Reframing Regulatory Science: Trans-Atlantic Conflicts over GM Crops

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Recadrer la science réglementaire : les conflits transatlantiques sur les cultures génétiquement modifiées

Résumé – La science réglementaire a été recadrée afin d'évaluer les risques que comportent les cultures génétiquement modifiées sur le plan écologique tant aux Etats-Unis qu'en Europe. Alors que se déchaînent des conflits de nature réglementaire de part et d'autre de l'Atlantique, le maïs 'insecticide' Bt fait figure d'étude de cas dans le cadre de deux problèmes de portée générale : comment les opinions à vocation réglementaire peuvent-elles réconcilier science et valeurs socioculturelles et quelle influence les conflits commerciaux exercent-ils sur ces opinions ? Les tensions sociales, de même que les critiques formulées par les écologistes, ont favorisé les controverses sur la validité des preuves scientifiques et, ce faisant, elles ont accentué la part d'incertitude scientifique. Les critères réglementaires ont fait l'objet d'une nouvelle interprétation à la lumière des valeurs socioculturelles, des protestations du grand public et des réactions institutionnelles. La capacité à prévoir ou à gérer les risques a été vivement contestée, et des critiques ont été formulées quant à l'état des connaissances actuelles. Cette controverse a incité à la poursuite des recherches. Celles-ci ont révélé d'autres mécanismes causals, dont la résistance des insectes ou l'existence de répercussions négatives non ciblées. En outre, les preuves antérieures avancées en matière de sécurité ont été étudiées de manière plus approfondie. On constate donc que l'intensification de la recherche scientifique a, à la fois, participé à l'émergence de débats publics et en a été une résultante.
Les amendements réglementaires sont liés à quatre processus interdépendants. Le débat public et scientifique a mis en lumière de nouvelles incertitudes scientifiques. Des avis 'extra-scientifiques' ont également été pris en compte dans les questions réglementaires et les expertises. Les critères de preuve en matière de sécurité sont devenus plus stricts. Les conflits commerciaux transatlantiques ont créé des opportunités politiques et des ressources scientifiques favorables à la mise en œuvre de ces modifications réglementaires, notamment aux Etats-Unis. Ainsi, la distinction entre critères scientifiques et critères 'extra-scientifiques' s'est-elle avérée casuelle, contestable et variable. Compte tenu de la législation nationale et de l'intérêt qu'ont les hommes politiques à se retrancher derrière l'avis des experts, les gouvernements s'efforcent toujours de justifier leur approche en présentant la disposition adoptée comme une 'disposition scientifiquement justifiée', voire même dotée d'une 'valeur scientifique rigoureuse'. Ils sont confrontés à un dilemme : soit nier, soit reconnaître le rôle implicite de cadrage politique que joue la science réglementaire.

Mots-clés :
science réglementaire, cultures génétiquement modifiées, évaluation, risques environnementaux

Reframing regulatory science : Trans-Atlantic conflicts over GM crops

Summary *– Regulatory science has been reframed for evaluating environmental risks of GM crops in both the USA and Europe. Social conflict has contributed to disputes over scientific evidence and thus increased scientific uncertainty. Environmentalist criticisms have influenced mainstream debates about how to define harm, how to evaluate GM crops vis-à-vis alternatives, and how to design risk research. Regulatory criteria have been reconstructed through socio-cultural values, public protest and institutional responses.*
Regulatory changes can be understood as four related processes. New scientific uncertainties have arisen from public-scientific debate. Extra-scientific judgements have been acknowledged within regulatory issues and expert advice, rather than remain hidden behind 'science'. Criteria for evidence of safety have become more stringent, specifically regarding environmental norms and causal pathways of potential harm. Trans-Atlantic trade conflicts have been a source of political opportunities and scientific resources for those regulatory changes, especially in the US.

Key-words:
regulatory science, GM crops, evaluation, environmental risks

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AS a central part of agricultural biotechnology, genetically-modified (GM) crops have become the focus of a wider debate over the role of science in regulation. This is manifest in the ongoing dispute between the United States (US) and the European Union (EU). The US has approved a wide range of GM crops and foods, but between 1998-2002 the EU approved none of the many products which were awaiting a decision. Various claims about science have been made to justify regulatory decisions or indecision.

Many arguments presuppose a dichotomy between science and politics. For example, according to proponents of safety claims, US approvals are based on science but European indecision is explained by politics – *e.g.* various 'non-risk issues'. In reverse, sceptics of safety claims argue that approvals are explained by politics because there is insufficient science to establish safety. Such arguments intersect with wider debates over the proper role of 'other legitimate factors' – *i.e.* 'extra-scientific' criteria, and how to distinguish these from 'scientific' criteria.

This paper [1] will analyse the US-EU conflict over GM crops in order to explore the relationship between science and regulation in more detail. In doing so, it will link three questions of general relevance:

– What are the origins of the science that guides or justifies regulatory decisions?

– How are boundaries drawn between scientific and extra-scientific criteria?

– What influences the way science is used in regulation?

To answer these questions, this paper analyses the regulation of Bt insecticidal maize. This is one type of GM crop whose environmental risks have been controversial on both sides of the Atlantic. The paper is structured as follows.

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[1] This paper draws on the results of four studies:

From Precautionary to Risk-Based Regulation: the Case of GMO Releases, funded by the UK's Economic and Social Research Council (ESRC) during 1995-1996.

Safety Regulation of Transgenic Crops: Completing the Internal Market?, funded by the European Commission, DG XII/E5, during 1997-1999. *http://technology.open.ac.uk//cts/srtc/index.html*

The Scientific Basis of Applying the Precautionary Principle in Biotechnology-Related Potential Trade Conflicts, funded by the European Science & Technology Observatory (ESTO) through the Joint Research Centre, European Commission, in 2001.

Trading Up Environmental Standards? Trans-Atlantic Governance of GM Crops, funded by the UK's Economic and Social Research Council (ESRC), during 2002-2004.

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

The first part introduces perspectives on regulatory science. In the second part Trans-Atlantic risk and regulatory issues are presented. The next two main parts compare Bt maize in the United States and Bt maize in the European Union. The last section concludes: reframing regulatory science.

PERSPECTIVES ON REGULATORY SCIENCE

Arguments about 'science-based regulation' can be illuminated using the concept of 'regulatory science' from the social studies of science literature. This concept focuses attention on the knowledge that is generated and used to underpin expert judgements in risk assessment. Analyses have asked: how are values involved in generating or interpreting such knowledge? For example, regulatory science has been defined as *'a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgement'* (Jasanoff, 1990, p. 229).

A key insight is that values frame criteria for evidence. In seeking and organizing more facts about risks, regulators implicitly make sociopolitical choices. For example, they choose what potential harms to prevent and, in so doing, what opportunities to forego. Jasanoff (1993, p. 129) has argued further:

'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.'

Such a vision, and the values that are involved, need not be clear or explicit. In practice, preferred norms may be subtly promoted by selectively emphasizing some accounts of reality rather than others.

Given this unavoidable mix of science and values in regulation, what are the implications for expert advice? In practice regulatory science will always be vulnerable to deconstruction because *'it involves issues at the frontiers of current scientific knowledge, where consensus among scientists is most fragile'* (Jasanoff, 1987). In the US, for example, experts and regulators have competed for authority to interpret scientific findings. They have contested the boundary between science and policy; often they attempted to control the boundary in order to legitimize their roles. To achieve this aim, for example, US regulators have emphasized uncertainties as a way to justify policy judgements which go beyond the available science.

In the mid-1980s Jasanoff contrasted that US context with Europe: *'European officials and the public tend to accept as "science" any issues that their technical advisory committees are prepared to treat as scientific'* (*ibid*. p. 225). Since the 1980s this deference has been challenged on the

grounds that expert advice often misrepresents value judgements as 'science' and downplays uncertainties about risk.

Such analyses also identify various ways that actors draw boundaries between 'scientific' and 'extra-scientific' judgements, or how they challenge such boundaries. 'Uncertainty' is often represented in ways which serve boundary-setting. The term can have contradictory meanings. For example it can denote technical imprecision which would be reducible through more research. Alternatively, the term can open up unknowns which are routinely present but hidden within the available scientific knowledge: *e.g.* assumptions about causal pathways of potential harm.

Although scientific uncertainty indicates limits of available knowledge, uncertainty cannot be properly explained as an objective shortfall of knowledge. Rather, the perceived uncertainty is subjective, influenced by complex social and cultural factors. As Wynne (1992, p. 120) has argued:

'Scientific uncertainty can be enlarged by social uncertainties in the context of practical interpretation, and it can be reduced by opposite social forces.'

From this perspective, uncertainty expresses rather than explains conflict.

The contested nature of uncertainty is seen particularly in the ideas of 'precaution' and 'sound science'. At one level, by invoking precaution, regulators can more readily cite uncertainty to justify restrictions or delays in product use. This might serve various political goals, such as accommodating public concerns or protecting markets from imports. By mobilising uncertainty, precaution can help policy-makers to avoid risks **and** to achieve political goals.

At the same time, precaution can be a tool which helps to discover unknowns. The concept aids demands 'to improve the quality of scientific information available to decision-makers' (Vogel, 2001, p. 23). At that level, precaution has been described as epistemologically humble about cognitive frameworks of scientific research, rigorous about investigative methods, and thus more scientific than 'sound science' (Stirling, 1999).

TRANS-ATLANTIC RISK ISSUES OF GM CROPS

In the early 1990s the US and the EU commited themselves to promoting biotechnology within a model of high-productivity agriculture and a policy framework of enhancing economic competitiveness. This commitment led to risk assessment being framed within narrow environmental norms. Safety claims took for granted the 'normal' hazards of

intensive monoculture, as a basis for accepting undesirable effects from GM crops. This approach required minimal evidence of safety and thus favoured approval (Levidow *et al*., 1996, 2000; Levidow and Carr, 2000a, 2000b).

By the mid 1990s, however, protests began to challenge the basis of safety approvals. On both sides of the Atlantic, similar concerns emerged from public opinion and environmental NGOs – though with different emphases and framings. Ultimately such challenges gained further impetus from the trade conflict. This section sketches public debates, regulatory differences, consequent trade conflicts and official arguments about these.

Public debate: US-EU similarities and differences

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 US and the EU, NGOs warned that agricultural biotechnology would further industrialize agriculture, would generate a 'genetic treadmill' (by analogy to the pesticide treadmill), and would perpetuate the inherent hazards of intensive monoculture cropping — whilst excluding beneficial alternatives. They counterposed 'sustainable agriculture' to the entire trajectory of GM crops (*e.g*. BWG, 1990; Haerlin, 1990).

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 one study in the US, people worry about unknown long-term health consequences potentially resulting from GM technology. They also emphasize previous regulatory failures and thus draw on other agri-food technologies to anticipate such consequences (Levy and Derby, 2000). When GM grain entered the food chain, some NGOs emphasized unknown hazards to human health, as well as agro-environmental issues.

Likewise, according to a European focus-group study, people feel that regulatory institutions downplay uncertainty about risks (environment and health), especially long-term and irreducible uncertainty, and exclude such consideration from their decision-making. The mad cow (BSE) crisis confirmed their earlier views about the limits of science, official failures to acknowledge this, and the inadequacy of risk regulation. Moreover, in their view, governments have not learned the lessons of the BSE crisis for regulating GM food (Wynne *et al*., 2001). Thus public suspicion towards GM food can be attributed less to the BSE crisis than to government failure to learn from it.

Despite these trans-Atlantic similarities in public concerns, there are significant differences in the political-economic context. US agricul-

ture has been widely regarded as analogous to a factory, distinct and distant from nature conservation areas which lie elsewhere. Although harmful intensive methods prevail in European agriculture too, numerous organizations have offered a different vision; they promote less intensive methods, the livelihoods of small-scale farmers, high-quality products, wildlife habitats, and so on. Pressed by NGOs and small-scale farmers' organizations, EU policy documents in recent years have somewhat accommodated demands for extensification, agro-environmental schemes and multi-functional agriculture (*e.g.* CEC, 1997).

The EU's alternative scenarios for agriculture have co-existed with an EU policy commitment to reduce agricultural subsidies under CAP reform, while liberalizing trade under the auspices of the WTO. Such co-existence is uncomfortable because these policies imply that the survival of farmers 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, mainstream European NGOs have portrayed GM crops as a threat by linking 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. French opponents denounced GM crops for extending productivist, profit-driven agriculture (Heller, 2002; Joly *et al.*, 2000; Joly and Marris, 2001). The chief of the UK's Consumers Association challenged the agro-food industry for its *'unshakeable belief in whizz-bang techniques to conjure up the impossible: food that is safe and nutritious but also cheap enough to beat the global competition'* (McKechnie, 1999). From their standpoint, GM crops epitomized a misguided agricultural model bearing known and unknown hazards.

Regulatory differences and official arguments

Regulatory differences in the US and the EU have been specially stark for GM crops. Of all such products commercialized in the US by 2002, the EU had approved only two varieties of Bt insecticidal maize and one of herbicide-tolerant maize for cultivation. Following approval at the EU level, their use has been subjected to further restrictions or bans by EU member states. The EU has approved a broader range of GM crops for food uses, though not all the ones cultivated by US farmers. Any EU decision on additional GM crops has been delayed since 1998, under a *de facto* moratorium.

Trade conflicts have resulted from the difference between EU and US approvals of GMOs. US grain shipments may include varieties which are not approved in the EU. To avoid this problem, grain traders have attempted to segregate supplies of non-GM grain, or at least to

exclude varieties which lack EU approval. But US and EU authorities have disagreed about who holds the burden of evidence for demonstrating the contents of shipments, so blockages have resulted.

Thus the political stakes are high in blocking products that are deemed safe by the US government. Since 1997, US exports of some seeds and grain to Europe have declined considerably. The decline has many possible sources, *e.g.* higher US prices (Cadot *et al.*, 2001) or market barriers from retailers in the EU (Levidow and Bijman, 2002). However, the US government blames government restrictions on GM products. How have the protagonists explained US-EU regulatory differences?

According to US government officials, as well as industry representatives, their safety judgements are based on science and are trusted by the US public [2]. They also argue that, unlike the US, EU governments have failed to follow expert advice or they have politicized expert committees by including non-scientists. Consequently, European authorities have based biotechnology regulation on politics rather than science, thus accommodating public fears. Moreover, some argue that EU delays and restrictions amount to 'non-tariff trade barriers', implying protectionist motives. Under the Clinton Administration in the late 1990s, such claims were downplayed in favour of appeals for cooperation to solve a common problem.

For a remedy, critics call upon Europe to follow the US model and rely upon 'sound science' whilst explaining this basis to the public. As the US Agriculture Secretary argued, *'both sides of the Atlantic must... work towards conflict resolution based on open trade, sound science and consumer involvement'* (Glickman, 1999). Implicitly, 'sound science' is counterposed to the precautionary principle.

According to some defenders of European delays or restrictions, uncertainty about risks justifies the application of the precautionary principle to GMOs. Also known as the Rio Principle 15, it states:

'Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation' (cited in CEC, 2000, p. 25; and in Haigh, 1994, pp. 245-46).

Defenders of regulatory delay also cite official EU statements on the precautionary principle, *e.g.* that 'civil society must be involved' in reg-

[2] Eventually some industry commentators acknowledged a more widespread distrust. According to the US-based President of Monsanto, speaking in vox pop style: That shift has been a movement from a "trust me" society to a "show me" society. We don't trust government – and thus government rulemaking and regulation is suspect. We don't trust companies – or the new technologies they introduce into the marketplace (Verfaillie, 2000).

ulatory procedures and public acceptability must be considered (*e.g.* EU Council, 2000). Also US-EU differences in agricultural policy, such as those mentioned in the previous section, have been cited in order to explain Europe's more stringent regulation of GM crops (*e.g.* Haniotis, 1997).

At the same time, some officials of the European Commission have criticized member states for their delays and restrictions on GM crops. According to DG-Environment, which holds responsibility for implementing EU legislation on GM crops:

'Regarding 12 of the 13 GM products now before the Commission, advice from the Scientific Committee on Plants (SCP) scientifically excludes any potentially negative effects on the environment or human health. Under these circumstances, recourse to the PP cannot be justified' (interview, 04.06.02).

Under these circumstances, Commission officials have argued that the products should be approved, based on 'sound science'.

As such appeals show, policy statements across the Atlantic can share a common language. However, in the GM crop case, the term 'sound science' hides difficulties in distinguishing between sound, unsound and inadequate science (Levidow and Carr, 2000b). It also implies that the boundary between science and values is easy to draw. '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 regulators set data requirements to clarify potential harm. These issues have become contentious on each side of the Atlantic.

Bt maize: risk debates

In order to analyse trans-Atlantic regulatory differences and changes, GM insect-protected Bt maize can serve as a useful case study because several varieties were approved for commercial cultivation in the EU and the US by the late 1990s. Although the public controversy has included health risks of GM food in general, this paper focuses on agri-environmental risks of Bt maize. These risk issues can be more clearly linked with cultural values.

Since the 1980s biotechnologists have been identifying and extracting the gene for insecticidal toxins in the microbe *Bacillus thuringiensis*, which farmers have sprayed onto crop leaves for many decades. These genes were inserted into GM crops to create in-built protection. In designing Bt insect-protected crops, an early target 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 insecticidal gene continuously and so could plausibly cause

unintended effects not previously seen from foliar Bt sprays or biopesticides in general. There has been a long-standing debate over two environmental hazards – insect resistance and non-target harm. These will be outlined in turn to provide background for later sections.

For both those risks, safety claims were challenged at two related levels. Narrow environmental norms defined some undesirable effects as acceptable, by analogy to intensive monoculture in general, but critics pushed regulatory procedures to broaden these norms. And risk assesments made optimistic assumptions about causal pathways of potential harm, but these were challenged and turned into uncertainties which must be investigated or managed. The next two main sections sketch how these debates developed in the US and the EU, each with its different framings and trans-Atlantic influences.

BT MAIZE IN THE UNITED STATES

From the outset, US regulation of GMOs invoked the concept of 'risk-based regulation'. Rather than develop new legislation, the government instructed regulatory agencies to use existing laws for any '-novel' GM products which may warrant control. Federal agencies were required to demonstrate risk even before they could regulate GMOs. Official arguments emphasized the precision of GM techniques. This underpinned claims that GMOs pose 'no unique risks' and that any risks were predictable. Implicitly the term 'risk' acknowledged some provisional uncertainty about safety, as a basis for ultimately classifying GM products as normal (Levidow and Carr, 2000a).

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the US EPA already had a duty to conduct a risk-benefit analysis of all pesticidal agents – to balance any 'unreasonable adverse effect' against environmental benefits. Initially it was unclear whether this duty extended to Bt toxins in plants, but the EPA claimed the authority to regulate such products, as proposed by environmental NGOs and industry. In the early 1990s it declared that Bt insect-protected crops would replace agrochemicals and thus would result in a 'significant reduction in risk'. In the mid-1990s it registered several Bt inserts in maize on the basis that they posed minimal risks and offered substantial benefits.

Amid ongoing disagreements about risks and benefits, the EPA has permitted widespread commercialization, while managing the conflicts within a relatively transparent procedure. Scientific evidence has been debated at open meetings of the EPA's Scientific Advisory Panel (SAP) ; regulatory and advisory views have been made available for public comment. NGOs used this access to challenge the criteria for evidence regarding risks and benefits.

Such a regulatory procedure accommodates an endemic public distrust of expert bias, rather than depending upon an *a priori* 'trust'. Like other industrial sectors in the US, 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 outsiders (Jasanoff, 1990; Vogel, 1986). The rest of this section sketches how three issues were reframed in the US regulatory procedure (for detailed references through the late 1990s, see Levidow, 1999).

Insect resistance

According to critics, insect resistance is a potential problem because the Bt protein could accelerate selection pressure for those few insects which have relatively greater resistance. This would gradually increase resistance in a whole population and eventually undermine the efficacy of the Bt crop. Likewise, resistance would undermine the efficacy of foliar sprays which otherwise could provide a future pest control option for organic farming. According to defenders of Bt technology, however, alternative Bt toxins could be found and be inserted into the crop. As a US company President boasted in the early 1990s: *'We have many bullets in the gun which we call Bt'* (cited in Cutler, 1991).

These arguments have framed regulatory procedures in various ways. Initially regulators implied that the genetic-treadmill scenario would be acceptable, though critics regarded this as environmental harm. At the same time, some companies sought to delay a treadmill effect by preventive measures.

Insect resistance became a public issue in the mid-1990s. In 1995 the EPA granted unconditional registration to Bt toxins inserted into potato, with no obligation on companies to prevent insect resistance. In response, that issue was raised vocally by a network of environmental NGOs, organic farmers and entomologists. They argued that Bt must be preserved as a public good, in order to maintain the long-term efficacy of Bt foliar sprays as well as the GM crop itself. The plausible prospect of insect resistance jeopardized EPA claims for long-term benefits in pesticide reduction.

At this time various stakeholder groups attended a series of conferences to debate the adequacy of proposals for Insect Resistance Management (IRM). The high-dose/refuge strategy combined two elements. Bt crops would be designed with a sufficiently high-dose expression to kill nearly all the pests. And nearby refuges of non-Bt crops would allow susceptible insects to interbreed with any resistant individuals which survive the Bt toxin, thus diluting resistance genes in the next generation.

In response to protest, the EPA and industry took some responsibility for IRM. 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. The refuge guidelines resulted from numerous discussions among scientists from government, academia and industry (Hutchison and Andow, 2000).

However, initial guidelines were based on optimistic assumptions which soon came under challenge. Entomologists presented new laboratory evidence – *e.g.* that insects could develop resistance more quickly than the EPA had assumed, and that some insects already had a gene which conferred cross-resistance to several Bt toxins. These results cast doubt on the option of substituting alternative Bt toxins. At the same time cultivation of Bt maize soon increased to approximately 1/3 of US maize fields, thus increasing any selection pressure for resistant insects.

The refuge-dilution strategy presumed that resistant individuals would be killed by a high dose of the toxin. According to this model, any Bt resistance would be a semi-recessive trait, by analogy to pesticide resistance already familiar in other pests[3]. According to new research, however, Bt resistance may be a semi-dominant trait, so that a single resistance gene confers high resistance. If so, then such genes could undergo much greater selection pressure than previously thought, and IRM measures would be less effective.

Consequently, demands mounted for more stringent controls. In response to critics, the EPA specified that farmers should plant larger refuges of non-Bt maize in specific regions, especially near cotton cultivation, where the two crops share a common pest. Representing a range of stakeholders, an expert body recommended larger refuges in some cases (ILSI, 1999). Refuge sizes were regarded by some companies as too stringent, and by NGOs as too lax. Moreover, there have been doubts about farmer compliance with refuge requirements (Dove, 2001). Nevertheless the refuge plans were standardized, thus providing a way to manage public debate as well as insect-resistance risks.

To detect any increased resistance at an early stage, some entomologists devised a new method, the F2 screen. This inter-breeds insects over two generations and tests the progeny for rare resistance alleles (Andow and Alstad, 1998). Initially this method was not adopted, partly because it is laborious and expensive. Eventually it was used to screen insects from US and French corn fields, but none could be found (Bourguet *et al*., 2003). When lab tests attempted to induce increases

[3] According to the prevalent theoretical model, insect resistance is a semi-recessive trait. That is, its expression varies with the number of resistance alleles in each individual. According to this model, homozygously resistant individuals can withstand a high dose. Heterozygously resistant individuals have an intermediate character: they can survive only minimal exposure to Bt. Homozygously susceptible individuals are killed by a low dose.

in resistance, this occurred but not enough for cornborers to survive on Bt corn (Huang *et al*., 2002). IRM measures rested on optimistic assumptions, some of which turned out to be invalid, yet no increased resistance could be found in pests of any Bt crop, even in cotton (Tabashnik *et al.,* 2003). In any case, these efforts indicate higher standards for detecting such problems in advance.

IRM methods became more controversial when Monsanto sought approval for a new Bt maize which produces a relatively low dose of the toxin, killing only about half of the rootworm pests. The EPA accepted company arguments that a 20 % refuge would be adequate to prevent resistance. According to EPA advisors, however, evidence was lacking for such an optimistic assumption, and a 50 % refuge would be appropriate for more conservative assumptions (SAP, 2002). After the agency granted approval anyway, advisors criticised its approach as 'register now, test later'. As an SAP member argued: *'The EPA called for science-based regulation, but here that does not appear to be the case… Internationally, it will hurt the case for GM crops'* (cited in Powell, 2003).

Non-target harm

Harm to non-target insects became an issue in the US in the late 1990s. Although environmental NGOs were always concerned about this risk, initially they had little basis for pressing the issue. A significant cultural obstacle was the widely presumed distinction between industrialized agriculture and far-away areas of nature conservation. An opportunity came when a lab study showed that pollen from Bt maize could harm Monarch larvae (Losey *et al*., 1999). These were followed by field studies which also reported harm, linked to pollen deposits on milkweed near maize fields (Hansen and Obrycki, 2000).

These results helped NGOs to catalyse a national debate, for various reasons. First, the Monarch butterfly has symbolic importance for nature conservation in US popular culture. Second, the prospect of toxic pollen contradicted the confident claims that GMOs pose 'no unique risks', or at least no unpredictable ones. Third, at the same time Europeans were rejecting GM products and US exports were being blocked, so challenges to safety claims gained greater attention in the US. Fourth, some US biologists now took a greater interest in non-target harm, and more sceptics of safety claims were now included in advisory bodies (NRC, 2000, 2002; SAP, 2000, 2001). According to an environmental NGO, several expert members *'are coming from our perspective'* (interview, Union of Concerned Scientists, 28.10.02).

Amid the public conflicts, the Monarch studies were cited to suggest that the EPA had inadequate scientific information for risk assessment. Advisors criticized the EPA for having failed to follow up on its own risk

concerns with appropriate research in the 1990s. At a 1999 meeting they proposed that the EPA require 'new or expanded sets of test data from registrants' (SAP, 2000). Environmental NGOs demanded that the EPA require farmers to plant buffer zones in order to protect Monarch larvae, as well as additional evidence to clarify non-target risks.

Pressures mounted on the EPA to treat evidence more rigorously when deciding whether to re-register Bt toxins in maize. In December 1999 the EPA announced that registrants would be required to submit more specific evidence about causal pathways of potential harm, especially from field studies. At the same time, EPA officers downplayed the risks through various arguments why Bt pollen could not expose Monarch larvae at harmful levels (US EPA, 2000, pp. 11-13). As advisors argued, however, the agency arguments lacked evidence or were later contradicted by additional data (SAP, 2001, p. 57).

Evidence of safety came under greater scrutiny for its relevance and quality. Regulators were criticised for double standards – applying more lax criteria to evidence of safety than to evidence of risk. In some experiments, Bt-exposed organisms fared less well than the controls, but the difference was interpreted as lacking statistical significance, because sample sizes were too small to detect differences in a meaningful way. In Bt non-target studies done for one company, moreover, investigators repeated experiments only when detecting a statistically significant effect – but not when failing to detect such an effect (Marvier, 2001). Thus further testing could identify false positives – but not false negatives. Criticizing such double standards, EPA advisors requested studies with larger sample sizes (SAP, 2000).

In a more ambitious survey, a European consultancy group scrutinized most company-sponsored safety tests on non-target harm from Bt maize. According to its report, the experimental designs were methodologically flawed – based on toxicological tests for chemicals, and so inappropriate for testing the biological pathways of plant Bt. Moreover, the experimenters did not confirm that the larvae had ingested the Bt toxin. For those methodological reasons, the negative results may have no meaning, argued the report (Ecostrat, 2000). These arguments were taken up by US environmentalists, entomologists and eventually by regulatory advisors there[4].

The US controversy over non-target harm gave greater prominence to European experiments which also indicated harm to a beneficial predator, the lacewing (Hilbeck *et al*., 1998). Initially the EPA dis-

[4] Such arguments were extended to a later type of Bt maize. Again, company-funded tests found no evidence of non-target harm. According to the agency, this product 'results in less impact on non-target invertebrates than conventional pest management practices'. In response, EPA advisors systematically questioned whether the evidence was meaningful, and they proposed better tests (SAP, 2002).

missed the lacewing results on methodological grounds. For example, technical officers suggested that no harm was attributable to the Bt toxin, or that the experiment had no relevance to field conditions. However, advisors criticized this response for double standards, *i.e.* for applying less stringent standards vis-à-vis other experiments which found no harm:

'The Hilbeck data was dismissed by the agency, based on standards that were not applied to all the work reviewed by the agency, and the Hilbeck work was singled out for an excessively critical analysis…' (SAP, 2001, p. 54).

Further taking up the Ecostrat arguments, some US scientists argued that risk research on Bt crops must 'consider the ecological complexity of agroecosystems'. They drew an analogy to past mistakes: in the rapid adoption of agrochemicals in the 1950s, ecologically based management practices had suffered, and adverse effects were ignored, thus limiting the management options for farmers. They warned against *'the acceptance of yet another silver bullet for pest management'* (Obrycki *et al.*, 2001a, p. 359).

Also at issue was the acceptability of non-target harm. Proponents of Bt maize reiterated earlier arguments that the product causes less harm than synthetic pesticides – if any harm at all. This favourable comparison implied that some harm would be acceptable, so that any uncertainties need not constrain commercial use. 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 became available for cultivation.

These pressures led to a shift in regulatory norms. When the EPA had favourably compared Bt maize to 'conventional' methods, NGOs questioned why the latter should mean insecticide sprays. Such arguments were likewise taken up by advisors, who proposed an environmental comparison with untreated fields (NRC, 2000, p. 11 and 80). Eventually EPA officials accepted the need for a non-chemical comparator:

'Comparison to chemically-treated fields does not make sense for risk assessment of Bt corn – except for sweet corn, half of which is sprayed with insecticides. An 'unreasonable adverse effect' would be any harm beyond the normal background fluctuations' (interview, EPA, 18.04.01).

Consequently the agency was now applying more stringent criteria for evidence that the toxins would not cause harm, though this did not resolve the risk issues. In early 2001 industry supplied evidence that non-target harm would not occur, mainly for three butterfly species which have the greatest resonance with public concerns (ABSTC, 2001). Environmental NGOs commissioned European entomologists to prepare a report, which criticized limitations of the available data and

of the EPA's entire approach to risk-assessment (EcoStrat, 2001). Drawing upon this report, NGOs opposed re-registration of the Bt toxins in maize. Nevertheless this was granted by regulators (US EPA, 2001).

Meanwhile risk research generated debate on further uncertainties. The new data clarified that pollen exposure from the main types of Bt maize would be inadequate to harm non-target insects, but the experiments did not test the real-world role of anthers in exposing insects to Bt toxin. According to earlier field tests, anthers could spread to milkweed and be ingested by Monarch larvae (Hansen and Obrycki, 2000). And evidence suggested that the larvae may be exposed to more maize anther material than previously assumed (Hellmich *et al*., 2001). Yet the industry-funded tests first purified the pollen, thus screening out anthers, as if they were irrelevant (ABSTC, 2001 ; cited in Ecostrat, 2001).

Several prominent US entomologists also criticized this fault in the experimental design. They proposed that the EPA requires new research using 'impure pollen', meanwhile limiting any re-registration for one year at most (Obrycki *et al*., 2001). Thus optimistic assumptions about causal pathways were again limiting the test design and available information on real-world risks. Yet the EPA accepted the data as adequate. At the same time, the agency still represents its judgements as science :

'We have reached a point where we can draw conclusions about what is a risk. We are now dealing with sound science rather than unknowns' (interview, EPA, 18.04.01).

Environmental benefits

A prominent argument for Bt crops has been that their use will result in various environmental benefits, but such claims have come under challenge. For its statutory assessment of benefits, the EPA presumed an agricultural norm of insecticide sprays, which would be substantially 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. Also, a few years after commercial use began, farmer surveys indicated that the insecticide reduction was minimal or limited to specific areas which formerly had the most spraying. Comparison was made difficult by an erratic or uncertain baseline, dependent upon annual variations in pest problems. In some cases, moreover, farmers increased sprays against secondary pests, *e.g.* the Southwest Corn Borer, which found new niches previously occupied by the ECB (USDA/ERS, 1999).

Within a few years of commercial approval, adoption reached approximately one-third of US fields. In other words, Bt cultivation became several times more widespread than the 5-10 % of maize fields

previously sprayed with pyrethroid insecticides against the ECB. EPA advisors requested evidence to demonstrate that Bt crops were really replacing insecticide sprays rather than supplementing them (SAP, 2001, p. 59). Indeed, according to surveys of farmer practice, Bt maize was being used by many farmers who had not previously sprayed pyrethroids, or was being used in addition to them. Many farmers were shifting from pest management 'to a prophylactic strategy', trying to prevent potential damage in advance (Obrycki *et al*., 2001a, p. 358).

Thus doubts were cast on claims for significant environmental benefits. Although pesticide sprays declined in some cases, they also began to increase in others. As a regulatory officer acknowledged, *'It is unclear what should be the baseline for comparison and thus whether Bt corn is saving chemical sprays'* (interview, EPA, 18.04.01). For the statutory risk-benefit analysis to justify approval, then, minimal benefits raised the stakes for any potential risks.

BT MAIZE IN THE 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.

Soon after the first GM grain was approved for food uses, it encountered commercial blockages. In 1996 the European Commission approved Monsanto's soybean for use in animal feed and processed products, without any requirement for 'GM' labelling or segregation. US exports of soybean shipments provided a target for NGOs. They encouraged or even coordinated consumer boycott campaigns against GM-derived foods. By 1998-99 supermarket chains decided to exclude GM ingredients from their own-brand products (Levidow and Bijman, 2002).

Likewise, when the first GM seed was approved for cultivation, it provoked much protest. In 1997 the European Commission authorized Novartis' Bt maize for all commercial uses, again with no specific requirements, 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 linked agriculture to ideas of aesthetic landscape, wildlife habitat, local heritage, peasant stewardship, and a traceable guarantor of food quality.

The EU regulatory procedure had no straightforward way to accommodate the protest, so member states imposed their own bans or

restrictions on GM crops. Commercial cultivation required national approval under plant variety legislation anyway. Using this procedure, France and Spain granted a time-limited approval, requiring companies to monitor fields for all risks which were cited in the public debate. Bt maize was banned at various times by Austria, Italy and Germany.

Commercial blockages and political protest together led to more cautious regulation and indecision in the EU. Extra demands and restrictions tended to circulate among member states, amid public hostility to GM crops. European regulators invoked or re-interpreted the Precautionary Principle to emphasize uncertainties which warranted more evidence of safety. However, the EU had no single authority to formalize such criteria, which anyway would remain subject to further change. Given the public opposition, since 1998 there have been no decisions on additional Bt crops in the EU-level regulatory committee which represents member states.

Let us examine how the two main risk issues for Bt maize were reframed in the European regulatory procedure (for detailed references, see Levidow *et al*., 2000.) Unlike the USA, the EU has no formal procedure for evaluating benefits, so there is no corresponding section on that issue.

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 (EC, 1997). It approved the product despite opposition from most EU member states.

Although the company had plans for measures to avoid insect resistance, doubts were raised about its optimistic assumptions, *e.g*. that the toxin would kill all heterozygous individuals (see previous footnote). Some could survive a large dose and thus transmit their resistance alleles, for several reasons. They may avoid the Bt crops, as acknowledged by Ciba-Geigy; for this scenario, more ecological information was requested early on by Belgium. As another possible reason for survival, the Bt levels declined in late-season, senescing plants. Ciba-Geigy acknowledged this decline as a weakness for its product. The low-dose problem later became an issue for farmers.

Facing protest against GM crops in general, companies attempted to

devise more credible measures for insect resistance management (IRM). For example, Monsanto submitted an undertaking to monitor its Bt maize for insect resistance during commercial use. The EU approval decision mentioned that undertaking, though without stating whether or not it was necessary in order to avoid adverse effects (EC, 1998).

In parallel, biotechnology companies planned further research to inform their high-dose/refuge strategy. The refuge design depends on assumptions about the distance traveled by insects to feed and breed, so companies also contracted entomologists to study these behaviours. Monsanto undertook to carry out lab tests for sampling insects from the field, to detect 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.

There remained the problem of how to detect any increase in resistance at an early stage. *'There is a difficulty in finding test insects whose antecedents have been exposed to Bt, survived and reproduced*', according to a Monsanto officer (interview, 08.05.98). By the time any surviving insects are found, presumably because they are homozygously resistant, resistance genes may have spread considerably in the population. Some member states demanded earlier detection through 'active monitoring'.

The EU's scientific committee recommended methods similar to the F2 screen, adapted from the USA, as an integral part of a high-dose/refuge strategy. It declared that these IRM measures would be 'adequate to delay resistance', thus implying that they were necessary (SCP, 1999). Such an imprimatur was important for a common Europe-wide approach, though the EU had no direct means to implement or enforce it. Ultimately the IRM issue remained low key : critics did not emphasize it, and few farmers bought Bt maize seeds, except in Spain. Organic farmers and others emphasized other arguments against GM crops instead *e.g.*, that contamination threatened the purity and thus market value of their products.

Non-target harm

For evaluating potential harm to non-target insects, early safety claims depended on two types of evidence. First, lab studies had indicated no harm to various insect species. Second, field monitoring found no fewer beneficial insects in Bt maize fields compared to conventional maize fields. However, in 1997 Swiss scientists obtained and publicized results which demonstrated harm to beneficial insects via tri-trophic pathways in lab tests (Hilbeck *et al*., 1998a, 1998b). A carnivorous predator – the lacewing – was harmed by eating cornborers which had ingested Bt toxin. Such predators could 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 these results. Company officers questioned whether the Swiss results had any relevance to the commercial context. According to the EU's Scientific Committee for Plants, the Swiss study had methodological weaknesses, *e.g.* 'unrealistic' experimental conditions, high mortality of the control insects, and statistical anomalies. For example :

'There is little information available on the food chain implications, e.g. at the tri-trophic level of predators. We were aware of some data which is incomplete and questionable. The Swiss study has not been replicated in the field ; and there is a question about why the controls had such a high mortality rate (37 %, as compared to 62 % for the Bt-fed insects). Non-target harm warrants further research, especially in the field, which would be the acid test' (chairman of SCP environment subcommittee, interview, 17.06.98).

In this way, the EU's expert committee was applying double standards to evidence of risk and of safety. Many studies which found no harm also warranted such criticisms, especially for their unrealistic conditions (Ecostrat, 2000). Control insects had even higher mortality in other lab studies, *e.g.* where the researcher reported that the experiment yielded no evidence of non-target harm (Riddick and Barbosa, 1998). Yet their methods or relevance were not challenged by official experts. The committee later reiterated that a series of lab studies 'have not recorded adverse effects'. When mentioning problems of 'experimental rigour', as a weak basis for extrapolating to field conditions, the committee singled out the Swiss study of lacewing, while ignoring weaknesses of other studies (SCP, 2000).

When the SCP began to acknowledge some uncertainty about non-target harm, it favourably compared Bt maize to agrochemicals. According to its advice, any harm to non-target arthropod insects 'will be less than that from the use of conventional insecticides' (SCP, 1998). Such a comparison assumed that Bt crops would simply replace pyrethroid sprays – notwithstanding their supplementary role among US farmers. Despite this contingency, some committee members portrayed their environmental norm as a purely scientific matter. According to the chair of the SCP's environmental sub-committee :

'We have to evaluate potential effects on the basis of existing agricultural practices. A comparison with chemical insecticides makes the potential harm acceptable…. This is a scientific issue… We are asked only scientific questions' (interview, 17.06.98).

A few years later, however, the same member gave a different answer to the same question :

'Safety should be understood as a relative absence of harm, which in turn depends upon a definition of unacceptable effects. This requires an extra judgement – i.e. beyond our advice…. In the future we could compare Bt maize to any non-target harm from pesticide and non-pesticide regimes' (interview, 08.07.02).

Thus an extra-scientific judgement was eventually acknowledged as such, and as an open-ended criterion for designing risk studies.

Criteria for evidence have remained contentious. Some European regulators have not accepted chemical-intensive methods as an environmental norm and they have sought to accommodate critics of GM crops through regulatory constraints or delays. To achieve this they can cite results of experiments whose design is no less realistic than the earlier experiments cited to underpin safety claims. Also, under public pressure, governments have sought to obtain more specific evidence about potential cause-effect pathways of non-target harm. The European Commission has been funding more research along those lines (CEC, 2001). Such studies have been extended to soil organisms, even though companies and the US EPA denied that Bt toxins could harm them.

CONCLUSION: REFRAMING REGULATORY SCIENCE

As this case study illustrates, regulatory science has been reframed for evaluating the environmental risks of GM crops in both the US and the EU. This process has been illuminated by the analytical perpectives surveyed earlier (and cited again here). Regulatory changes can be understood as four related processes:

– New scientific uncertainties have arisen from public-scientific debate.

– Extra-scientific judgements have been challenged within expert advice and regulatory decisions, thus being opened up to greater accountability.

– Criteria for evidence of safety have become somewhat more stringent, specifically regarding environmental norms and causal pathways which must be tested.

– Criticisms of safety claims, and demands for more rigorous tests or monitoring methods, have circulated back-and-forth across the Atlantic.

The criteria for scientific evidence have been reconstructed through socio-cultural values, public protest and institutional responses. Social conflict has contributed to disputes over scientific evidence and thus increased scientific uncertainty in some respects (cf. Wynne, 1992). Safety assumptions have been progressively challenged and turned into questions which warrant research, in turn generating new uncertainties.

As a result, regulatory criteria have been contested and often changed. Environmentalist criticisms have influenced mainstream

debates about how to define harm, how to evaluate GM crops vis-à-vis alternatives, and how to design risk research. Criteria for evidence became controversial. These criteria can be analysed as two related types of standards – environmental norms and causal pathways which must be tested.

There have been pressures for more stringent environmental norms. Early safety claims had accepted the normal hazards of intensive monoculture as an implicit baseline for GM crops. By narrowly defining environmental harm, regulation complemented the overall political agenda of economic competitiveness and trade liberalization. In response, critics counterposed wider accounts of harm or non-agrochemical comparators, thus implying a different vision of agricultural futures (cf. Jasanoff, 1993). Those demands were eventually accommodated in criteria for evaluating environmental harm or benefits from GM crops.

In parallel, there have been challenges to optimistic assumptions about the capacity to predict or manage any risks. The available knowledge was criticized as inadequate or even as misleading, *e.g.* for concealing relevant uncertainties (cf. Stirling, 1999). The controversy stimulated further research, whose results revealed more causal pathways, *e.g.* of insect resistance or non-target harm. Moreover, earlier evidence of safety was subjected to greater scrutiny; its methods or assumptions were sometimes undermined by later findings. Thus new scientific research has been both a consequence and cause of public debate.

These regulatory pressures undermined the commonplace distinction between science and politics, or (more subtly) between scientific and extra-scientific criteria. Regulatory science was opened up to debate on its value judgements – for example, what 'environment' must be protected from harm, what causal pathways must be investigated, what claims (for risk or safety) hold the burden of evidence, and what counts as adequate or relevant evidence. Initially, narrow environment norms were defended as obvious or as purely 'scientific'. Later such an issue was acknowledged to be an extra-scientific one, *e.g.* as a risk-management decision or policy judgement.

Moreover, test methods have been criticized as inadequate to model relevant causal pathways and obtain meaningful data, while regulatory judgements have been criticized for double standards which favour safety claims. Such debate has stimulated efforts to devise test methods which are more rigorous, a criterion which is debated as an extra-scientific judgement. This pressure coincides with a shift in public expectations for expert roles: from 'trust me' to 'show me'.

In those ways, any boundary between scientific and extra-scientific criteria has been contingent, contestable and changeable. At the same time, a rhetorical distinction between scientific and extra-scientific criteria has played various strategic roles – as in other cases of a contested

boundary between science and policy (cf. Jasanoff, 1987). Given the terms of their legislation and politicians' interest in hiding behind expertise, governments still attempt to justify their approach as 'science-based regulation', or even as 'sound science'. They face a dilemma in either denying or acknowledging the implicit policy-framing of regulatory science. Such an acknowledgement may gain public credibility for official judgements but would force the authorities to take responsibility for extra-scientific judgements.

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