RISK GOVERNANCE OF GENETICALLY MODIFIED CROPS – EUROPEAN AND AMERICAN PERSPECTIVES

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Introduction and Background

Genetically Modified (GM) crops occupy a unique place in the evolution of risk governance approaches to dealing with modern, path-breaking technologies. They were the first such technology to be regulated on a precautionary basis, in a generic sense, from the earliest stages of a technology development process that began in the 1980s and is still evolving.

Today, distinctively different risk governance processes are in place in the European Union (EU) and the USA and the roots of these differences can also be traced back to the 1980s. The European regulatory process is more complex and demanding than that for any other technology; as a result, few GM crops are grown in or imported into Europe. And yet, although GM crops are grown on millions of hectares in the rest of the world, and GM foods are consumed on a daily basis by millions of people, under much less demanding regulatory regimes, there is so far no evidence of environmental or health risks associated with approved products based on this technology, and considerable evidence of their benefits.

The history of the risk governance of GM crops in Europe has been played out over the past twenty years without the benefit of the IRGC Risk Governance Framework (hereafter, the IRGC framework). This case study examines that history in the light of the IRGC framework, considers whether and how it might have made a difference if it had been applied, and suggests where modifications to the framework could improve its applicability to such cases.

A range of interesting sub-texts is relevant to the governance of GM crops:

- The GM crop example has demonstrated the ability of internationally organised coalitions of advocacy of groups to counter successfully the power of multinational corporations, creating a new societal balance in power structures (Tait and Bruce, 2004).
- In Europe, these coalitions have led the way toward development of new processes of stakeholder engagement as part of a new *governance*, as opposed to *government*, policy agenda[1].
- In Europe, which has experienced delays and difficulties in bringing GM crops to the market, this new risk governance process has led to major challenges to the evidence base for risk-related decision making, partly because the adoption of the precautionary principle in European legislation has enabled advocacy groups to invoke 'risk' as an issue to attain leverage in political debates which have very little to do with risk.
- The European approach to risk governance of GM crops, with heavy reliance on a precautionary approach, has been widely acclaimed as more democratic than that of the US, but its outcomes in practice have mainly been undemocratic.

[1] The "*Governance*" approach attempts to set the parameters of the system within which people and institutions behave so that self-regulation achieves the desired outcomes, implying a move away from the previous "*Government"* approach (a top-down legislative approach which attempts to regulate the behaviour of people and institutions in detailed and compartmentalised ways) (Pierre and Peters, 2000; Lyall and Tait, 2005).

- The US approach, on the other hand, is simpler and faster and has been more successful in enabling companies to bring GM crops into wide scale agricultural production. However, it has been showing some strains as the complexity of the technology and the product types to be regulated increases.
- Finally, the GM crops experience has illustrated the role of regulation in increasing the development time for new products and hence in increasing the number and variety of opportunities for stakeholder engagement including the integrated and co-ordinated framing of the technology as either negative or positive, depending on their perspectives, by a wider range of stakeholders.

Analysis of risk governance of GM crops in accordance with the IRGC framework

This section is structured according to the different stages of the IRGC framework. It comments, where relevant, on the separate and distinctive risk governance approaches that have evolved in the USA and the EU from the late 1980s. In the USA, GM crops made a relatively rapid and straightforward passage through the existing risk governance process for comparable products and went subsequently into commercialisation , first in the USA itself and then in many other countries. In the EU on the other hand, the first European Commission (EC) Directive 90/220, which was developed after lengthy consultation, was abandoned and replaced by a temporary moratorium on GM crops. This step allowed the entire regulatory system and its basis to be re-assessed, leading to a much more restrictive set of regulatory regimes co-ordinated under a revised Deliberate Release Directive 2001/18/EC (von Homeyer, 2002; Jaffe, 2004). Compared to that of the US, the European risk governance approach has appeared to be less evidence based and more driven by political and advocacy group influences, rather than by formal approaches to risk governance.

Risk governance context

Three distinct periods in the governance of GM crops can be identified (referred to as 'periods' here to avoid confusion with the various 'stages' of the IRGC framework).

Period 1

In the early to mid 1980s, most scientists, industry managers and regulators in Europe, and many in North America, supported the adoption of a precautionary approach to the early development of GM technology. They mainly regarded this approach as an exercise in public reassurance, rather than a measure justified by expected risks.

Period 2

In the mid to late 1980's and early 1990's, some GM crop products were in the development pipelines and relatively close to market; and companies became frustrated by delays caused by the European precautionary approach. Monsanto was in a potentially leading position in bringing GM crops to market, moving ahead faster than other multinational corporations. The company was very influential in setting up an organisation, the Senior Advisory Group for Biotechnology (SAGB) to lobby the European Parliament for relaxation of the precautionary approach to GM crops. In the US, the Vice President's Committee on Competitiveness was equally active, and much more effective, in promoting a product-based approach to GM crop regulation. From this point on, the divergence between the US and EU approaches became increasingly marked. The role of the OECD in international co-ordination of regulatory systems was also very prominent in this phase, with the OECD favouring the industry/US position and opposing that of the EU (OECD, 1993).

Period 3

From the mid 1990's onwards, relations between US and EU regulators became increasingly strained. A similar, but unprecedented, rift emerged between US-based and European based multinational companies; and the concerted, co-ordinated opposition of European advocacy groups to GM crops became increasingly strident and influential in shaping public opinion.

Risk pre-assessment – framing new technology

The IRGC Framework, had it been applied to GM crop governance in Period 1, would have promoted a comprehensive pre-assessment of the technology, scientific, and regulatory contexts for the GM issue. Key aspects of these contexts should have included the overall framing of the technology, issues related to early testing and monitoring arrangements, linkages to existing regulatory systems (or alternatively judgements about the inadequacy of existing regulatory systems), and the scientific conventions and assumptions in use. All of these aspects were indeed discussed at one point in time or another. However, they were not part of a formal, overall, internationally co-ordinated approach. The work of the OECD came closest to such an approach, but it lacked several of the important features present in the IRGC framework. Thus, the roots of the eventual conflict can be found at this point but no nationally or internationally implementable mechanism for reconciliation was then available.

With any very new technology where there is no previous experience of either its benefits or its potential risks, it is the process of framing the technology *as a whole* that is important rather than the framing of any individual product. The IRGC approach to '*problem framing*' includes risk scope, risk perception and public awareness.

In Period 1, the early development period of this path-breaking technology[2], framing of both benefits and risks was based more on conjecture than on evidence, as no products were yet available for testing. Those developing the technology were very active in trying to ensure that it was framed in terms of its benefits, rather than its risks. In general, for any new technology for which there is no obvious precedent, its framing by regulators is as important as its framing by those developing the technology in contributing to its subsequent framing by citizens.

In the competition to influence the public framing of GM crops, companies emphasised their potential contribution to the development of more sustainable farming systems, whereas advocacy groups emphasized their role in supporting intensive farming systems which they claimed were inherently unsustainable. Companies were at a disadvantage in this debate because they were unwilling or unable to use one of the strongest arguments supporting their case – the ability of GM crops to reduce the use of pesticides in intensive farming systems without reducing crop yields. As pesticide producers, they felt that they could not claim that it would be 'a good thing' to reduce the use of pesticides and most of them were not at that time prepared to discuss publicly the realities of developing an alternative product range that would undermine their existing product base in pesticide development (Tait and Chataway, 2007, in press). Interestingly, the expectations and voices of farmers (other than organic farmers) were almost entirely absent from the debates throughout all periods of the development of GM crops.

The language used to describe the technology was also part of this framing process, with scientists initially referring to it as 'genetic engineering', then seeing 'genetic manipulation' as a less pejorative term, and finally settling on 'genetic modification' (Kornberg, 1988). Likewise, in referring to the use of GM crops in an open farming environment, there was an unsuccessful attempt to move from the term, 'deliberate release', of GMOs (the term used in the European Directive) toward 'intentional introduction' instead, which was seen (by scientists and industry managers) as less pejorative.

Industry framing of GM crop technology in Periods 1 and 2 was, however, inconsistent. Presentations and publications from scientists and company managers seeking financial support to develop the technology emphasised its novelty as a radical break with previously available products (i.e. a path-breaking technology). At the same time, their papers and reports written in a regulatory context emphasised the continuity with previous generations of technology such as conventional plant breeding, baking bread and brewing beer, (i.e. its path-dependent nature), as a justification for avoiding additional regulatory constraints.

The differences between EU and US approaches to the regulation of GM crops can also be traced to a very early difference in the framing of the technology for regulatory purposes. In the EU, because GM crops were framed as a radical departure from any products that had previously been on the

[2] Path-breaking technologies have been defined as involving discontinuities in science and technology developments, in the nature of markets and in relationships among firms in a sector (Spinardi and Williams, 2005)

market, with potentially unpredictable properties, they were seen to require a *de novo* consideration of the risks they might present and the regulatory systems that could be put in place to control them, i.e. they were seen as requiring path-breaking regulatory approaches. The analogy most frequently used for GM crops by European regulators was the introduction of alien species with the attendant risks of uncontrollable spread in the natural environment (Royal Commission on Environmental Pollution (RCEP), 1989).

Most companies and US regulators on the other hand, in line with the OECD approach, framed them as inherently similar to existing products developed through conventional plant breeding programmes and therefore not requiring any additional scrutiny beyond existing regulatory systems, for example for pesticides, food for human consumption or animal feeds (i.e. they were seen as requiring path-dependent and evolutionary regulation).

The regulatory language in which this debate was framed was thus that of 'product vs. process' (Tait and Levidow, 1992) with the US looking for analogous *product* categories subject to existing regulatory systems and assigning GM crops to them according to their properties, while the EU viewed the *process* of genetic modification as potentially leading to novel properties requiring a new approach to regulation. This distinction has been a major contributor to World Trade Organisation disputes over GM crop regulation between the US and EU.

Some interesting parallels exist between IRGC's risk 'pre-assessment' phase, particularly the framing issues discussed here, and company innovation strategies. GM crops were 'path-breaking' for agrochemical company innovation strategies (see footnote 2) in that they required new approaches to research and development. The crops could not be marketed by the same routes as chemical pesticides, requiring them to be distributed through seed marketing routes. They also challenged the product base of other powerful industry sectors, namely food producers and supermarkets (Tait, 2007). However, there was also considerable 'path dependency' in the strategies companies chose to develop GM crops. For example Monsanto's choice of herbicide tolerance as an early application of the technology fitted well with its earlier development of the very successful herbicide glyphosate, and had strong synergies with its existing product development and market strategies (Chataway *et al.*, 2004).

Many of the framing debates surrounding the governance of GM crops can similarly be seen in terms of demands for either path-breaking or path-dependent regulatory systems. US regulators and multinational companies advocated path-dependence in the form of a product-based regulatory system for GM crops, while EU regulators saw a need for at least considering a path-breaking approach, if only until preliminary, precautionary risk assessments had been completed.

Risk appraisal

The risk appraisal stage of the IRGC framework juxtaposes the results of risk assessment with the concerns of stakeholders and public groups.

Risk assessment

As part of a formal precautionary approach, a wide range of risks has been evaluated for GM crops in Europe and elsewhere. , An increasingly sophisticated array of experiments has been conducted throughout all three periods identified above, so far with no clear evidence of harm. For example:

- One early concern was that the use of antibiotic resistance markers[3] in crops used as food or animal feed could lead to the emergence of antibiotic resistant strains of micro-organisms in the intestines of humans and animals. Although it was demonstrated that there was a very small chance of this happening, the risk was calculated to be several orders of magnitude less than the risk of emergent strains arising from human or animal treatment with antibiotics. Given the negative publicity around this issue, however, companies agreed to phase out the use of antibiotic resistance markers.

[3] Since not all attempts to insert genes into cells are successful, scientists use genetic "markers" as a tool for recognizing when they have been successful. An "antibiotic resistance marker" is a gene that, when inserted into plant cells, conveys resistance to a particular antibiotic. Plant cells that survive exposure to that antibiotic are thus "marked" .

- Laboratory experiments in the United States demonstrated that that pollen from maize rendered insect resistant through incorporation of a gene coding for a toxin from *Bacillus thuringiensis,* was toxic to larvae of the monarch butterfly (Losey *et al.*, 1999). These results were widely reported in the press, and were particularly promoted by environmental groups. However, the subsequent failure to demonstrate such effects outside the laboratory was not so widely publicised (Council for Biotechnology Information, 2001).
- An influential experiment on food-related risks of GM crops carried out by Ewen and Pusztai (1999) purported to show that feeding GM potatoes to rats had damaging effects on their intestines. These results were widely reported in the press and are seen as one of the most important stimuli for the public backlash against GM crops in the UK, even although their experimental design was widely criticised by scientists expert in this field.
- Cross-pollination and uncontrollable spread of novel genetic material in the environment has been a long term concern for members of the public and also for some scientists. Several studies have shown that these events are possible and indeed that, under some circumstances, transgenic plants can be detected at considerable distances from the source crop. However, there is as yet no evidence for long term viability or spread of transgenic plants arising from such events. A major UK research initiative on *Gene Flow in Plants and Micro-organisms* by the Biotechnology and Biological Sciences Research Council (BBSRC) and the Natural Environment Research Council (see www.bbsrc.ac.uk, accessed on 07/05/06), summarised in a BBSRC press release issued on 23rd June 2005, claimed that gene flow from GMOs to soil bacteria is vanishingly small and that introduced traits by GM methods can have less impact on overall gene expression than conventional breeding methods.
- Concerns have also been expressed about the impact of the adoption of GM crops on farming practices and consequently on farm wildlife biodiversity. Another series of experiments (GM Crop Trials) carried out in the UK examined such effects relevant to herbicide resistant oilseed rape, sugar beet and maize.[4] The differences attributable to genetic modification were small, but statistically significant, with GM oilseed rape (canola) and sugar beet showing a reduction of biodiversity and maize showing an increase. However, Les Firbank, who led the scientific team, has commented that the results reflect the effects of overall crop management practices rather than of genetic modification per se, and that similar evaluations of non-GM crop introductions in the past would have found similar impacts[5] . Thus, despite the challenges and uncertainties to which the regulatory system for GM crops has been subject, at least in the EU, before any significant exposure to GM crops, a wide range of potential hazards has been identified and their risks estimated with no evidence of harm.

As part of the risk assessment phase, the IRGC framework calls for the categorisation of risk with regard to the degree and cause of "complexity, uncertainty, and/or ambiguity." Categorisation of risks should be based on judgement by risk analysts, taking account of the nature and quality of evidence available including: hazard identification and estimation; exposure and vulnerability assessment; and risk estimation. However, in the case of GM crop regulation, the categorisation of risk has been primarily dependent on 'Concern Assessment' (see below) which drew largely from the 'Pre-assessment' stage during which the particular framing of the technology was established (as discussed above). Essentially, GM crops fell into the "ambiguous" category, where agreement does not exist on the fundamental values driving evaluation of the risk. Under the precautionary regime that was established, the extent of public concern was determined more by the success of various stakeholder groups, mediated via the press, in raising public concerns for political purposes than by a formal, more balanced, risk assessment process.

When risk assessments are strongly influenced by advocacy groups that have a principled, ideological opposition to a particular technology, no amount of evidence, regardless of its scientific quality, will lead to a change of opinion or of risk-related behavioural responses (Tait, 2001). For

[4] The results of this experiment can be found in a special issue of Philosophical Transactions of the Royal Society of London, B (Biological Science), 29th November 2003.

5 (http://www.innogen.ac.uk/Events/Annual-Conference/Precaution-and-Progress-Lessons-from-the-GM-Dialogue-2003, accessed on 07/05/06).

example, the precautionary approach adopted for the development of the regulatory system in the EU, required very careful control and monitoring of trial releases of GM crops. The failure of these early experiments to demonstrate any potential hazards was the trigger in Period 2 for industry to lobby for relaxation of the precautionary regime. On the other hand, it also triggered demands from activist groups for additional, more stringent testing. These positions related back to the original framing of the technology; on the one hand, many members of the UK public saw the adoption of the precautionary principle as reassuring (Martin and Tait, 1992) while on the other, scientists and industry managers believed it was leading to unnecessary alarm, with members of the public questioning "If this technology is as safe as you claim, why do we need to be precautionary?"

Concern assessment

Public attitudes to GM crops are one of the most intensively surveyed technology-based issues, at least in the EU. Those surveys with a valid statistical base generally show that 30% or less of the population would avoid purchasing or eating GM foods, and yet the overall impression in the press is that most Europeans 'reject GM crops' (Bauer and Gaskell, 2002). As the issue has faded from intense public debate in Europe, the proportion of the population expressing negative opinions on GM crops has also declined (Gaskell, 2005), emphasising the labile nature of public attitudes as gauged by opinion polls, and as driven by a press that sells newspapers by generating controversy.

In the United States, although some citizens express concern about GM crops, opponents of the technology have not been able to dominate its public framing as they have in the EU. Although there have been some risk-related incidents following the marketing of GM crops, they have not led to long term, sustained public opposition to the technology as a whole. To give just two examples:

- The monarch butterfly is an important icon for American conservationists, and there was a flurry of public concern about GM crops in the American press when the initial research about the toxicity of pollen from GM maize to butterfly larvae was published, but it subsequently faded and did not prevent the adoption of insect resistant GM maize on farms.
- In another case which had widespread press coverage, GM Starlink corn which was approved for animal feed but not for human consumption, was found to be present in taco shells on sale to the public (Oliva *et al.*, 2006). Because of fears of allergenicity arising from an introduced protein in the corn (Cry9c), the tacos were withdrawn from supermarket shelves and the crop itself was withdrawn from sale to farmers, at considerable cost to the companies concerned, and to US corn farmers through loss of export markets. However, this incident has not led to a generalised rejection of GM crops in the USA.

For the European public, the economic benefits from GM crops were perceived to be in terms of increased profits for farmers and for multinational companies, which was seen as unacceptable (Martin and Tait, 1992). A constant refrain in the European press has been that there are no public benefits from GM crops. As noted above, benefits in terms of reduced use of pesticides were not emphasized by industry in the early stages of the development of GM crops). However, the press also largely passed over the fact that one of the first products to be available in Europe that was produced from GM crops, Zeneca's GM tomato paste, was cheaper than alternative products and very popular.

Both Europe and the United States have a minority of the population that is fundamentally opposed to the introduction of GM crops, but the two regions have taken very different regulatory paths. The difference between the two regulatory contexts is related to the extent to which the minority in each region has been able to influence wider public opinion, and, ultimately, policy thus determining the options available to the significant proportion of citizens who are uncommitted and unconcerned.

Balancing Risk Assessment and Concern Assessment

The IRGC Framework proposes an early stakeholder engagement that is well integrated into the overall governance process. Although stakeholder engagement was ongoing from the early period of GM crop development, the various initiatives were *ad hoc*, disconnected from one another, and not well integrated into the subsequent stages of the risk analysis. In such circumstances, risk categorisation becomes dominated by a political process, rather than being part of conventional risk

assessment. In other words, risk categorisation carries with it the power to influence which technologies are developed and which are rejected, often on a basis of ideological preferences (for example, in the case of GM crops, opposition to globalisation or preferences for particular agricultural landscapes or types of farming system), rather than actual risks.

In such circumstances, there will be multiple risk categorizations which will evolve over time as part of an unstable and turbulent process. As outlined in Table 1, the balance of these multiple categorisations of GM crops shifted during the three periods outlined earlier as more information about the products became available and as new players/stakeholders came onto the stage.

In the US, the dominant categorisation among industry, regulatory and public actors moved from 'uncertain' through 'complex' to 'simple'. In the EU on the other hand, although industry categorisations followed the US pattern, public and regulatory perspectives moved from 'uncertain' to 'ambiguous' with no sign as yet of a resolution of the ambiguities. In the EU, 'risk categorisation' itself, rather than risk appraisal or actual risk became the battle ground on which the political process was played out, with consequences which were largely negative for overall risk governance of this technology.

Table 1. Risk Categorisation of GM Crops

Period of Development	**Perspective**	**Dominant Categorisation**	
		US	**EU**
Period 1	Regulators	Uncertain	Uncertain
	Industry	Uncertain	Uncertain
	Public	No opinion, uncertain	No opinion, uncertain
Period 2	Regulators	Complex	Uncertain, ambiguous
	Industry	Complex	Complex
	Public	Uncertain	Uncertain, ambiguous
Period 3	Regulators	Simple	Ambiguous
	Industry	Simple	Simple
	Public	Simple	Ambiguous

Risk characterisation and evaluation

Scientific, evidence-based risk profile

In the US, decisions to anchor GM crop regulation as a whole on the existing *product-based* system were taken on the basis of scientific extrapolation, rather than on new scientific evidence. This system was thus reactive, rather than precautionary, in the sense that it reacted to evidence of any hazard found to be arising from a GM crop following its introduction and put in place measures to prevent such hazards in future (Tait and Levidow, 1992).

Another example of such a reactive process is the internationally applied principle of 'substantial equivalence' whereby a GM food is scrutinised to ensure that it is not significantly different from other foodstuffs available in the market place, and hence not in need of any additional regulation or

restriction. For example, any foodstuff that had been genetically manipulated to incorporate nut proteins would be regarded as **not** equivalent because it might also contain nut allergens.

The European *process based* approach, in contrast to that of the US, is much more precautionary. It is not based on evidence of harm but on societal concerns about potential risks that may arise at some future date. The principle of substantial equivalence has been strongly criticised in the EU as being insufficiently precautionary about currently unforeseen hazards in GM foodstuffs. Some authors have suggested that we should test GM foods in a similar manner to current drug testing regimes (Millstone *et al.*, 1999), although how these might be operationalised for a foodstuff has not been explained.

The UK decision in 2003 on whether to approve cultivation of GM herbicide tolerant (HT) maize, oilseed rape and sugar beet was directly related to the scientific evidence from the GM crop trials. Genetically modified HT maize supported a higher level of biodiversity than non-GM and so was approved. In the trials for oilseed rape and sugar beet, the balance of evidence suggested that biodiversity had declined in the GM crops, so these were not approved. However, as noted in the next section, societal values played an important part in the initial design and subsequent interpretation of these experiments.

Societal, value-based balancing of benefits and risks

The example of the UK GM crop trials illustrates the difficulty of maintaining a clear separation between scientific, evidence-based risk characterisation and societal, value-based characterisation. The assumption underlying the criteria chosen for evaluating the risk of GM crops was the societal value judgement it was desirable to encourage weeds to grow in agricultural crops in order, in turn, to support a higher diversity of insect species as part of a wider food web. This value judgement is unlikely to be shared by many in the farming community. Yet assessment of crop yields or other management benefits were specifically ruled out of the comparisons made in these experiments – the participating farmers and companies were prohibited from collecting these data. Thus, one of the potential benefits, improved efficiency of crop production, was treated as irrelevant to the decision – there was no balancing of benefits and risks. Rather than collecting a range of evidence which would enable the balancing of an array of benefits and risks of interest to different societal sectors, the UK GM crop trials focused on only one environment-related aspect of GM crop production.

Where GM crops have been introduced with less public opposition, their widespread use by farmers implies that they do have benefits in the management and efficiency of crop production. The adoption of insect resistant GM crops, particularly cotton, has also led to major reductions in the exposure of farm workers to dangerous insecticides which is both a benefit to farming communities and a public benefit (James, 2002; Bennett *et al.*, 2006). The societal consensus in parts of the world where the technology has been adopted seems to be that, so long as there are no risks (or unacceptable levels of risk) and no public dis-benefits, the provision of agricultural benefits is sufficient justification for the adoption of the technology – there is not a perceived need for the provision of additional public benefits before new technology can be introduced.

European demands for public benefits from a new technology that cannot be incorporated into the price which can be charged for that technology are probably not financially supportable in a globally competitive environment. In the case of GM crops, it seems likely that the eventual outcome will be the demise of a European based GM crop industry sector, to the disadvantage of European farmers in a global trading environment.

Conclusions on risk acceptability or tolerability

In the case of GM crops it is more appropriate to consider *product*, rather than *risk*, acceptability or tolerability, given the comments above on the relative lack of risk-related evidence underlying public opposition to GM crop development and use. In both the US and EU, there is a fairly large minority of the population for whom these products are intrinsically unacceptable, regardless of risks or benefits. This opposition relates to societal concerns about globalisation and the industrialisation of the human food chain, rather than to evidence of tangible risks associated with GM crops themselves. The difference between the US and the EU regulatory positions lies in the extent of the influence this minority has had on largely uncommitted and un-engaged members of the population and on

politicians involved in developing risk governance processes. Nevertheless, it is still the case in both the US and EU that most members of the public do not particularly care whether their food is produced from GM or conventional crop varieties.

Risk management

For those members of the public who are fundamentally opposed to the growing of GM crops, there are no acceptable risk management options.

Most others, including companies developing the technology, would recognise that, although no major hazards have yet been demonstrated for the GM crops in use, there may still be unexpected side effects. Several senior managers in multinational companies have suggested that there should be post marketing surveillance of GM crops to ensure rapid detection of any such effects (Chataway and Tait, 2000). In the case of the Starlink corn incident noted above, the US regulatory system was changed to require that any GM crop approved for animal feed must also be approved for human consumption. The EU regulators have adopted a similar requirement. This rapid action on the part of the regulatory authorities seemed to pre-empt any further public opposition to the technology in the US.

However, this example also illustrates the complexity and inter-connectedness of risk governance and innovation systems. One potentially environmentally beneficial outcome of GM crop technology would be the development of animal feeds that are tailored to the nutritional requirements of particular species, pigs, cattle, chickens, etc. Such feeds could avoid the need to feed protein supplements to these animals and could also reduce the levels of phosphate pollution from farm effluent. Although such a product has yet to be tested in the regulatory process, it seems unlikely that a crop tailored to the nutritional requirements of, say, pigs, would be accepted also for human consumption. The choice of this particular risk management option thus seems likely to halt further development of such potentially environmentally beneficial products.

Although not yet included in the IRGC framework, there are cases where it would be useful to encourage technological innovation as a potential alternative or contributing factor to risk management, alongside risk regulation. Such options are often referred to disparagingly as 'technical fixes' but they can nevertheless be very effective. Indeed, generally speaking we are better at technical fixes than we are at 'social or regulatory fixes'. One such example would be the often-raised possibility that the genes engineered into GM crops might 'escape' to contaminate wild species, generating 'super-weeds' or other undesirable and uncontrollable new species. A potentially useful technology-based approach here would be for policy makers to require the incorporation of one of several genetic use restriction technologies (GURTs) into plants, restricting their ability to propagate through viable pollen or seeds (Daniell, 2002), obviating the need for the complex societal and regulatory restrictions to maintain separation distances between organic and GM crops in Europe, which are likely to be difficult and expensive to monitor and enforce.

Risk communication and stakeholder participation

Communication and stakeholder issues were intimately linked throughout the various stages of the development of GM crops and they have been brought together in one section here.

The GM crops case study provides numerous examples of communication failures:

- Linking the dialogue between industry and regulators in Period 1 to public groups and interested citizens
- Communication among multinational companies involved in GM crop development, particularly in Period 3 and the later part of Period 2.
- Communication between the agro-biotechnology industry sector and the food processing and distribution sectors;
- Communication with 'wider society' – the largely un-engaged and un-interested public
- Communication between policy makers and the public, particularly the failure by policy makers to explain the potential public benefits of the new technology, given the agro-biotechnology industry's reluctance to promote these benefits

On the other hand, the advocacy coalition, involving groups with environmental, third world and consumer-related agendas, that came together in Period 3 and dominated the media presentation and the framing of the GM crops debate, provided an example of a very successful, integrated communication strategy that enabled this coalition to dominate the agenda in Europe and to have significant impacts internationally.

IRGC's framework suggests that there is a specific type of discourse that can be identified and used as appropriate to different risk categorisations and stakeholder groups. In this case study, the recommendation proved not to be feasible in practice. The type of discourse is intimately linked to the framing of the technology. For a situation like GM crops which involved numerous, actively engaged stakeholders competing to frame the technology for different audiences, the process could not be controlled by risk managers and regulators. This problem is particularly difficult where conflicting values and ideologies are involved. However, there are likely to be competing perspectives on any risk issue of sufficient complexity to warrant the application of the IRGC framework.

Failures of communication have been identified by activist groups as the main reason for the emergence of European public opposition to GM crops. However, policy makers made numerous attempts to encourage public engagement, and both policy makers and companies in the UK and Europe regularly took part in meetings with advocacy groups representing public opinion, needs, and desires. None of these efforts seemed to reduce the level of opposition or conflict that eventually emerged. As this case study has attempted to show, the evolution of the European response to GM crops was multi-dimensional and highly complex.

Nevertheless, building on this presumed communication deficit, more 'upstream' engagement with public representatives is now being advocated for emerging technologies like nano-technology as the route to avoiding future conflicts of the type experienced in Europe with GM crops (Willis and Wilsdon, 2004). This simplistic analysis of the cause of the problem and its solution are unlikely to lead to improvements in risk governance and may indeed perpetuate and exacerbate problems of the type experienced by GM crops.

Conclusions and recommendations

The value of a democratic governance process lies in its ability to prevent powerful vested interests from dominating decision making. There are many who regard the European GM crops regulatory outcome as an example of this process in action, the triumph of advocacy groups, acting in the public interest, over the power of multinational companies.

However, the European outcome could equally be seen as the replacement of one vested interest (the agro-biotechnology industry) by another more recently influential group, at least in the EU (public interest advocacy groups), with equally negative outcomes for democratic decision making on risk issues.

The following conclusions and recommendations mainly address the problems that emerged in the European risk governance of GM crops, although many of the recommendations could equally be applied to future developments of GM crops in a global context and also to new innovative technologies more generally.

GM crops and their risk governance provide a particularly complex example for a case study to test the IRGC framework. On the one hand, it would be legitimate to claim that the framework cannot be expected to deal with such very general cases. On the other hand, most of the complexity, turbulence and conflict arising from this case was related to public and stakeholder perspectives on the technology and the responses of governments and industry to these perspectives. The IRGC framework could usefully be developed further to improve its future applicability to such situations – the development of highly innovative technologies in a globally competitive environment which challenges the capacities of existing regulatory systems.

Experience in applying the IRGC framework to the development of GM crops

The most important deficits in the risk governance of GM crops in Europe which the application of the IRGC framework might have prevented related to the societal context and the categorisation of risk related knowledge. Because these were both early stages in overall risk governance, difficulties experienced then, had serious implications for later stages of risk governance.

If the earliest pre-assessment and framing of the technology and its associated risks in Period 1 had been undertaken in a more formal manner, as a conscious component of a risk governance process, rather than the open competition to frame the technology, then greater control of subsequent stages of the analysis by risk policy makers and regulators might have been possible. However, the multiple framings of the technology that emerged among different stakeholders, leading to multiple risk categorisations that in turn evolved over time (see Table 1), led to a highly politicised debate within Europe and internationally that was beyond the control of any risk governance process. European policy makers, rather than having overall control of the risk governance process, were in the unenviable position of having to respond to increasingly vehement waves of public protest, amplified by the press and political lobbying, partially and temporarily countered by pressures from industry.

A window of opportunity for a less contentious process existed around 1990. If policy makers could have resisted industry pressures to relax the European regulatory system for GM crops and at the same time explained to the public the potential sustainability benefits of the technology, they might have been able to take a lead in the framing and subsequent governance of the technology (Tait, 1993). Even so, the complexity of the interactions they faced may have defeated this purpose.

As it was, there was little input from the formal 'Risk Assessment' stage into the Risk Categorisation step for GM crops, the latter being influenced mainly by the risk perceptions and concerns of a vocal minority in European society. These factors also dominated the 'Risk Evaluation' and 'Risk Management' phases. The decision that the technology itself was not tolerable or acceptable to the European population was unrelated to any formal risk assessment, and risk reduction measures, particularly those demanded by the organic farming lobby, which seemed more designed to make it impossible to develop the technology than to counter any demonstrable risks to health or the environment. The Risk Management options now being implemented in keeping with the EC Directive 2001/18 and subsequent regulations likewise bear little relationship to any evidence-based assessment of risks and are unlikely to be compatible with a profitable European agro-biotechnology industry sector.

One might argue that there has in fact been a gradual erosion of the evidence base for risk-related decision making about GM crops due to confusion generated by inputs from vested interests on all sides of this debate. The evidence produced by companies to support product registration is regarded as suspect by the public and is scrutinised carefully by regulators. In addition, any mistakes or deliberate biases in this evidence can have serious implications for the company concerned, so there are disincentives for a company to introduce such biases. The same does not apply to some public interest advocacy groups who quote selectively from evidence that supports their case, without suffering any loss of public confidence in their impartiality.

Unless we can develop standards and procedures to help decision makers to reach conclusions on the best available evidence from both social and natural sciences we risk retreating into a series of interlocking enclaves of indecision, challenge and counter-challenge. Rather than building stakeholder engagement into the risk governance of new technology in a manner that reduces the so-called democratic deficit in such decision making (Tait, 2004).

Further development of the IRGC Framework

If we are to extend use of IRGC framework beyond first generation GM crops to later developments of GM other innovative technologies (e.g., stem cells or nanotechnology), a range of additional modifications could usefully be built into its operation. One of the most distinctive aspects of the IRGC framework is its careful consideration of public and stakeholder engagement processes, and this

is perhaps where there is most need of further refinement if it is to prove of real value to risk regulators and policy makers and also to industry.

Timescales of development of innovative technology

For the risk governance of many technologically innovative products, where the pace of development is very rapid, products appear on the market before there is time to begin to explore, far less prevent, any negative societal impacts. It then becomes a matter of consumer choice whether the product succeeds or fails. The speed of development in such cases, for example in information and communication technology (ICT), is one reason why innovations such as the world wide web, with major societal impacts, receive very little regulatory attention prior to their being publicly available. Where potential risks are discussed after a product is widely available (e.g. mobile phones and the associated transmission towers), risk management is evidence-based rather than precautionary.

In such cases, the speed of innovation is driven by intense competition. There are likely to be difficulties in convincing industry of the value of the careful and thorough engagement procedures, particularly on socio-economic implications and public concerns, which are part of the IRGC approach. It is therefore unlikely that there will be pressure for application of the IRGC framework to ICTs and other technologies with short development times.

The life science industries offer a dramatic contrast to innovation in ICTs. Innovative developments (e.g. pharmaceuticals and pesticides) arising from these industries are already subject to very demanding and lengthy regulatory processes. Risk regulation is the primary driver of innovation 'pipelines' in these industries. The process imposes major constraints on the dominant multinational companies, although by acting as a barrier to entry for small companies it helps maintain their dominance in the market (Tait, 2007). Thus, for a company engaged in the economically risky development of new technology, the existence of a familiar regulatory system which supports its 'first mover' advantage is a considerable asset.

On the other hand, this lengthy development process (up to fifteen years) also creates opportunities for extensive public and stakeholder engagement, as advocated by the IRGC framework. The twin circumstances in the USA, of more rapid passage of GM crops through the regulatory process and lower levels of effective public opposition to the technology, are probably related.

Framing innovative technology and control of engagement processes

Ideally, public policy makers and regulators should take the lead in managing the framing of the risks and benefits of new technology to minimise the biases likely to be introduced by both industry and public advocacy groups.

Effective engagement processes require responsible behaviour by all stakeholders. As noted above, although industry managers do not always behave responsibly in such situations, there are major risks to the company, for example if biased or invalid evidence is used in support of risk regulatory processes. Most companies now accept the need for what has become known as a 'license to operate' – a general recognition of publicly responsible behaviour. Similarly, public advocacy groups should also exhibit responsible behavior if they are to contribute properly to risk governance. Although some NGOs behaved very responsibly in representing the views of citizens, others adopted a strongly adversarial, uncompromising approach and were less careful about the validity of the evidence used to support their views. It would thus be helpful to build into the IRGC approach a set of standards for engagement covering responsible and unbiased use of evidence and willingness to compromise to accommodate the views of other groups.

Even with such safeguards, and given an effective application of the IRGC framework, there can be no reassurance that the kind of anomaly experienced for GM crop regulation in Europe will not be repeated for other technologies. Pressures for more 'upstream engagement', moving engagement processes to earlier stages in research and development (Willis and Wilsdon, 2004), an approach that has considerable support from political and scientific communities in Europe, is likely to encounter several problems:

- The evidence base for decision making will be even weaker than it has been for GM crops;

- There will be even greater uncertainty about the validity of the science base and the eventual nature of products available on markets than there has been for GM crops;
- In framing the technology, public stakeholder groups are more likely to focus on potential risks than on benefits while industry stakeholders will focus more on benefits, exacerbating the potential for acrimonious conflict;
- Given the long timescale and uncertain nature of future risks and benefits, only those with a vested interest in the issues and outcomes will be prepared to engage in discussions and decision making;
- Public opinion is likely to change dramatically over a lengthy development period so early engagement cannot be a valid base for decisions taken later in the development process.

Choice of regulatory approach for innovative technology – path-breaking or path dependent?

Although companies in highly regulated industry sectors can cope very well with existing, even if onerous, regulatory systems, they find it very difficult to operate in a climate of uncertainty over the eventual nature of the risk regulatory regime to which they will be subject. This is another issue which the IRGC could usefully address – suggesting criteria for the development and choice of regulatory systems for innovative technologies which relate to the properties of the products and the nature of stakeholder views and requirements. Such criteria might remove some of the uncertainty about, and thus the time required, to develop such regulatory systems

For similar reasons, a path-dependent regulatory approach, such as the product-based approach to the regulation of GM crops, is likely to encourage faster, and hence more profitable, development of new technology. A path-dependent approach should be desirable provided it can ensure effective and acceptable regulation.

Guidelines for policy makers for the governance of innovative technology should address the following questions:

- What are the relevant regulatory precedents?
- What are strengths and defects of various approaches?
- What kinds of technology will emerge from new scientific knowledge, how long will it take, who are the relevant stakeholders?
- What degree of influence should be given to conflicting stakeholder groups or to powerful advocacy coalitions?

What kinds of decision should they have the power to influence, e.g. should value-based or ideologically committed stakeholder perspectives be allowed to dictate the choices available to society as a whole, in the absence of evidence of risks to people or the environment, as has been the case for GM crops in Europe, particularly when labeling legislation allows consumers to avoid GM foods should they wish to do so.

Path breaking technologies present particular challenges for policy makers and risk regulators. For such radical innovations there may be no obvious match between the properties of the new technology and an existing regulatory system. In the early phases of the technology development, the properties, benefits and risks of the new products may be difficult to judge. However, path-breaking technology does not necessarily imply the need for a path-breaking regulatory system.

A technology can be path-breaking for one group of companies in an industry sector and path dependent for another. For example stem cells would be a path-breaking technology for a multinational pharmaceutical company whose current innovation strategies are built around small molecule drugs. On the other hand, the technology would be path-dependent for a small company that has specialised in bone marrow transplants or tissue engineering products. Choosing a regulatory system for stem cell based therapies that follows that in place for the pharmaceutical industry will favour large companies and disadvantage small companies, with major implications for the scope and direction of innovation arising from this new set of technologies.

In other examples, path dependent regulatory systems may be appropriate at one stage in the development of a technology but not at another. In the case of nanotechnology, path dependent regulatory systems may be appropriate for early stage developments, but not for later more complex developments. Likewise, although our conclusion here is that the path-dependent, product based

approach was appropriate to the regulation of GM crops in the early stages of the technology's development, a more path-breaking regulatory approach may be required for later developments (for example the production of drugs in plants grown outdoors).

Risk governance of innovative technologies

The development of internationally effective approaches to the risk governance of innovative technology, particularly in the life sciences and nanotechnology, is likely to remain a challenge for the IRGC and could usefully become an important future activity. This analysis has identified some of the most important issues that should be part of an extension of the IRGC framework in this area:

- Development of effective and impartial systems of stakeholder engagement
- Support, where possible, for individual choice
- Maintaining and improving the integrity of the evidence base for risk governance-related decision making
- Developing robust criteria for the development and choice of risk regulatory systems and instruments, including both existing and new regulatory frameworks.

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