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Risk Governance of Genetically Modified Crops in Europe:

Decision nodes and incubation periods in generating a risk governance deficit

By Joyce Tait[1]

1. GM crops as a governance deficit

The development of genetically modified (GM) crops and the global disparities that exist in their governance provide one of the most widely quoted examples of a risk governance deficit. However, although the controversy began in the 1980s, there is still very little agreement on the nature of the deficits, or on where and why they arose. From the perspective of industry and risk regulators the European regulatory system for GM crops that has emerged from ten years of controversy is seen as a failure of evidence-based risk governance – we have the most onerous regulatory system in existence for a commercially traded product, despite steadily increasing evidence that the products do not represent any health or environment-related risks and indeed could reduce the risks attached to crop production based on pesticide use. Internationally, US policy makers see the European regulations as an attempt to erect trade barriers against commodity crops produced in the USA or in other countries using seed developed largely by American companies. Environmental, consumer and third world advocacy groups see the current situation as a triumph of 'David and Goliath' proportions where, since the mid-1990s, they (the 'Davids') have increasingly dominated European policy decision making on chemicals and pesticides as well as GM crops. Many farmers in developed and developing countries would like to grow GM crops but are worried about their ability to sell the resulting crops to their traditional European markets.

Unlike the GM crops example, the other governance deficits identified by IRGC can all be addressed in terms of numbers killed or disabled, infrastructure destroyed, financial ruin, and a failure by decision makers to predict and plan for such consequences. The deficit in the case of GM crops is in the other direction – opportunities and jobs lost, companies and countries disadvantaged, regulatory time and resources wasted, with no corresponding benefits to set against these costs. It is a governance deficit in the sense of being inadequate and defective, but could perhaps more accurately be described as an 'overload'.

This kind of risk governance deficit may seem to be unusual but it may merely be more difficult to identify or less attractive to those who set risk governance agendas. It is also likely to become more prominent in future given that the GM crops example is being cited as a precedent for the regulation of innovative technologies in other areas of life sciences such as synthetic biology.

This case history looks at this governance deficit as seen from the perspectives of the companies that were developing the technology throughout the 1980s and 90s, based on interviews with key players throughout that period, in industry and policy roles, mainly in the UK and EU. A more general perspective on these issues is given in Tait [2008].

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[1] Innogen Scientific Advisor, ESRC Centre for Social and Economic Research on Innovation in Genomics, University of Edinburgh, UK.

2. Incubation periods and decision nodes in the development of a governance deficit

Despite major investments in risk-related research on GM crops since the 1980s, there has been no well-supported evidence for risks to people or the environment. However, things were different in the 1980s when governance of GM crops first began to be discussed – there was considerable uncertainty about their future, about whether companies would be able to make a profit from them, about their possible risks, and about what would be the appropriate regulatory system.
At several points between 1985 and 2000 there were key decision nodes where either industry managers or policy makers could have made a different choice which could have fundamentally altered the outcome for this technology, at least in Europe. Between these key decision nodes there were periods of more diffuse incubation of problems which radically altered the decision environment in the build-up to a new tipping point. Without exception, although not always obvious at the time, these decisions acted against the smooth and rational long term development of safe GM crop technology.

2.1 Agrochemicals as a maturing industry sector: looking for a way out of the commodity trap

By the mid-1980s the agrochemical industry sector was already experiencing the onset of maturity in that the pesticides that were easy to find and cheap to develop were off-patent, cheap and readily available to farmers. It was increasingly difficult to find new products that could compete with these older products. GM crops were identified by most (but not all) of the major multinational agrochemical companies as giving them the opportunity to start off on a new high value-added research and development trajectory.
In these early stages, there was also interest in GM crops from other sectors including seed companies and multinational food producers like Unilever, but the dominant group was the agrochemical industry and eventually over a considerable period the others dropped out or reduced their involvement.

The agrochemical industry sector was not the most obvious location for this fundamentally new technology but it did determine the kinds of development that were given priority – properties like herbicide, insect and disease resistance that were compatible with the existing R&D trajectories of the agrochemical companies. Development priorities would no doubt have been different if food and seed companies had had a dominant or even an equal role in development of the new technology. Also, interviews with company managers at the time demonstrated that food companies had a much more sensitive approach to consumer relations than did the agrochemical companies [Chataway and Tait, 1993].

The fact that most of the research and development on GM crops was located in an industry sector with a very bad history of public relations and with a controlling role in the development of intensive farming systems, by then the subject of campaigning pressure by environmental activists, set the scene for many of the following developments. This could be described as a crucial early incubation period for the deficit in GM crop governance, with companies in different sectors jockeying for position in a new technology area but with no clear idea of how they would develop the technology or what its benefits would be. In the end, unsurprisingly, the initiative passed to the most powerful group with the strongest incentive to develop and control the new technology.

2.2 Early decisions on appropriate regulatory systems for GM crops

Unlike information and communication technologies, in the life sciences there is generally a presumption that regulation will be required to control potential risks, mainly on a precautionary basis, at least in the EU. Regulators generally respond by looking for the most appropriate precedent and at this decision node, for GM crop governance there were two key sets of choices. The first choice was in whether to regulate GM crops 'as if' they were new crop varieties, or 'as if' they were new pesticides or food additives. Basing risk governance on an expanded version of the regulatory systems for new plant varieties would have favoured seed and food companies as the main locus of GM crop development and could have ensured a stronger representation of the interests and needs of these companies in the development of the technology. However, the decision taken, to adopt a more risk-based approach similar to that for pesticides, favoured the agrochemicals sector. This reflected the relative power and influence of the regulators involved as well as the fact that the agrochemical industry was the dominant group developing the technology. In an off-the-record question to a regulator in the late 1980s, we asked whether he appreciated that this decision would favour large multinational companies and disadvantage smaller, perhaps more innovative seed companies. His answer revealed some of the concerns and uncertainties at the time – that this was a good thing since, if something were to go wrong, a small company could not afford to clean up. Clearly these regulatory decisions were not taken in ignorance of their long-term downstream implications for the overall shape of the sector developing the technology.

A subsequent and very contentious set of decisions then emerged that led to a long-running dispute between the US and the EU. The US, in line with recommendations of the OECD, decided to make use of existing regulations for pesticides, food and feed in the evaluation of GM crops – what became known as the product-based approach. The EU on the other hand adopted a more precautionary approach, examining each new GM crop on a case-by-case basis, building a new regulatory system – described as a process-based approach [Tait and Levidow, 1992]. The dispute was (and still is) over whether a GM crop should be regulated on the basis of the properties of the product itself or the process by which it was developed. However, one of the most contentious aspects of the EU decision was its considerably more precautionary nature in practice that that of the US.

The companies developing GM crops initially collaborated willingly with the European approach to risk governance on the basis that they saw it as a means of reassuring a potentially sceptical public, and that they expected the EU system to become less precautionary in future, as more evidence of the safety of GM crops became available.

2.3 GM crops as a path-breaking technology for the agrochemicals industry

First generation product choice

The agrochemical industry began developing GM crops in the 1980s and faced a range of challenges related to the path-breaking nature of these new products compared to the development of pesticides. Path-breaking, disruptive innovation steps outside existing paradigms leading to discontinuities in innovation pathways, to major shifts in product types and their place in the market, and potentially to the creation of new industry sectors or radical re-structuring of existing sectors [Tait, 2007].

To illustrate the problems raised by the path-breaking nature of GM crops, the agrochemical companies had always been dominated by chemists and chemistry and now had to give at least an equal role to biologists and to integrate the inputs from the two disciplines, a process that took at least ten years. The development pathway for a GM crop was different from that of a chemical, the product (seed) required different handling from chemicals and a different route to market. On top of this, the early decisions had to be taken without any clarity as to the nature of the

regulatory system that would prevail once the products reached the market stage. The decisions companies made at this point, based on internal company rationales, had unexpected consequences in the wider public environment and led to further incubation of the GM crops risk governance deficit.

Product choice and public relations

Given the scale of the uncertainty, the huge costs involved in setting up new development pathways for a totally new technology, and the lack of knowledge of what could eventually be made to work, companies chose to develop new products in areas where they had at least some relevant experience. Monsanto had been doing research for some time on the genetic basis of herbicide resistance to its main product glyphosate and GM glyphosate resistant crops were the mainstay of its early GM crop development strategy. While still path-breaking in the senses outlined above this had the enormous advantage of enabling synergy between its pesticide and GM product lines (farmers would buy both the pesticide and the linked GM crop from Monsanto). Other multinational companies were less fortunate – they were either faced with developing a GM crop that was resistant to another company's herbicide (Zeneca Plant Sciences) or to a herbicide on the verge of withdrawal in the EU because of environmental damage and presence in drinking water sources (Novartis).

Companies remained oblivious for too long to the public relations difficulties of basing their early product strategies on a combination that seemed to amplify their controlling influence on the world's food production systems. The complicated explanations for how glyphosate resistance in a GM crop could lead to environmental benefits as well as increased profits for a multinational company were easily countered by the simpler messages from environmental groups opposed to GM crops.

The other properties that companies focused on in the first generation of GM products were insect and disease resistance. Given that these properties in a GM crop would reduce the use of pesticides, they should have been more acceptable to environmental groups. However, for the companies developing them, they were considerably more problematic and path-breaking than herbicide resistant crops because any effective GM crop would undermine the company's existing pesticide product range.

Thus, despite being informed in the late 1980s that emphasising the ability of GM crops to reduce pesticide use could influence the public debate in their favour, companies felt unable to go down that route. The response was that they could not persuade the company Main Board to fund the development of new technology that would undermine their existing product range and that it would also be difficult for them to sell a reduction in pesticide use as 'a good thing' given their claims since the 1950s that pesticides were safe when used as recommended. There was a period in the early 1990s when such a PR strategy might have made a difference, but this irreconcilable internal ambiguity in the agro-biotechnology companies made that impossible. A few years later the public controversy had crystallised to a stark contrast between GM crops (bad) and organic agriculture (good) with no room for any finer nuances related to relative risks and benefits and this remains the situation in 2008 [Tait and Chataway, 2007].

Because of Monsanto's lack of internal contradictions in the development of GM crops (it had no significant involvement in insecticides and fungicides), the company chose to press home its advantage and to move up several gears in its speed of development of GM technology. This alarmed the other agro-biotechnology companies who wanted to proceed more cautiously with the development of GM crops. They claimed that they were being more sensitive to the concerns of the European public, but the internal company ambiguities were also undoubtedly a part of this concern. The outcome was a break-up in the agro-biotechnology industry hegemony with Monsanto being publicly criticised by other companies in a manner that was unprecedented.

Whatever the reason for it, this development seriously undermined the industry's ability to counter the swelling European public opposition to GM crops.

Finding and protecting routes to market

In the development of first generation GM crops, companies also faced the challenge that they needed a new route to market – they could not sell seeds through the same routes that they had used for chemicals. While some agro-biotechnology companies planned to develop partnerships with seed companies to find a route to market others, most aggressively Monsanto, decided to 'buy the route to market' setting off a spate of purchases of seed companies. Another factor in agro-biotechnology company decisions to collaborate with or purchase seed companies was their need to gain access to germplasm – the seed companies owned the rights to the elite plant varieties that agro-biotechnology companies needed as the foundation for their GM products. Because of competition between agro-biotechnology companies, purchases of seed companies were often made at very inflated prices, considerably beyond their calculated market worth [Chataway et al., 2004].

Having made purchases of seed companies, managers then discovered that 'you cannot make money out of seeds the same way you can out of chemicals'[2]. This realisation led them to look for ways to protect their investments and they began to consider the development of genetic use restriction technologies (GURTs), labelled 'terminator technology' by an environmental group. GURTs are genetically modified traits that, by a variety of means, would prevent crops from reproducing from seed saved by farmers, requiring the farmers to buy new seed from the company each year. Initially this did not seem problematic to the companies as it was in practice no different from the widely accepted use of hybrid seed. However in public relations terms it proved to be a bomb-shell as it was exploited by advocacy groups, particularly those with developing country interests who claimed it was an attempt to stop the legitimate practice of farmers' using their own seed to grow the next year's crop.

Incubation of a public relations disaster

The buying of seed companies, linked to the so-called 'terminator genes' and the focus on herbicide resistance in first generation GM products, added up to the case made by opponents that multinational agro-biotechnology companies were intent on gaining control of the world's food supplies and had to be stopped.

The individual company decisions that led to this outcome were each rational and were dictated by strategic internal company needs of agrochemical companies in their transition to agro-biotechnology. What was lacking was an equally strategic approach to managing external relations on a co-ordinated industry basis. Their actions had been disconnected responses to internal problems as they arose and managers were often distracted by the difficulties of introducing a radically innovative technology within an existing very well established innovation system. By the time they realised the extent of their public relations problems in Europe it was too late to regain the initiative.

2.4 Industry pressures for regulatory relaxation and EU revision of the regulatory system

As noted in Section 2.2 above, companies initially collaborated willingly with the EU precautionary approach to GM crop regulation for two reasons: they thought that it would act to reassure the public that these products were being developed under strong public oversight and would therefore be safe; and they expected the regulatory regime to be relaxed as more evidence emerged to support the industry view that there were no dangers associated with them.

[2] As in any sector with an apparent, surprising blind spot there were undoubtedly some managers who were aware of this potential trap, but they were clearly not in a strong enough position for their views to prevail at senior management level.

However, in the early to mid-1990s, as the first GM crops came close to market-readiness, the industry became increasingly frustrated by the slow progress of the European regulatory system and the continuing uncertainty about its future shape. They also became increasingly concerned that, rather than reassuring the public, the precautionary approach was fuelling public alarm – 'if this technology is as safe as you claim, why do we need to be precautionary?'. They began to lobby strongly at national and EU levels for a move to a more US-style product based regulatory approach.

There was much talk at government levels of European industry being disadvantaged compared to their US counterparts, but strong rebuttal of any relaxation of the EU regulatory system by policy makers and politicians and also by environmental advocacy groups. The outcome, if anything, was a reinforcement of the negative European public attitudes to GM crops in general.

In the USA, on the other hand, GM crops had made a relatively rapid and straightforward passage through the existing product-based risk governance process for comparable products and went subsequently into commercialisation, first in the USA itself and then in many other countries.

The first European Commission (EC) GM crops Directive 90/220 was developed after lengthy consultation but it came under intense pressure from the rapidly developing European public opposition to GM crops described in Section 2.3 and, at another important decision node in the development of this risk governance deficit, it was replaced by a temporary moratorium on GM crop development. This was followed by a re-assessment of the entire European GM crop regulatory system, leading to a much more precautionary set of regulatory regimes, co-ordinated under a revised Deliberate Release Directive 2001/18/EC. Compared to that of the US, the European risk governance approach is less evidence-based and more driven by political and advocacy group influences, rather than by formal approaches to risk governance.

This is in contrast to the expectations of the agro-biotechnology industry who had presumed that the European regulatory system would become less precautionary and more open to the rapid development of GM crops for European markets as evidence for their safety accumulated.

3. Risk governance deficits illustrated by governance of GM crops

Given the different nature of the governance deficits related to GM crops identified in Section 1 above, some of the deficits identified in the IRGC list may need to be reworded, but many are still clearly relevant to this case.

Assessing and Understanding Risks (Cluster A)

Factual knowledge about risks (A2)

This aspect has clearly been important here. All participants were aware that knowledge was lacking in the 1980s, but this deficit has now largely been removed. However, improved knowledge has had little impact on the development of European regulatory systems which have become more onerous over time despite the reassuring nature of most of the knowledge acquired.

Perceptions of risk, including their determinants and consequences (A3)

Considering acknowledgement of different interests, values and perceptions, GM crops provide an example of a risk that is almost entirely socially constructed. In this case, scientists, industry managers and policy makers think that the technology is safe, while the public (or at least a number of very vocal public groups) continue to insist that it is dangerous. The industry and policy makers were always aware of the potential of GM crops to arouse public concern, but they

expected this to be a short-lived phenomenon, beginning to fade after approximately two years. They have been surprised by the persistence and vehemence of the opposition.

Stakeholder involvement (A4)

Stakeholders were involved in consultation processes from the 1980s onward, at the EU level, the country level and by companies. However, the usual interpretation this GM crop risk governance deficit is that the failure lay with lack of public engagement. Section 2.3 describes how the fundamental disagreements between companies and public groups were exacerbated by the actions of the companies over a considerable period. However, given the pressures companies were under it is not clear that they could have behaved differently. Likewise it seems unlikely that any softening of industry positions would have led more accommodation on the part of advocacy groups. This was a fundamental, ideological difference of values and in these circumstances, engagement exercises are unlikely to lead to an amicable resolution. However, a more effective and earlier *public* engagement strategy by companies and policy makers may have been able to dilute the influence of the more strident advocacy groups, resulting in a more tractable outcome in the long term. There are many lessons from this case on how and when to conduct stakeholder engagement in areas with complex, highly polarised conflicts.

Misrepresenting information about risk (A6)

Both industry and advocacy groups misrepresented knowledge in the process of making a case for or against GM crops. However the reception of this knowledge was seriously unbalanced. Any data with even a tenuous connection to the industry was regarded as suspect and was dismissed, at least in public debates. On the other hand, data put forward by advocacy groups was not subjected to public challenge. There is a case to be made for more equitable scepticism in the interpretation of data brought to the table by those with a vested interest in the outcome of decisions.

Managing Risks (Cluster B)

The challenge described in the introduction to Section B of the Risk Governance Deficits overview paper, of 'aligning innovation and society through policy and regulation' proved impossible in the case of GM crops and there will probably be similarly irresolvable cases in future. However, this was more a case of failure of alignment of the important interest groups involved in decision making than of failure to convince risk managers of the right way to go.

Designing efficient and equitable risk management policies (B4)

The European regulatory system for GM crops provides a classic example of 'wasting scarce resources on the wrong risk or an inappropriate policy or regulation as a result of inadequate analysis of costs, benefits and other social and environmental impacts', as described in the RGD overview paper.

Europe's early adoption of a precautionary approach to regulating the development of GM crops can be justified given the lack of evidence of safety for the new technology in the 1980s. Likewise European legislation requiring labelling of foods containing GM produce was justified on the grounds of consumer choice, given that a significant proportion of the European population (up to 15%) would want to avoid eating such produce and there is likely to be a price premium for non-GM produce. However, there is now steadily accumulating evidence for safety of GM crops and, given that they are grown and eaten world wide, there is less justification for the increasingly onerous nature of the European system for governing GM crop development and production.

An area particularly open to challenge by vested interests is the setting for threshold levels for contamination with GM produce of food that claims to be GM-free (currently set at 0.9%). The decision to require labelling of GM foods was opposed unsuccessfully by industry on grounds of

the cost of separating GM and non-GM commodity foods in bulk shipping consignments but this decision has much wider significance than this up-front cost. As well as contamination in transit, regulations are being developed to avoid cross-contamination between GM and non-GM crops of the same species grown in adjacent fields. Both these aspects have led to major research programmes to provide data in support of required separation distances for different crops to ensure compliance with the 0.9% threshold level – a recent UK consultation document (DEFRA, 2006) proposed distances ranging from 35 m to 110 m for different crops with additional special measures in relation to organic farming where, for example, a 0.5% threshold may be introduced in future. Other measures being considered in this consultation document are requirements for a farmer to notify neighbours about planting intentions well in advance of the sowing season, compensation for economic losses and the setting up of a public register of GM crops. Much of this consultation is theoretical as there are currently no commercial GM crops grown in the UK.

In addition to the costs of administering and policing these regulations and monitoring non-GM foods. there are the steadily mounting costs of destroying non-GM products found to be GM-contaminated even although they would be safe to consume – interestingly re-labelling as GM does not seem to be considered as an option.

Two important principles of good risk governance should be (i) that threshold levels for contamination are based on the degree of human or environmental risk caused by that contamination and (ii) that threshold levels cannot be dictated by groups with a vested interest in the outcome, and both principles have been seriously strained during the European development of these regulations. Decision making on the threshold level has been dominated by demands from the organic farming lobby, initially for a zero threshold for foods labelled as organic and, once the decision had been made on a 0.9% threshold, for a reduction for organic produce. There are cases where thresholds exist for unwanted material of a non-hazardous nature in agricultural produce (e.g. weed seeds) and such thresholds are usually set at between 1% and 5%. There is little justification for a threshold lower than 1% where the standard is cosmetic and related only to potential economic risk. A report by Brookes (2004) notes that tools to facilitate good co-existence have been working successfully in North America where GM crops are widely grown without government involvement. The very open influence of the organic lobby on these decisions has been contrary to normal practice and would not have been tolerated from an agro-biotechnology industry lobby.

The very early decisions in the EU, to use risk-based rather than crop based regulatory systems for the governance of GM crops and to embrace a precautionary approach, have had a profound influence on the subsequent course of events which certainly was not predicted at the time (further comments on this are given below in ‘Managing conflicts of interest, values and ideology, B12’). The impact is related to the failure to understand the properties and dynamics of a complex system (governance deficit B1) although the system in this case is a socio-economic one.

Organisational capacity (B9)

Ideally, people and organisations need to be able to mobilise the necessary skills, knowledge and capability and to have the appropriate structure, culture and attitude for governing the relevant risks. In the EU case, given the starting point of policy makers and regulators, there has been a very logical progression in the course of action they have taken. The complexity of the systems they have set up and are implementing shows that they have the skills, knowledge and capability to undertake risk governance for GM crops.

But underlying the logic of the progression there is a sense of desperation and an inability to halt what is becoming an increasingly dysfunctional system. The failure is in structure, culture and attitudes and it may be an inevitable outcome of the European political system where so many European governments are reliant on green votes and these are strongly influenced by

environmental advocacy groups ideologically opposed to GM crops. At the moment there is no clear route back to a more rational basis for GM crop governance in Europe.

One important lesson to emerge from this course of events is that, given power, public interest advocacy groups can be just as unscrupulous as any multinational company in their manipulation of policy processes and their misrepresentation of information to support their case. These groups also have the skills, knowledge and capability to pursue their interests and they are untrammelled by conflicting attitudes and cultures. In the GM crops case they have had no competition from the previously powerful agro-biotechnology industry sector.

Managing conflicts of interest, values and ideology (B12)

GM crop disputes globally have been highly contentious and have illustrated very clearly the problems of dealing with ideologically motivated protagonists [Tait, 2001]. Unlike an interest-based conflict (where information, negotiation and compensation can lead to resolution, and giving of concessions leads to mutual accommodation), there is often no clear means to resolve an ideology-based conflict – information is regarded as propaganda, compensation as bribery and negotiation as betrayal, and giving concessions usually leads to an escalation of demands. Such cases are more likely to be exacerbated by engagement with the relevant parties than to lead to consensus, as has been the outcome for GM crops.

Where such conflicts have occurred in the past they have often been resolved by research to provide scientific evidence related to the risk in question and clarification on how it can be mitigated. This case has been more akin to dealing with religious groups who predict the end of the world and whose faith seems to be strengthened by its failure to appear at the predicted time. The early decision to adopt a risk-based governance system for GM crops in Europe, along with the adoption of the precautionary principle, set in train many of the subsequent systemic problems. Advocacy groups have been able to maintain a public perception that GM crops are risky, despite the available evidence, and can always find a way to shift dialogue away from potential benefits of the technology towards more negative future visions.

4. Outcomes - Improving risk governance and avoiding future deficits

Section 2 of this paper gives the industry perspective on the issue of GM crop development in Europe, mainly because that perspective is usually presented in very simplistic terms and is not based on research conducted in the industry. Our research has shown that companies were faced with very complex internal and external decision environments and, even if they had understood how to promote more effectively the development of GM crops there was little they could have done in practice. As Section 3 shows, policy makers and regulators were the ones who could have made a difference, but it is unrealistic to expect a different approach given the constraints they were facing.

It is therefore not appropriate to present ‘lessons learned’ in terms of what various groups could have done differently. However it is also not appropriate to treat this case as being of only historical interest. The shadow of this GM crop experience, in Europe and in many other parts of the world, hangs over future developments in biological science for food production. Scientists, company managers, regulators and policy makers working in frontier areas such as nanotechnology and synthetic biology are already tailoring their research and development so as “ … not to attract the attention of the regulators or the public”. There are strong echoes here of earlier generations of scientists who have had to work within the constraints of politically powerful, ideologically motivated political and advocacy groups. Advocacy groups themselves are seeking opportunities to build on their past success, so that future innovative biologically-based

approaches to enhance food crop production are also negatively framed in the minds of members of the public [Chataway *et al.*, 2008; GM Freeze, 2008].

Attempts to ignore this past experience, to side-step the shadow of GM and to progress unhindered to new generations of biological innovation are unlikely to be successful. New biological approaches would benefit from a move to governance systems (including regulatory approaches) that are better attuned to the opportunities presented by 21st Century science, and that are robust, flexible and democratic in the face of current societal pressures while continuing to ensure safety for people and the environment. As noted above, policy makers and regulators (given political backing) will be best positioned to guide the change process.

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International Risk Governance Council

Chemin de Balexert 9
1219 Châtelaine
Geneva – Switzerland

www.irgc.org

Tel.: +41 22 795 17 30
Fax: +41 22 795 17 39