Unsound Science?
Trans-Atlantic Regulatory Disputes over GM Crops

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Introduction

Agricultural biotechnology has become a focus for a wider debate over the regulatory role of science. In this debate, 'science-based regulation' implies that decisions could be based entirely on the available scientific information. The more ambitious slogan, 'risk-based regulation', implies that all risks can be known before data requirements are set. These meanings have become contentious within each country, as well as across countries.

In free-trade treaties which underpin the European Union and WTO, science is expected to play a central role. Official procedures presume that non-tariff trade barriers can be overcome by reconciling or adjudicating regulatory differences through expert judgements on scientific evidence. Yet some trade conflicts have strained the official procedures rather than resolved the differences. Indeed, they have intensified earlier controversy over whether regulatory decisions should be -- or already are -- based on more than scientific evidence. As the international body which sets standards for food safety, Codex Alimentarius has been discussing the appropriate role of 'other legitimate factors', as if these were not already involved in criteria for evidence.

US-EU regulatory differences have been specially stark for genetically modified (GM) crops. Of all the GM crops commercialized in the USA, the EU has approved two varieties of Bt insecticidal maize for cultivation. However, their use has been subjected to further restrictions or bans by member states. Any EU decision on further GM crops has been delayed since 1998. For food uses, the EU has approved a broader range of GM crops, mainly varieties of Bt insecticidal maize. However, US exports have been complicated by mixed shipments of grain which may or may not have EU approval, as well as the possibility that some grain could be inadvertently cultivated in Europe.

These regulatory differences have high political stakes, since they block exports deemed safe by the US government. Since 1997, US exports of some seeds and grain to Europe have declined - for which the US government blames EU restrictions on GM products. The real reasons may lie elsewhere, e.g. higher US prices (Cadot et al., 2001) or European supermarkets' decisions to exclude ingredients derived from GM crops (Levidow and Bijman, 2002). Nevertheless the EU regulatory restrictions have been publicly attacked as a 'non-tariff trade barrier', thus generating fierce debate over their validity. Let us examine how the respective governments explain the US-EU regulatory differences.

According to US government officials, as well as industry representatives, their safety judgements are based on science and trusted by the US public. Unlike them, European governments have failed to follow expert advice and/or have politicized expert committees by including non-scientists. Consequently, European authorities have based biotechnology regulation on politics rather than science, thus accommodating public fears. For a remedy, Europe should join the USA in relying upon science and explaining that basis to the public. As the US Agriculture Secretary has argued, 'both sides of the Atlantic must... work towards conflict resolution based on open trade, sound science and consumer involvement' (Glickman, 1999).

According to some defenders of European delays or restrictions, by contrast, the precautionary principle has been justifiably applied in order to manage uncertainties about potential harm. According to official documents, moreover, 'civil society must be involved' in such procedures (EU Council, 2000), which could imply that decisions may

justifiably consider public acceptability. Also US-EU differences in agricultural policy have been cited in order to explain Europe's more stringent regulation of GM crops. According to a European Commission official based in the USA, that country has promoted high-productivity agriculture to maximize cheap exports, while the EU has been attempting to favour higher-quality production, which thereby encourages greater caution towards biotechnology (Haniotis, 1997).

The above arguments mainly concern the regulatory role of political-cultural factors beyond science. Implicitly at issue is their role within regulatory science, i.e. the knowledge which is designed or evaluated for regulating risks. This paper explores such issues through a case study of a GM insecticidal maize, chosen because the environmental regulation has undergone significant change and differences across the Atlantic Ocean.

Overall the paper will argue the following: The criteria for evidence depend upon socio-cultural values, public protest and institutional responses. Consequently, it is misleading to distinguish between scientific and extra-scientific criteria. As a practical implication, regulatory science cannot readily reconcile or adjudicate conflicts over contentious products in a way which gains public legitimacy.

To develop that argument, the paper has the following structure:
- analytical perspectives on regulatory science;
- public debate and concerns over GM products, within the USA and Europe;
- environmental risk issues for Bt maize;
- how the regulatory criteria changed in the USA and Europe;
- implications for regulatory science.

2. Regulatory Science: analytical perspectives

To develop the above argument about regulatory science, this paper draws upon perspectives from the social studies of science and from political science. The former perspectives probe beneath official representations of 'science-based regulation'. Regulatory science can be understood as 'a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgement' (Jasanoff, 1990: 229). Values enter in various ways. In seeking and organizing more facts about risk, regulators implicitly make socio-political choices, e.g. about what potential harms to prevent and, in so doing, about what opportunities to forego: 'We can hardly order, rearrange, or usefully supplement our knowledge about risk without incorporating these issues into a clear, framing vision of the social and natural order that we wish to live in' (Jasanoff, 1993: 129). Such a vision may be less than clear or explicit. Preferred norms may be subtly promoted by selectively emphasizing some accounts of reality rather than others.

As a related way that values enter regulatory science, risk-management frameworks influence risk research, not just vice versa. As government acknowledges or even emphasizes uncertainty about risk, this provides a basis for postponing or restricting hazardous activities. Policy depends on expectations about what useful knowledge can be provided by science in the future, rather than on specific risk claims or available

knowledge. Expert networks construct a 'seamless web' of science and policy around a particular account of uncertainty (Shackley & Wynne, 1995).

In that context, science does not necessarily reduce uncertainty about potential harm. According to some accounts of the Precautionary Principle, it provides a means to challenge indeterminacy and ignorance in the available scientific knowledge, not simply to clarify known uncertainties. Epistemologically humble and rigorous about investigative methods, precaution can be more scientific than 'sound science' (Stirling, 1999).

From political science, various perspectives have analysed trans-Atlantic regulatory differences. In many industrial sectors, safety regulation has become more stringent than before in the USA and Europe, though in somewhat different ways. Long before the mad cow (BSE) crisis and the subsequent controversy over GM crops, Europe was already moving towards tighter regulation of agro-food products in 1980s. Its ban on hormone-treated beef led to a trade dispute with the USA, which won a favourable ruling from the WTO. The EU also issued a temporary ban on rBST for increasing milk production in dairy cows.

Three features of those bans have great relevance for subsequent cases. First, Europe has sought to protect food, the environment and farmers from industrialized methods:

> ... transatlantic differences in food safety regulations both reflect and have contributed to fundamental differences in agricultural policy. Americans have sought to sustain agriculture by introducing new productivity-enhancing technologies. Europeans have chosen precisely the opposite strategy: they have sought to protect farmers by restricting the use of new agricultural technologies (Vogel, 1997: 61; cf. Haniotis, 1997).

Indeed, that difference relates closely to the US political-economic policy of maximizing production of cheap grain for global export, benefiting mainly the agricultural supply industry and grain traders (McMichael, 1998).

Second, European economic integration has often meant levelling up environmental and health standards, partly through NGOs exerting pressure in economically stronger countries. Europeanisation brings more codified environmental standards and more explicit policy rationales, while opening up the policy process to groups previously excluded (Jordan, 1999a: 25-26; also 1999b). By attempting to eliminate internal trade barriers, EU procedures have provided greater opportunity for the most stringent national approach to be considered across Europe, even to become the EU standard. The creation of the single market has depended upon maintaining consensus and consumer confidence, thus 'increasing the leverage of Europe's greener nations over a wide range of regulatory policies' (Vogel, 1997: 59).

Third, through the Precautionary Principle, European regulators could more readily cite uncertainty to justify restrictions or delays in product use, thus accommodating public concerns (Vogel, 2001). This result can be politically convenient for regulators reluctant to take decisions. Regardless of the political motives involved, however, this process effectively generates more stringent criteria for evidence of safety. In the case of GM crops, such criteria express different framing visions for future agriculture (Levidow, 2001). Taken together, those three features can help illuminate the different regulatory outcomes in the USA and Europe.

3. Risk framings in dispute across the Atlantic

In the early 1990s both the USA and EU had a policy commitment to promote biotechnology as essential instruments for economic competitiveness, within a model of high-productivity agriculture. Complementing that model, safety claims took for granted the normal hazards of intensive monoculture, as a basis for accepting some undesirable effects from GM crops. In decisions to grant commercial approval, US and EU regulators accepted the company safety arguments. Eventually protest challenged the safety approvals on both sides of the Atlantic. This section sketches the various challenges to the original policy commitment.

3.1 Public concerns

In some respects, agro-environmental concerns about GM crops have been raised in similar ways across the Atlantic since the late 1980s. In both the USA and Europe, NGOs warned that agricultural biotechnology would further industrialize agriculture, would generate a 'genetic treadmill' (by analogy to the pesticide treadmill), would perpetuate the inherent hazards of intensive monoculture cropping, and would preclude beneficial alternatives. They counterposed 'sustainable agriculture' to the entire trajectory of GM crops. When GM grain entered the food chain, they emphasized unknown hazards to human health.

Concerns about GM food have arisen among ordinary people in similar ways across the Atlantic, as indicated by their comments in focus groups in the late 1990s. According to such a study in the USA, the public worry about unknown long-term health consequences potentially resulting from GM technology. They emphasized previous regulatory failures to anticipate such consequences from other agricultural technologies, as reason to doubt the capacity of science to do so for GM food (Levy and Derby, 2000).

Likewise, according to a European focus-group study, people feel that regulatory institutions downplay uncertainty about risks, especially long-term and irreducible uncertainty, and exclude such consideration from their decision-making. The mad cow crisis had confirmed their previous views about the limits of science and the inadequacy of risk regulation. Moreover, government had not learned the lessons of that crisis for regulating GM food, in their view (Wynne, 2001).

Despite those trans-Atlantic similarities, there is a significant difference in political context. US agriculture has been widely regarded as analogous to a factory, distinct and distant from nature conservation areas elsewhere. Although harmful intensive methods prevail in European agriculture too, various critics have counterposed a different vision; they promote extensification, livelihoods of small-scale farmers, high-quality products, wildlife habitats, etc. Pressed by NGOs and small-scale farmers' organizations, EU policy documents have favoured less intensive methods, agro-environmental schemes, multi-functional agriculture, etc.

Those scenarios have co-existed with an EU policy commitment to reduce agricultural subsidies under CAP reform, while liberalizing trade under the WTO agreement. If these polices are fully implemented, then farmers' survival may depend upon more efficient

cultivation methods. In that vein, proponents of GM crops have represented them as essential tools for clean, sustainable high-yield agriculture.

In response, European NGOs portrayed GM crops as a threat by linking the environmental, agro-food and socio-economic issues, in various ways. They linked 'efficient' agbiotech products to the hazards of other new technologies designed to intensify agriculture, e.g. by analogy to mad cow disease. For example French opponents denounced GM crops for extending a productivist, profit-driven agriculture (analysed in Joly et al., 2000; Joly and Marris, 2001). While US environmental NGOs strategically focused on specific tangible risks, their European counterparts articulated risks in the broader sense of unknown hazards being imposed on behalf of a misguided agricultural model.

3.2 Bt maize: environmental risk issues

For analysing trans-Atlantic changes in regulatory decisions and science, Bt insect-protected maize serves as a useful case study because it is the only GM crop approved for commercial cultivation in the EU as well as the USA. Although the public controversy included health risks, this paper focuses on agri-environmental risks, analysing such issues within a wider debate over future agricultural models.

Since the 1980s the prospect of GM insect-protected crops has been celebrated as a means to reduce the spraying of synthetic agrochemicals. An early target for Bt maize was the European Corn Borer (ECB), which infests maize by boring into the stalk and so cannot easily be reached by agrochemical sprays. However, Bt crops express the Bt gene continuously, thus more plausibly causing unintended effects not previously seen from biopesticides. That scenario underlies a long-standing debate over two agri-environmental hazards.

- Insect resistance: According to critics, persistent expression of the Bt gene could accelerate selection pressure for resistant insects, thus undermining the efficacy of the Bt crop -- as well as the foliar sprays which provide a future option for organic farming. According to companies, Insect Resistance Management (IRM) measures were available, e.g. by ensuring that high-dose plants kill all the insects and/or by inserting alternative Bt toxins into the crop. If insects nevertheless developed resistance, then farmers anyway could revert to spraying agrochemicals, they argued.

- Non-target harm: According to critics, the Bt gene could harm beneficial insects, some of which could help control the pest. According to companies, however, lab tests and field monitoring indicated no evidence of risk. When that evidence came under challenge, proponents argued that any harm would be less than that of agrochemical sprays.

When new scientific research provided some evidence of non-target risk, e.g. to lacewing or Monarch larvae, some scientists criticized the test methods and thus their relevance to agricultural contexts. In response, other scientists scrutinized the earlier evidence of safety from company-sponsored lab tests. In particular a consultancy group argued that the designs were methodologically flawed -- based on toxicological tests for chemicals, and so inappropriate for testing the biological pathways of plant Bt; nor did the experimenters confirm that the larvae had ingested the Bt toxin. On those grounds,

critics questioned whether the negative results had any meaning (e.g. Ecostrat, 2000). Thus evidence of both safety and risk came under challenge.

4. The United States

The US regulatory system for GMOs was shaped around the slogans, 'risk-based regulation'. Such arguments emphasized the genetic precision of GM techniques, as a basis for the predictability of any risks. Federal agencies were assigned a strong burden of evidence to demonstrate risk even before regulating GMOs at all. Rather than propose additional legislation, the government instructed regulatory agencies to use existing laws in any cases where GM products warranted extra controls.

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the US EPA has a duty to conduct a risk-benefit analysis of pesticidal agents. This duty did not clearly extend to Bt toxins in plants, and even less clearly extended to the insect-resistance issue. Nevertheless the EPA claimed the relevant authority to regulate them. In the early 1990s the US EPA declared that insect-protected crops would significantly reduce the use of synthetic insecticides and thus the associated risks. Accordingly, in the mid-1990s it registered several Bt inserts in maize on the basis that they posed minimal risks and offered substantial benefits.

Amid scientific disagreements about risks and benefits, the EPA has managed the conflicts within a transparent procedure, while permitting widespread commercialization. Scientific evidence has been debated at open meetings of the EPA's Scientific Advisory Panel (SAP); regulatory and advisory views have been made available on the EPA webpage for public comment. NGOs used this access to challenge the criteria for evidence regarding risks and benefits. Such a regulatory procedure accommodates a public distrust of expert bias, rather than depending upon an *a priori* 'trust'. Like other industrial sectors there, regulation of GM crops exemplifies the US adversarial style, whereby regulators must make explicit the scientific basis of risk assessment, which is readily disputed by external bodies (Jasanoff, 1990; Vogel, 1986).

4.1 Benefits claims

Early on, claims for significant environmental benefits came under challenge. For its benefits assessment, the EPA assumed an agricultural norm of insecticide sprays, which would be simply reduced by Bt maize. Yet few farmers had previously sprayed maize fields against the European Corn Borer, so there was little scope to reduce spraying.

Within a few years of commercial approval, adoption reached approximately half of US fields - several times more widespread than the 5-10% of maize fields previously sprayed with insecticides. The SAP questioned whether Bt crops were simply replacing insecticide sprays. The EPA had favourably compared Bt maize to 'conventional' methods, so NGOs and advisors questioned why the latter should mean insecticide sprays.

Farmer surveys indicated that the insecticide reduction was minimal or limited to specific areas which formerly had the most spraying. Such judgements were made difficult by an erratic or uncertain baseline for comparison, dependent upon annual variations in pest

problems. In some cases, moreover, farmers increased spraying of secondary pests, e.g. Southwest Corn Borer, which found new niches previously occupied by the ECB.

For the statutory risk-benefit analysis, then, doubts were cast on claims for significant benefits. That challenge raised the stakes for any potential risks, as indicated by new evidence. More specifically, let us examine developments around the two main risk issues.

4.2 Insect resistance

After the EPA granted unconditional registration to Bt toxins inserted into potato, the issue of insect resistance was raised vocally by a network of environmental NGOs, organic farmers and entomologists. They argued that Bt must be preserved as a public good, e.g. for the long-term efficacy of Bt foliar sprays as well as the GM crop itself. The various stakeholder groups attended a series of conferences to debate the adequacy of proposals for Insect Resistance Management (IRM) strategies. The plausible prospect of insect resistance potentially jeopardized long-term benefits.

In response to the protest, the EPA and industry took some responsibility for IRM measures for Bt maize. In 1995-96 the EPA registered Bt toxins in maize on a time-limited basis, conditional upon monitoring and reporting back. Companies asked farmers to plant refuges of non-Bt maize in order to delay resistance.

Soon pressures mounted for more stringent controls. Entomologists presented new laboratory evidence -- that insects could develop resistance more quickly than the EPA had assumed, and that such resistance could extend to alternative Bt toxins. Moreover, Bt maize increased rapidly to approx. 1/3 of US maize fields, thus increasing any selection pressure for resistant insects.

In response to critics, the EPA specified that farmers should plant larger refuges of non-Bt corn in specific regions. A stakeholder-based expert body recommended larger refuges in some cases. The scientific basis of the refuge sizes were questioned by some companies as too stringent, and by NGOs as too lax. Moreover, farmer compliance was also questioned. Nevertheless the refuge plans have been standardized, thus providing a way to manage public debate as well as insect-resistance risks.

4.3 Non-target harm: Monarch butterfly

Although environmental NGOs were always concerned about the prospect of non-target harm, initially they had little basis for pressing the issue. An opportunity came when a 1999 Cornell lab study reported harm to Monarch larvae, followed by semi-field studies which also reported harm. Given that the Monarch butterfly has symbolic importance in US popular culture, NGOs were now able to catalyse a national debate. US scientists took a greater interest in non-target harm, while Europeans were rejecting GM products in general, so challenges to safety claims now gained greater attention in the USA.

Although the Monarch studies were inconclusive about actual harm under commercial field conditions, the results were used to attack the EPA for failing to require adequate scientific information for risk assessment. The SAP criticized the EPA for having failed to follow up its own risk concerns with appropriate research in the 1990s. Environmental

NGOs demanded that the EPA require farmers to plant buffer zones in order to protect Monarch larvae, as well as extra evidence to clarify non-target risks.

In response to these pressures, the EPA requirements became more stringent. Initially the agency dismissed any scenario of harm to Monarch larvae. Yet its various arguments were criticized by the SAP as lacking any scientific basis, or were even refuted by subsequent evidence from maize fields. At the same time, the EPA required more specific evidence about causal pathways of potential harm, especially through field studies, as a basis for deciding whether to re-register Bt toxins in corn. In April 2001 industry supplied such evidence, mainly for three butterfly species which have the greatest resonance with public concerns.

An underlying issue was the normative basis for evaluating non-target harm. Proponents of Bt maize reiterated earlier arguments that the product causes less harm than synthetic pesticides. Their argument implied that some harm should be acceptable, so that any predictive uncertainties need not impede commercial approval. By contrast, NGOs argued that any harm from Bt crops should be compared to the environmental effects of non-chemical insect-control methods, which had been prevalent before Bt maize cultivation. Eventually EPA officials accepted a non-chemical comparator. In various ways, then, the EPA strengthened its criteria for evidence to demonstrate that non-target harm would not occur, though this requirement did not mean restricting cultivation.

5. European Union

The EU has regulated GMOs under the Deliberate Release Directive, enacted in 1990 and revised in 2001. This established a procedure for deciding whether to approve a GM product on an EU-wide basis, as well as for allowing a member state to impose restrictions on grounds of risk. Member states have a duty to ensure that GMO releases do not cause 'adverse effects', which were left undefined in the 1990 Directive. In 1996 the European Commission approved Monsanto's soybean for use in animal feed and processed products.

In 1997 the European Commission granted authorization to Novartis' Bt maize for all commercial uses, with no specific requirements placed on companies, despite objections from most member states. The European Parliament overwhelmingly denounced the European Commission for that decision. NGOs cast GM crops as a threat to 'sustainable agriculture', variously defined; they appealed to concepts of agriculture as an aesthetic landscape, wildlife habitat, local heritage, peasant stewardship, and a traceable guarantor of food quality. Europe-wide NGOs circulated or coordinated consumer boycott campaigns against GM-derived foods in supermarket chains, which eventually decided to exclude GM ingredients from their own-brand products.

The EU regulatory procedure had no straightforward way to accommodate the protest. Partly by default of the European Commission, member states imposed bans or restrictions on GM crops. Commercial cultivation anyway required national approval under plant variety legislation; France and Spain used this procedure to grant a time-limited approval, with a monitoring requirement for all risks which were cited in the public debate. Bt maize was banned at various times by Austria, Italy and Germany.

European regulators invoked or re-interpreted the Precautionary Principle to emphasize predictive uncertainties which warranted more evidence of safety.

Such demands tended to circulate among member states, given the efforts at European integration, amid public hostility to GM crops. Consequently, criteria for evidence became more stringent in Europe than in the USA. However, the EU had no single authority to formalize such criteria, which anyway remained subject to further change; nor was it politically possible to approve additional Bt crops. More specifically, let us examine the two main risk issues.

5.1 Insect resistance

The 1990 Deliberate Release Directive gave the EU authority to regulate all health and environmental risks of GMOs. Nevertheless proponents of Bt maize argued that insect resistance would be an 'agronomic problem', not an 'adverse effect', and therefore irrelevant to the Directive. That normative argument provided a basis for approving Ciba-Geigy's Bt maize. The emergence of insect resistance 'cannot be considered an adverse environmental effect, as existing agricultural means of controlling such resistant species of insects will still be available', declared the European Commission.

Facing protest, companies came under greater pressure to devise more credible IRM measures and to specify their scientific basis. They undertook to carry out lab tests for sampling insects from the field and detecting Bt resistance at an early stage. Meaningful laboratory testing depends on knowing the previous level of Bt susceptibility in the insect population, so Novartis (formerly Ciba-Geigy) commissioned entomologists at the University of Milan to establish a baseline. The refuge design depends on assumptions about the distance travelled by insects to feed and breed, so biotechnology companies also contracted with entomologists to study these behaviours.

The EU's expert committee declared that these IRM measures would be 'adequate to delay resistance'. Such an imprimatur was important for a Europe-wide approach, though the EU had no direct means to implement it. The IRM issue remained low key, partly because critics did not emphasize it, and because few farmers anyway bought Bt maize seeds. Organic farmers' and peasants' organizations instead emphasized other arguments, e.g. that GM crops threatened the purity or quality of their products.

5.2 Non-target harm: lacewing

For evaluating potential harm to non-target insects, safety claims depended on two types of evidence. Lab studies had indicated no harm to various insect species. And field monitoring found no fewer beneficial insects in Bt maize fields than in conventional maize fields.

Safety claims were challenged in 1997 by results of Swiss lab tests on tri-trophic pathways. A carnivorous predator, lacewing, was harmed by eating aphids which had ingested Bt toxin. Such predators could otherwise enhance the efficacy of IRM measures by controlling the pest. According to the experimenters, these preliminary results warranted more study on indirect pathways of non-target harm.

A debate ensued over the relevance and adequacy of all the available evidence. Companies (and the EU's expert committee) disputed whether the Swiss results had any relevance to the commercial context. They criticized the Swiss study on methodological grounds -- e.g. for 'unrealistic' experimental conditions, high mortality of the control insects, and statistical anomalies. Yet similar criticisms could have been directed just as well at the lab tests which were originally submitted by companies; thus the EU's expert committee applied double standards. It also declared that any harm from Bt crops would be less than the harm from agrochemicals, as if the latter were the norm in maize fields.

All those judgements have remained contentious. Under various pressures, companies have sought to obtain more specific evidence about potential cause-effect pathways of non-target harm. Such studies have extended to soil organisms, despite claims (from companies and the EPA) that Bt toxins cannot harm them. Unlike the EU committee, most regulators have not assumed that any particular level of harm would be acceptable. In accommodating opponents of GM crops, the authorities can cite results of experiments whose design was no less realistic than the earlier experiments underpinning safety claims.

6. Conclusion: science-based regulation?

In conclusion, it is misleading to distinguish between scientific and extra-scientific criteria in risk regulation. As the case of Bt maize illustrates, the criteria for evidence have depended upon socio-cultural values, public protest, and institutional responses. A wide range of actors has been involved in framing the uncertainties which scientific research may test and which expert advisors may evaluate. In both the USA and EU, regulatory science has remained controversial in several related aspects: what 'environment' must be protected, what causal pathways must be investigated, what claims hold the burden of evidence, and what counts as adequate or relevant evidence.

In both the USA and EU, the original safety claims for GM crops came under challenge in two related ways. First, they had adopted a narrow account of environmental harm, accepting the normal hazards of intensive monoculture as an implicit baseline for GM crops, thus complementing the overall political agenda of economic competitiveness. Critics counterposed wider accounts of harm, while questioning the available evidence of safety as inadequate.

Second, the controversy stimulated further research, whose results revealed more causal pathways of undesirable effects, thus undermining earlier scientific ignorance. Scientists have continued to debate how to test or monitor non-target harm from tritrophic effects and pollen. Thus 'uncertainty' increased, though in somewhat different ways across the Atlantic.

The US debate emphasized specific risks - first insect resistance and then non-target harm. Insect resistance was turned into an issue of sustainable agriculture by environmental NGOs creating networks which included organic farmers and entomologists. Later, non-target harm was turned into an issue by environmental NGOs publicizing results of experiments on Monarch larvae. Given the symbolic role of that species, the debate undermined the US cultural distinction between factory-type farming and nature conservation areas far away.

The European debate located specific risks of Bt maize within broader concepts - e.g. the regulatory incapacity to predict health or environmental risks, and the general threat of intensive productivist methods, already under suspicion from earlier food scandals. Environmental regulation came under indirect pressure as public hostility grew towards GM-derived food, and as retailers excluded GM ingredients.

In response to those pressures, US and European regulators imposed a greater burden of evidence for safety upon companies. In the USA such a burden has served to justify past or new approvals, e.g. by using commercial cultivation as means to generate additional evidence of safety. In Europe the burden of evidence has become relatively more stringent and open-ended, e.g. by invoking the precautionary principle to emphasize unresolved uncertainties and unknowns.

Regulatory criteria for evidence are informed by a vision of the socio-agricultural order. At least implicitly, there has been a shift towards non-agrochemical or less intensive comparators of environmental harm for GM crops. This shift has increased controversy over the methods for preventing or detecting such harm.

Amongst these regulatory changes and trans-Atlantic differences, any particular standpoint remains open to criticism on scientific grounds. Environmental NGOs argue that US approval decisions lack adequate scientific evidence of safety, while industry argues that European regulatory delays lack adequate evidence of risk. On both sides, some argue that regulatory policy is based on politics rather than science. Yet this is a false dichotomy, since socio-cultural values invariably enter the criteria for evidence.

Their value-laden character becomes more accessible through public controversy, thereby undermining the rhetorical appeals to scientific neutrality in 'science-based regulation'. Consequently, regulatory science cannot readily be used to reconcile or adjudicate differences over contentious products in a publicly legitimate way. Such adjudication would necessarily privilege some socio-cultural values over others. Under some interpretations of the WTO SPS, for example, the Disputes Panel can judge only whether a trade barrier is justified by adequately strong evidence of risk, even if the putative evidence of safety is weak. At both the national and international level, risk regulation faces a dilemma in either denying or acknowledging its implicit politics.

As a way forward, the precautionary principle offers a possible framework for acknowledging and deliberating the socio-cultural values inherent in risk assessment. Such prospects depend upon how precaution is interpreted. In some accounts, predictive uncertainties are represented as technical gaps which will be readily filled, as if a truly 'science-based regulation' were being temporarily deferred until then. In other accounts, by contrast, predictive uncertainties are represented as issues of environmental norms, scientific ignorance, causal indeterminacy, cognitive frameworks, expert framings, etc. - thus challenging prevalent models of regulatory science (Levidow and Marris, 2001).

Means are needed for publicly deliberating all those issues among the diverse actors who have already led government to reframe risk assessment. Only on such a basis can regulatory decisions regain legitimacy and be meaningfully compared across countries.

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For details of reports and publications from those research projects, see Biotechnology Policy Group webpages at http://www-tec.open.ac.uk/cts/bpg.htm

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Note: For detailed references to scientific and policy documents on the Bt maize debate through 1999, see the author's previous papers, listed below. This paper updates the story by drawing on more recent documents and research interviews from 2000-2001; detailed references will be provided in a subsequent paper.

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