Union', *Journal of Public Health Medicine,* Vol 21 No 3: 278–82

Gieryn, T., 1993, 'Boundary-work and the demarcation of science from non-science: strains and interests in professional ideologies of scientists', *American Sociological Review*, 48: 781–95

—— 1995, *Cultural Boundaries of Science. Credibility on the Line*, Chicago: University of Chicago Press

Gottweis, H., 1998, *Governing Molecules: the discursive politics of genetic engineering in Europe and the United States*, Cambridge, MA: MIT Press

Grindle, M. and Thomas, J., 1991, *Public Choices and Policy Change*, Baltimore: Johns Hopkins UP

Grove-White, R., 1999, 'On sound science, the environment and political authority', *Environmental Values,* 8: 277–82

Gupta, A., 1999, 'Framing "biosafety" in a transnational context: the biosafety protocol negotiations under the Convention on Biodiversity', *ENRP Discussion Paper*, E-99-10

—— 2000, 'Governing biosafety in India: the relevance of the Cartagena Protocol', *Belfer Center for Science and International Affairs Paper*: 2000–24

Haas, P., 1992, 'Introduction: epistemic communities and international policy co-ordination', *International Organisation,* 46: 1–36

Hacking, I., 1983, *Representing and Intervening. Introductory Topics in the Philosophy of Science*, Cambridge: Cambridge University Press

Hajer, M., 1995, *The Politics of Environmental Discourse,* Oxford: Clarendon

Hansen, M., 2000, 'Genetic engineering is not an extension of conventional breeding', www.biotech-info.net/wide_crosses.html

Ho, M.W. *et al*., 1998, 'Gene technology and gene ecology of infectious diseases', *Microbial Ecology in Health and Disease*

Hodgson, J., 2000, 'Crystal gazing and the new biotechnologies', *Nature Biotechnology*, Vol 18 No 1

Holmes, T. and Scoones, I., 2000, 'Participatory environmental policy processes: experiences from North and South', *IDS Working Paper* 113, Brighton: Institute of Development Studies

Hunt, J. and Shackley, S., 2000, 'Reconceiving science and policy: academic, fiducial and bureaucratic knowledge', *Minerva*, 37: 141–64

Irwin, A., 1995, *Citizen Science: a study of people, expertise and sustainable development*, London: Routledge

Irwin, A. *et al*., 1997, 'Regulatory science: towards a sociological framework', *Futures* XXIX: 17–31

Irwin, A. Simmons, P. and Walker, G., 1999, 'Faulty environments and risk reasoning: the local understanding or industrial hazards', *Environment and Planning,* A. 31: 1311–26

Ives, C. and Bedford, B. (eds), 1998, 'Agricultural biotechnology in international development', *Biotechnology in Agriculture Series*, 21 Wallingford: CABI

Jasanoff, S., 1990, *The Fifth Branch: scientific advisors as policymakers*, Cambridge: Harvard University Press

—— 1995, 'Product, Process or Program. Three Cultures and the Regulation of Biotechnology', in M. Bauer (ed.), *Resistance to New Technology*, Cambridge: Cambridge University Press

—— 2000a, 'Between risk and precaution: reassessing the future of GM crops', *Journal of Risk Research*, 3: 277–82

—— 2000b, *Learning from the crisis: how (not) to read the GM food controversy*, Harvard: Centre for International Development, www.cid.harvard.edu/cidbiotech/comments/comments53.htm

Jasanoff, S. and Wynne, B., 1998, 'Science and Decision-Making', in S. Rayner (ed.), *Human Choice and Climate Change*, Ohio: Battelle Press

Joss, S., 1999, 'Public participation in science and technology policy and decision-making: ephemeral phenomenon or lasting change', *Science and Public Policy,* Vol 26 No 5

Kass, G., 2000, 'Public debate on science and technology: issues for legislators', *Science and Public Policy*, 27: 321–6

Keeley, J. and Scoones, I., 1999, 'Understanding environmental policy processes: a review', *IDS Working Paper* 89, Brighton: Institute of Development Studies

Kingdon, J., 1984, *Agendas, Alternatives and Public Choices*, Boston: Little Brown

Kleinman, D.L., 1998, 'Pervasive influence: intellectual property, industrial history and university science', *Science and Public Policy,* Vol 25 No 2: 95–102

Knorr-Cetina, K., 1981, *The Manufacture of Knowledge. An Essay on Constructivist and Contextual Nature of Science*, Oxford: Pergamon Press

—— 1999, *Epistemic Cultures. How the Sciences Make Knowledge*, Cambridge: Harvard University Press

Komen, J. and Persley, G., 1993, 'Agricultural biotechnology in developing countries. A cross-country review', *ISNAR Research Report* 2, ISNAR: The Hague

Komen, J. Cohen, J. and Lee, S. (eds), 1995, 'Turning priorities into feasible programs', proceedings of a regional Seminar on Planning, Priorities and Policies for Agricultural Biotechnology in SE Asia, ISNAR: The Hague

Krimsky, S., 2000, 'Risk assessment and regulation of bio-engineered food products', *International Journal of Biotechnology*, 2: 231–8

Krimsky, S. and Golding, D. (eds), 1992, *Social Theories of Risk*, Westport, CT: Praeger

Krimsky, S. and Wrubel, R., 1996, *Agricultural Biotechnology and the Environment: science, policy and social issues*, Urbana: University of Illinois Press

Krimsky, S. Rothenberg, L.S. *et al.*, 1998, 'Scientific journals and their authors' financial interests: a pilot study', *Psychotherapy and Psychosomatics,* Vol 67 (4–5): 194–201

Larson, B.A., and Knudson, M.K., 1991, 'Public regulation of agricultural biotechnology field-tests – economic-implications of alternative approaches', *American Journal of Agricultural Economics,* Vol 73 No 4: 1074–82

Lash, S., Szerszynski, B. and Wynne, B. (eds), 1996, *Risk, Environment and Modernity: towards a new ecology*, London: Sage

Latour, B., 1987, *Science in Action: how to follow scientists and engineers through society,* Milton Keynes: Open University Press

Levidow, L., 1994, 'Biotechnology regulation as symbolic normalization', *Technology Analysis & Strategic Management,* Vol 6 No 3: 273–88

—— 1998, 'Democratizing technology – or technologising democracy? Regulating agricultural biotechnology in Europe', *Technology in Society,* Vol 20 No 2: 211–26

—— 1999, 'Regulating Bt maize in the USA and Europe: a scientific-cultural comparison', *Environment,* 41: 10–21

Levidow, L. and Carr, S., 1996, 'UK: disputing boundaries of biotechnology regulation', *Science and Public Policy,* Vol 23 No 4: 164–70

—— 2000, 'Unsound science? Transatlantic regulatory disputes over GM crops', *International Journal of Biotechnology,* 2: 257–73

—— 2000a, 'Normalizing novelty: regulating biotechnological risk at the US EPA', *Risk*, forthcoming

Levidow, L. and Carr, S. *et al.*, 1997, 'European biotechnology regulation: framing the risk assessment of a herbicide-tolerant crop', *Science Technology & Human Values,* Vol 22 No 4: 472–505

—— 1999, 'Market-stage precautions: managing regulatory disharmonies for transgenic crops in Europe', *AgBiotechNet,* Vol 19 No 1: 1–8

Levidow, L. Carr, S., von Schomberg, R. and Wield, D., 1996, 'Regulating agricultural biotechnology in Europe: harmonisation difficulties, opportunities and dilemmas', *Science and Public Policy*, 23: 135–57

Levidow, L. Carr, S. and Wield, D., 1998, 'European regulation: harmony or cacophony?', *BINAS News* 4, Issue 1

—— 2000, 'GM crops in the EU: regulatory conflicts and precautionary opportunities', *Journal of Risk Research*, 3: 189–203

Levidow, L. and Tait, J., 1992, 'Release of genetically modified organisms: precautionary legislation', *Project Appraisal*, 7: 219–31

Levidow, L. *et al.*, 2000, 'Genetically modified crops in the EU: regulatory conflicts as precautionary opportunities', *Risk Research,* 3: 189–208

Lipsky, M., 1979, *Street Level Bureaucracy,* New York: Russell Sage Foundation

Lipton, M. and Longhurst, R., 1989, *New Seeds and Poor People*, London: Unwin Hyman

Lu, Y. *et al.*, 1999, 'Development time and resistance to Bt crops', *Nature*, 400: 519

Lutman, P. (ed.), 1999, 'Gene flow and agriculture: relevance for transgenic crops', *British Crop Protection Council Symposium Proceedings*, 72

Majone, G., 1997, 'From the positive to the regulatory state: causes and consequences of changes in the mode of governance', *Journal of Public Policy*, 17: 139–67

McElroy, D., 1999, 'Moving agbiotech downstream', *Nature Biotechnology,* Vol 17 No 11

McKenzie, R. and Newell, P., 2000, 'The 2000 Cartagena protocol on biosafety: legal and political dimensions', *Global Environmental Change,* Vol 10

McMillan, G.S.F., Narin *et al.*, 2000, 'An analysis of the critical role of public science in innovation: the case of biotechnology', *Research Policy,* Vol 29 No 1: 1–8

Millstone, E., Brunner, E. and Mayer, S., 1999, 'Beyond substantial equivalence', *Nature*, October 7

NAS, 1989, *Field Testing Genetically Modified Organisms: framework for decisions*, Washington, D.C.: National Academy Press

Nida, D. *et al.*, 1996, 'Glyphosate-tolerant cotton: the composition of the cottonseed is equivalent to conventional cottonseed', *J. Agricultural food Chemistry,* 44: 1967–74

O'Riordan, T. and Cameron, J., 1994, *Interpreting the Precautionary Principle*, London: Earthscan

OECD, 1993, *Safety Evaluation of Foods Derived by Modern Biotechnology: concepts and principles*, Paris: OECD

—— 2000a, *Overview of Food Safety Systems and Activities*, Paris: OECD, Ad Hoc Group on Food Safety

—— 2000b, *Report of the Task Force for the Safety of Novel Food and Feeds*, Paris: OECD, Council

—— 2000c, *Report of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology*, Paris: OECD, Council

—— 2000d, *Substantial Equivalence and the Safety Assessment of GM Foods*, Paris: OECD

Osborne, M., 1999, 'Harmonization of biotechnology regulation in the OECD' [online], 20 August, available at www.cid.harvard.edu/cidbiotech/comments/comments17.htm

Padgette, S., Taylor, N.N., Bailey, N., MacDonald, J., Holden, L and Fuchs, R., 1996, 'The composition of glyphosate-tolerant soybean seeds is equivalent to conventional soybeans', *Journal of Nutrition*, 126: 702–16

Panetta, F., 1993, 'A system for assessing proposed plant introductions for weed potential', *Plant Protection Quarterly*, 8: 10–4

Paoletti, M. and Pimental, D., 1996, 'Genetic engineering in agriculture and environment', *BioScience,* 46: 665–73

Parker, I. and Kareira, P., 1996, 'Assessing the risks of invasions for genetically engineered plants: acceptable evidence and reasonable doubts', *Biological Conservation,* 78: 193–203

Perkins, J., 1997, *Geopolitics and the Green Revolution*, Oxford: Oxford University Press

Pimental, D. *et al.*, 1989, 'Benefits and risks of genetic engineering in agriculture', *BioScience,* 39: 606–14

Qaim, M., Krattiger, A.F., von Braun, J. (eds), 2000, *Agricultural Biotechnology in Developing Countries: towards optimizing the benefits for the poor*, Dordrecht, NL/ Boston, USA: Kluwer Academic Publishers

Regal, P., 1993, 'The true meaning of "exotic species" as a model for genetically engineered organisms', *Experientia*, 49: 225–34

—— 1994, 'Scientific principles for ecologically based risk assessment of transgenic organisms', *Molecular Ecology*, 3: 5–13

—— 1999, 'A brief history of biotechnology risk debates and polices in the United States', *Occasional Paper*, Washington, D.C.: Edmonds Institute, www.edmonds-institute/regal.html

Renn, O., 1995, 'Styles of using scientific expertise: a comparative analysis', *Science and Public Policy*, 22: 147–56

—— 1997, 'Three decades of risk research: accomplishments and new challenges', *Journal of Risk Research,* 1: 49–71

Rip, A., 1996, 'Controversies in informal technology assessment', *Knowledge*, 8: 349–71

Rissler, J. and Mellon, M., 1996, *The Ecological Risks of Engineered Crops*, Cambridge, Mass.: MIT Press

Royal Society, 1992, *Risk Analysis, Perception and Management*, London: Royal Society

Sahl, J.D. and Bernstein, B.B., 1995, 'Developing policy in an uncertain world', *International Journal of Sustainable Development and World Ecology,* Vol 2 No 2: 124–35

Salter, L., 1994, *Mandated Science: science and scientists in the making of standards*, Princeton University Press

Scientists Working Group on Biosafety, 1998, *Manual for assessing ecological and human health effects of genetically engineered organisms*, Washington, D.C.: Edmonds Institute, www.edmonds-institute.org/manual.html

Scoones, I., 2002, 'Agricultural biotechnology and food security: exploring the debate', *IDS Working Paper* 145, Brighton: Institute of Development Studies

Shackley, S. and Wynne. B., 1995, 'Global climate change: the mutual construction of an emergent science-policy domain', *Science and Public Policy*, 22

Shiva, V., 2000, *Stolen Harvest. The Hijacking of the Global Food Supply*, New Delhi: India Research Press

Simmons, P. and Walker, G., 1999, 'Tolerating risk: policy principles and public perceptions', *Risk, Decision and Policy,* 4: 179–90

Slovic, P., 1987, 'Perception of risk', *Science,* 236: 280–5

Snow, A. and Moran, P., 1997, 'Commercialisation of transgenic plants: potential ecological risks', *BioScience*, 47: 86–96

Steinbrecher, R., 1996, 'From green revolution to gene revolution: the environmental risks of genetically engineered crops', *The Ecologist*, 26: 273–82

Stirling, A., 1998, 'Risk at a turning point?', *Journal of Risk Research,* 1: 97–110

Stirling, A. and Mayer, S., 1999, *Rethinking Risk: a pilot multi-criteria mapping of a genetically modified crop in agricultural systems in the UK*, University of Sussex: SPRU

Stirling, A. *et al.*, 1999, *On Science and Precaution in the Management of Technological Risk*, Seville: EC Joint Research Centre

Tait, J. and Levidow, L., 1992, 'Proactive and reactive approaches to risk regulation – the case of biotechnology', *Futures,* Vol 24 No 3: 219–31

Tappeser, B. *et al.*, 1998, *Survival persistence, transfer. An update on current knowledge on GMOs and the fate of their recombinant DNA,* www.oeko.de/english/gentech/gmo.html

Thornstrom, C., 1999, 'CGIAR in the context of proprietary science', *Currents*, 19/20: 41–3

Tiedje, J *et al.*, 1989, 'The planned introduction of genetically engineered organisms: ecological considerations and recommendations', *Ecology*, 70: 297–315

Tripp, R., 2000. *Crop Biotechnology and the Poor. issues in technology design and delivery*, London: ODI

van der Sluijs, J., van Eijndhoven, J., Shackley, S. and Wynne, B., 1998, 'Anchoring devices in science for policy: the case of consensus around climate sensitivity', *Social Studies of Science*, 28: 291–323

van Zwanenberg, P. and Millstone, E., 2000, 'Beyond skeptical relativism: evaluating the social constructions of expert risk assessments', *Science, Technology and Human Values*, Vol 25 No 3: 259–82

Vogler and Jordan, 2002, 'Governance and the Environment', in F. Berkhaut, M. Leach and I. Scoones (eds), *Negotiating Change. New Perspectives from Environmental Social Science*, Aldershot: Edward Elgar

von Schomberg, R., 1998, *An Appraisal of the Working in Practice of Directive 90/220/EEC on the Deliberate Release of Genetically Modified Organisms*, Scientific and Technological Options Assessment, European Parliament

Webber, D.J., 1995, 'The emerging federalism of US biotechnology policy', *Politics and the Life Sciences*, Vol 14 No 1: 65–72

Weinberg, A., 1972, 'Science and trans-science', *Minerva*, X: 209–22

Williamson, M., 1996, *Biological Invasions*, London: Chapman and Hall

Wright, S., 1994, *Molecular Politics: developing American and British regulatory policy for genetic engineering, 1972–1982*, Chicago: University of Chicago Press

Wrubel, R., Krimsky S. and Wetzler, R., 1992, 'Field testing transgenic plants: an analysis of the USDA's environmental assessments', *BioScience*, 42: 280–9

Wynne, B., 1992, 'Uncertainty and environmental learning', *Global Environmental Change*, 2: 111–27