Regulatory standards for environmental risks: understanding the US-European Union conflict over Genetically Modified Crops

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Regulatory standards for environmental risks: Understanding the US-EU conflict over GM crops

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Abstract

US (United States) and EU (European Union) approaches to the regulation of GMOs (genetically modified organisms) are often explained using the ideas of 'sound science' and the 'precautionary principle'. These stereotypes, however, can be misleading. They can conceal conflicts within jurisdictions and important interactions between them. This paper avoids these ideas and instead analyzes conflicts and interactions associated with the regulation of GMOs in the US and the EU, using the example of *Bt* maize -- a genetically modified crop. It focuses on risk assessment as a standard-setting process, and explains changes in regulatory standards. In this case, public protest and trade conflict created an opportunity for a transatlantic network of critical scientists to challenge regulatory standards and for NGOs (non-government organizations) to press for higher ones. The paper links two analytical perspectives to account for how this happened. 'Regulatory science' helps explain what happens when the 'private' government-industry-academia network associated with risk regulation is opened up to greater public scrutiny. It also helps to explain how the context and content of regulatory science mutually shape each other. 'Trading up' helps to explain opportunities and pressures to raise regulatory standards associated with US-EU trade liberalisation and trade conflict.

Key words: regulatory science; trading up; genetically modified organisms (GMOs); Bt maize; European Union; United States; transatlantic networks.

Introduction

The US (United States) claims to base its regulation of genetically modified organisms (GMOs) on 'sound science' whereas the European Union (EU) regularly invokes the 'precautionary principle'.[1] Politicians and officials from both jurisdictions have emphasised these concepts in relation to the transatlantic conflict over GM crops and foods. With this in mind it is perhaps not surprising that these ideas underlie many explanations of this conflict. Critics of the US have argued that its government ignored scientific unknowns in the name of 'sound science' and thus generated the dispute. Critics of the EU often argue in reverse that the 'precautionary principle' in Europe allowed politics to over-ride science.

In our view, however, such explanations are often misleading. They miss the complex ways in which policy makers (and others involved in the conflict on both sides of the Atlantic) use these concepts strategically and rhetorically to support their agendas. Moreover, labelling whole jurisdictions -- sound science in the US vs. precautionary principle in the EU -- overstates the level of consensus and consistency within each jurisdiction, whilst at the same time concealing important interactions between them. This concealment is particularly problematic and likely to happen during a trade conflict when the positions of the antagonists are highly polarised.

In this paper we move beyond these jurisdictional stereotypes and examine instead the role that science plays in risk assessment, which we analyse as a regulatory standard-setting process. We focus on the arguments and interactions surrounding one genetically modified crop, *Bt* maize, in the US and the EU. To analyze this case we use analytical perspectives from two areas of debate; 'regulatory science' (from Science and Technology Studies) helps us to understand the shaping of scientific knowledge used in risk assessment and 'trading up' (from Political Science) draws our attention to interactions between jurisdictions involved in trade liberalisation and conflict, as well as links to regulatory standards. Overall, for the case of *Bt* maize, we answer three questions: What types of regulatory standards can be identified? What changes in regulatory standards have occurred? How can these changes be explained?

Analyzing Changes in Regulatory Standards

'Regulatory Science' and Risk Assessment

STS scholars have studied science and its role in risk assessment in great detail. In particular they have analysed how values and interests frame the generation and interpretation of scientific evidence. As Jasanoff (1993: 129) has argued:

'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'.

The knowledge referred to here, which is used in risk assessment and is often generated specially for this purpose, has been called 'regulatory science' (also trans-science and mandated science). One early commentator described it as a 'new branch of science… in which norms of proof are less demanding than are the norms in ordinary science', particularly because of the need to predict potential effects (Weinberg, 1985: 68). Although also emphasising its predictive role, later commentators argued that it is impossible to make a straightforward distinction between regulatory and academic science. They focused instead on the complex and contingent relationship between these two.

[1] 'EU' is used throughout the paper to refer to the European Union. It is also used to refer to the European Community, the political organisation the EU replaced in 1995.

In an important contribution Jasanoff distinguished between regulatory and research science by focussing on their 'content', 'context' and relationships between these. She argued that the content of regulatory science involves three types of activities: the production of knowledge which fills gaps in the knowledge base; the synthesis of knowledge, more so than original research; and the prediction of potential effects. As regards to context, she pointed out that regulatory science is often carried out by the private sector, which can keep the results confidential, and that moreover, 'Science carried out in non-academic settings may be subordinated to institutional pressures that influence researchers' attitudes to issues of proof and evidence' (Jasanoff, 1990: 77-79). This account hints at how the context can shape the content of regulatory science.

Such observations focus our attention on peer review processes and the special ways in which regulatory science can be held accountable. Here we also see significant differences between regulatory science and research science. As Jasanoff (1990: 80 in table and 81-82) has observed, peer review of regulatory science can involve methodological assumptions that have their origins in the compositional biases of expert advisory bodies. This is somewhat different (although related) to the problem of disciplinary biases shaping academic science. In a regulatory setting, peer review by an expert advisory body plays an important role in gate-keeping, for example by judging what science is adequate or even relevant for regulatory purposes. Here again we see how the context can shape regulatory science.

Building on earlier approaches, Irwin et al. (1997) have also analysed regulatory science. They confirm its 'significance for future research and policy-making' (p. 30) but argue that researchers must avoid one-dimensional approaches. The two most common, they suggest, are the 'concerns' and 'context' approaches. The first suggests that regulatory science is different from research science simply because it deals with different questions and has a different purpose.[2] The second approach suggests that special contextual factors shape regulatory science in ways that they do not shape research science. Irwin et al. (1997: 22) argue that neither of these approaches on their own does justice to the complex nature of regulatory science. Instead they link concerns with context in order to highlight its '*heterogeneous and hybrid* character' (emphasis original). They draw attention to the many different types of regulatory science that exist, such as speculative research and the development and validation of regulatory tests.

Irwin et al. (1997: 20) also argue that public sector involvement in regulatory science can mean that it sometimes resembles academic science. They suggest that this is more often the case in the Europe than the United States. For the case of agrochemicals regulation in the UK, they emphasise the 'private' world of government-industry-academia relationships which shape regulatory science. In their conclusion they say:

> …the implications …for environmentalist and 'public interest' groups deserve serious attention: it seems possible that regulatory science effectively disenfranchises groups which cannot play an intimate role in the largely confidential negotiations discussed so far. (Irwin et al., 1997: 28)

Regarding peer review in this context, they wonder 'whether the institutional context of regulatory science will hinder external scrutiny and hence diminish the quality of scientific work' (Irwin et al., 1997: 29).

[2] Following Jasanoff, we will speak about content rather than concerns because the latter seems to be a subset of the former.

From this survey we can see that accounts of regulatory science emphasise that it is provisional and often remains vulnerable to challenge. In particular, risk assessment depends on science done 'at the margins of existing knowledge, where science and policy are difficult to distinguish', and where there is little agreement on research methods (Jasanoff, 1990: 77-79). New knowledge in this context can provoke further disputes among policy actors. More fundamentally the policy demand of predicting risk means that regulatory science 'has to transgress its own cognitive boundaries and limitations' (Irwin et al., 1997: 19).[3] Such accounts also emphasise interactions between the context and content of regulatory science, and between regulatory and research (or academic) science.

'Trading Up' and Trade Liberalization

The concept of 'trading up' tries to theorise the relationship between trade liberalisation and regulatory standards, particularly those that relate to protection of the environment and human health. According to David Vogel (1995: 5) '…trade liberalisation can just as easily be achieved by forcing nations with lower standards to raise them as by forcing nations with higher standards to lower them'. After examining various sectors and liberalising contexts, such as agri-food and the World Trade Organisation, he concludes:

'To the extent that trade liberalization has affected the level of consumer and environmental protection, it has more often strengthened than weakened it' (Vogel, 1995: 5).

Vogel identifies various mechanisms to explain why trading up rather than levelling down occurs in some situations. On the whole, these involve political power or economic rationality. For example, he argues that domestic producers can campaign for higher standards as a source of competitive advantage. In his account Vogel focuses mainly on powerful states interacting with less powerful ones through the formal institutions associated with trade liberalisation.

Beyond political power and economic rationality as trading up mechanisms, this work can also help us to understand how NGOs and public controversy might influence regulatory standards. For example:

> …when rich nations with large domestic markets …enact stricter product standards, their trading partners are forced to meet those standards in order to maintain their export markets. This in turn often encourages consumer and environmental organizations in the exporting country to demand similar standards for products sold in their domestic markets. (1995: 6)

Similarly, Vogel (1997) argues that negotiations to achieve trade liberalisation can create new opportunities for NGOs to campaign for higher standards. He gives few examples of how this mechanism works in practice but, as we show below, the case of GM crops and the EU-US conflict can provide such an example.

Vogel also discusses the role of science and risk assessment in trade liberalisation. For example, in relation to the EU-US conflict over hormone treated beef, he asks:

> …what standards of scientific proof should be required to justify a regulation that interferes with trade? In the case of the EU hormone ban, should the EU be obligated to prove that the consumption of meat from cattle which have been fed on hormones is *unsafe*, or must the United States prove that meat from hormone-fed cattle is *safe*? In

[3] By this they mean that prediction of effects in the real world is in fact beyond regulatory science because the real world will always be more complicated than any models used.

> other words, what makes a regulation that restricts trade 'necessary'? And on whom does the burden of proof of demonstrating that it is necessary or unnecessary fall? (Vogel, 1997: 16-17)

As this passage indicates, Vogel defines 'regulatory standard' broadly and in a way that intersects with the regulatory science literature discussed above.

Context and Content: Politics and Regulation of *Bt* Maize

In the rest of this paper we examine the regulation of *Bt* maize in the US and the EU. This is a valuable case because several varieties of this GM crop were approved for cultivation in both jurisdictions during the 1990s. It therefore allows us to examine conflicts and interactions. In this section we outline some key political and risk issues associated with the regulation of GM maize in general and *Bt* maize more specifically. This establishes essential background for the rest of the paper.

Trade Liberalisation and Trade Conflict

In 1995, acting on an invitation from governments, US and EU business leaders created a network called the Transatlantic Business Dialogue (TABD). This network then began to campaign for transatlantic trade liberalisation and regulatory harmonisation in a wide variety of sectors. From the outset agri-food biotechnology was one of these areas. The TABD argued that the EU and the US should adopt the same regulatory standards for GM crops and foods in order to avoid barriers to trade. The TABD argued that a longer-term goal should be 'approved once, approved everywhere'.

TABD recommendations in the area of GMOs were taken up in the late 1990s by the Transatlantic Economic Partnership (TEP, 1998a), an EU-US government-to-government network organised by trade officials as part of a 'New Transatlantic Agenda'. The TEP formed a Biotechnology Working Group, which amongst other things aimed to carry out a pilot project on simultaneous assessment of a GMO in the US and the EU (TEP, 1998b). This project would have been a first step towards regulatory harmonisation across the Atlantic. It aimed to establish that both jurisdictions would assess the same GMO in the same way and draw the same conclusion. If not, this project would highlight differences in approach which could then be examined further.

Such steps towards regulatory harmonisation were undermined in the late 1990s by European protests against GMOs. The political response to them made the TEP's work impossible. In 1999 EU Environment Council members declared that they would not consider additional GM products for commercial authorisation until new legislation was in place. As a result of this *de facto* unofficial moratorium, the TEP had to abandon its pilot project on simultaneous assessment of a particular GMO. Another consequence was that several varieties of GM maize already being grown in the US remained illegal in the EU.

From the late 1990s onwards GMOs occupied a lot of time of government officials in both jurisdictions. GM maize was at the centre of the trans-Atlantic trade conflict. Prior to 1997, the US exported 1.75 million tons of maize annually to Spain and Portugal. This quantity filled a tariff-free quota that was agreed when Spain and Portugal joined the EU. Before the 1999 conflict, this represented 4% of total US maize exports but this dropped to less than 0.1% in 2002 (PEW, 2003). This loss of exports was highlighted in 2003 when the US eventually made a formal complaint to the World Trade Organisation regarding the *de facto* Council moratorium.

Bt maize is a conventional maize plant that is genetically modified to include a gene from the microbe *Bacillus thuringiensis* (*Bt*). This gene produces a toxin that helps to protect the maize from insect pests. Target insects ingest the toxin when they consume parts of the maize plant. *Bt* maize was one of the first commercial products associated with the scientific and technological developments that made it possible to insert genes into crop plants (*Bt* cotton and *Bt* potatoes are also currently available). However, critics of *Bt* crops have identified various related environmental risks. We focus on two in this paper.[4] First, they have pointed out that constant exposure to the *Bt* toxin could generate insect resistance in the target pest population. Second, they argue that the *Bt* toxin could also harm non-target insects, including beneficial predator insects.

Supporters and critics of *Bt* crop technology have framed both of these risks in different ways at different times. For example, some proponents have argued that these risks are acceptable because they are no worse than those that already associated with the use of chemical insecticides in conventional agriculture. Critics, however, have challenged this. They argue that it is wrong to simply assume that chemical insecticide-based agriculture is the right comparator. They point to other agricultural regimes that could also be used for the purpose of comparison. We argue below that the choice of comparator -- a normative judgement -- is an implicit regulatory standard, which frames regulatory science and risk assessment in particular ways.

More specifically there have been scientific disagreements about the detection and assessment of impacts. For example, non-target harm was originally examined using direct toxicity tests drawing on the model of toxicity that underpins the testing of agricultural chemicals. This model assumes that a toxin is ingested directly by a non-target insect. However, critics challenged the use of this model in relation to *Bt* crops and pointed instead to research on indirect causal pathways of harm. Critical scientists tested whether non-target insects might be harmed if they ate target insects that had previously ingested the *Bt* toxin. In this paper we analyze such conflicts around test methods as a standard-setting process.

Much of the evidence that shows how companies and regulators have dealt with these issues can be found in company submissions to regulators and the responses to them. In both the US and the EU, the regulatory process for a *Bt* crop begins with the submission of a dossier to the regulator. The dossier includes basic information about the product and information on safety tests that have been carried out. The regulator then evaluates the submission and makes a judgement. Explicit and implicit regulatory standards are involved (devised and agreed) in this exchange and they can be uncovered through interviews with participants and analysis of the relevant documents.

US Regulation of *Bt* Maize

The starting point for the regulation of GMOs in the US was the Coordinated Framework for Regulation of Biotechnology (OSTP, 1986). In this document the US Government made it clear that GMOs would be regulated under existing legislation, such as regulations for food

[4] To emphasise the fact that this discussion does not cover all risks associated with GM crops it is worth noting that herbicide tolerant crops also became controversial in the 1990s. This was largely due to impacts associated with broad-spectrum herbicides, which kill all other plants and thus wildlife habitats. In contrast, *Bt* crops became controversial because of their internally produced toxin, even though biotechnologists emphasised the specificity and targeted nature of its impact. In each crop category different risks have come to the fore at different times. Associated efforts to open up or shut down discussion of risks is central to the conflict between those in favour and those against the technology.

and agricultural chemicals. No new legislation was planned. Various judgements underpinned this decision: GM techniques produce precise genetic changes; GMOs pose 'no unique risks'; and risks associated with GMOs are predictable. GMOs generally were not seen as a novel category of organism, nor a source of unique risks (Levidow and Carr, 2000).

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the US Environmental Protection Agency (EPA) was required to conduct a risk-benefit analysis of all new pesticides. This act required the EPA to balance any 'unreasonable adverse effect' against environmental benefits. Initially, however, it was unclear whether this requirement extended to *Bt* toxins *in* plants -- eventually called Plant Incorporated Protectants (PIPs). However, in the early 1990s, the EPA claimed the authority to regulate PIPs. It assumed that *Bt* crops would mainly replace chemical insecticides, thus leading to a 'significant reduction in risk' with additional environmental benefits. In the mid-1990s, using similar arguments, the EPA approved several types of *Bt* maize.

Insect Resistance to Bt

Insect resistance to *Bt* crops emerged slowly as an issue during the 1990s. In the early part of the decade some biotechnology companies argued that it was not a risk regulation issue or even a significant problem. They argued that if insect resistance developed they could identify and insert alternative *Bt* toxins into crop plants. The President of one US company stated: 'We have many bullets in the gun which we call *Bt*' (cited in Cutler, 1991). In the mid-1990s, however, the issue began to attract more attention and interested individuals and groups began to attend conferences to discuss Insect Resistance Management (IRM). The consensus was that IRM strategies would have two key elements: (1) *Bt* crops designed to express the *Bt* toxin in a sufficiently high dose to kill nearly all insect pests; (2) refuges of non-*Bt* crops planted nearby so that susceptible insects could interbreed with resistant ones. Not surprisingly, there were differences of opinion on what a sufficiently high dose might be and how close and how large non-*Bt* crop refuges should be.

Insect resistance also became a more public issue in the US in the mid-1990s. The EPA's unconditional registration of a *Bt* potato in 1995 was one of the main triggers for this. The EPA placed no obligation on the company involved to prevent insect resistance. In response, a network of environmental groups, organic farmers and entomologists began to protest. They argued that 'natural' *Bt* is a public good and should be protected as an option for organic farmers and that widespread commercial planting could generate insect resistance.[5] This growing concern produced a commercial response. Significantly, biotechnology companies began to ask farmers to plant non-*Bt* maize refuges on a voluntary basis. However, refuge guidelines and their implementation remained a contentious issue. Refuge sizes in the US corn belt varied from 0-20% of planted area (Hutchison and Andow, 2000; US EPA, 2001). In 1998 one company regulatory manager argued that a 5% refuge level might be enough to delay resistance. He added that farmers might ignore more stringent guidelines anyway (Head, 2000).

In the late 1990s entomologists and environmental groups mounted a more sustained challenge to the EPA's hands-off approach. New scientific research played a central role. For example, evidence from laboratory studies suggested that insects could develop resistance more quickly than originally thought. Research also showed that some insects had a gene that conferred resistance to several *Bt* toxins. This cast doubt on the possibility of substituting one *Bt* toxin for another (Andow and Hutchison, 1998).

[5] *Bt* sprays from naturally accruing micro-organisms can be used for pest control.

At this time, the EPA's approach was also challenged by agronomic developments. The EPA had argued that conventional maize fields would delay insect resistance by providing 'unstructured refuges'. However, *Bt* maize cultivation had increased rapidly to approximately 1/3 of all fields. This raised doubts about the efficacy of unstructured refuges. In addition this level of cultivation was high in comparison to the 5-10% of maize fields that had previously been sprayed with insecticides against the European Corn Borer. This indicated that *Bt* maize was not simply replacing conventional maize in areas where agricultural chemicals had been used to control specific pests, thus raising doubts about the EPA's belief in wider environmental benefits associated with *Bt* maize.[6]

In the late 1990s the EPA's own Scientific Advisory Panel (SAP) recommended that it should embrace the idea of mandatory refuges to control insect resistance to *Bt* maize (SAP, 1998). In doing so they drew on the work of critical scientists published by the Union of Concerned Scientists (UCS, 1998). Eventually an expert body representing biotechnology companies and academic scientists reached a consensus on refuges. This group made recommendations on refuge sizes whilst also acknowledging ongoing scientific uncertainties (ILSI, 1999).[7] Building on some existing requirements, the EPA then put in place mandatory refuge requirements for all *Bt* field corn products for the 2000 growing season (US EPA, 1998; US EPA, 2001). The target pests were European Corn Borer, Corn Earthworm and Southwestern Corn Borer. For any area sown with *Bt* maize, a refuge area of one-fifth its size was required to be planted with conventional (non-*Bt*) maize within half a mile, or within a quarter of a mile in areas where insecticides had historically been used to treat corn borers. For areas where most cotton was grown, the EPA required a refuge of half the size to be planted with conventional maize for certain types of *Bt* maize. This larger refuge was deemed necessary to delay resistance in Corn Earworm populations that feed on both maize and cotton.

Risks to Non-Target Insects

Environmental groups were concerned about the impact of Bt crops on non-target insects from the outset, but this did not become a public issue in the US until the late 1990s. Drawing on the results of direct toxicity tests -- of the kind used to test agricultural chemicals -- applicants and the EPA had judged that *Bt* crops did not represent a risk. The significant development in 1999, however, was a Cornell University laboratory study showing that pollen from *Bt* maize could harm the larvae of the Monarch butterfly (Losey et al., 1999). This was followed by further research that linked harm to pollen deposits on milkweed plants, an important food plant of the Monarch caterpillar (Hansen-Jesse and Obrycki, 2000).[8] For several reasons environmental groups were able to use this research to launch a national debate in the US. Significantly, the Monarch butterfly is a wildlife symbol so NGOs were able to use it to undermine the cultural distinction between areas where industrial agriculture is practised and areas where nature conservation takes place. Also, the Monarch butterfly migrates internationally, has special aesthetic qualities and butterfly fanciers are an organized constituency. In addition, they could argue that 'toxic pollen' contradicted the claim that GMOs posed no unique or unpredictable risks.

[6] A number of factors help to explain the wider adoption of *Bt* maize as compared with chemical control methods. Insecticides are not very effective after the corn borer larvae have tunnelled inside the plant. Also, corn borers are not a pest in all areas every year, and so chemical control methods are not always used. *Bt* within a plant acts against corn borers in the stalk; because the seeds are planted at the beginning of a season, they do not simply respond to the emergence of a problem during the season.

[7] '…any recommendation of refuge size must be based partly on scientific evaluations and partly on a consensus of perceived risk… Because of the uncertainty surrounding several of the model parameters, other interpretations and recommendations could be made' (ILSI, 1999: 6).

[8] This experiment involved feeding larvae, in the lab, on milkweed plants that had previously been placed within, and at varying distances from, a *Bt* maize crop shedding pollen.

Responses to the Monarch research were defensive at first. Critics argued that the methodology involved an unrealistically high dose of *Bt* pollen, so that it was impossible to draw conclusions about exposure in the field. As a result, they argued, the regulatory implications were at best unclear (see for example Hodgson, 1999). Such criticisms circulated at Cornell University and more widely. On a pro-biotech website linking scientists cross the Atlantic (BioScope), articles questioned the research methods and raised concerns about exaggerated risks as a political use of science (Rautenberg, 1999a, 1999b).

Despite the efforts to ignore or discredit the research, it was used to criticise the EPA. Critics claimed it showed that EPA risk-benefit assessments had been based on inadequate science. At a meeting in 1999 the EPA's Scientific Advisory Panel stated:

'It is disappointing and perplexing that the Agency failed to follow through and address the questions its personnel identified in the 1980s. These same questions now appear to be emerging issues, i.e. monarch butterfly and *Bt* corn' (SAP, 2000: 16).

At the same time environmental groups argued that the EPA should require farmers to plant buffer zones to protect Monarch larvae.

In the late 1990s the stakes were high because the EPA was approaching a deadline to decide whether or not to re-register *Bt* toxins in maize. This decision was expected in 2000. At this time the US was also already embroiled in the trade conflict with the EU with potential implications for the worldwide regulation of GMOs. There was, therefore, considerable pressure on the regulatory oversight system for GM crops in the US and perhaps not surprisingly there were significant institutional changes in the area of expert advice. The US Department of Agriculture asked the National Research Council to evaluate existing regulatory procedures and capacities in the area of GM crops. The panels that were set up for this purpose included sceptics of safety claims, whose input was reflected in the final reports (NRC, 2000, 2002). As one NRC expert member stated:

'[The NRC] have got more sophisticated about who they put on committees in order to represent the diversity of opinions. That is one of the ways in which change internationally has affected US policy' (interview, NRC expert member, September 2003).

Similarly, more critical scientists were included in the EPA's own advisory bodies (SAP, 2000, 2001).

In December 1999 the EPA issued a Data Call-In in relation to the re-registration of *Bt*-toxins in maize. Companies had to submit more evidence on causal pathways of potential harm, drawing particularly on *Bt* pollen field studies. Industry supplied evidence that non-target harm would not occur in practice. This evidence related mainly to three butterfly species. Industry admitted that harm might result from one *Bt* maize variety, *Bt*-176 from Novartis, because it had relatively greater expression of *Bt* in pollen (ABSTC, 2001). However, this variety was being phased out anyway, partly because its *Bt* levels declined during the growing season. The research results were published by the National Academy of Science and pre-publication copies were made available to inform the re-registration debate (see for example Hellmich et al., 2001).

US NGOs commissioned a group of European entomologists to prepare a report (EcoStrat, 2001) and then used its arguments to oppose re-registration (UCS, 2001). In addition, the NGOs argued that the industry submission evaded further questions about research methods. For example, although the new research showed that pollen from *Bt* maize would not harm non-target insects, it did not examine the role of maize anthers. Industry-funded research had

used purified pollen with anthers screened out, as if they were irrelevant (ABSTC, 2001; cited in EcoStrat, 2001). This was despite the fact that earlier field tests had indicated that anthers could spread to milkweed and be ingested by Monarch larvae (Hansen-Jesse and Obrycki, 2000; see also Hellmich et al., 2001). Several prominent US entomologists also criticised the research in the industry submission to EPA (Obrycki et al., 2001b). In their view, optimistic assumptions about causal pathways were again limiting research design and the available information about real-world risks.

The EPA eventually made a judgement on the re-registration of *Bt* maize based on the new safety data in 2001 -- the *Bt* re-registration decision had been delayed by a year because of the various difficulties. The EPA decided in favour of *Bt* maize, registration was not limited to one year and they did not impose any buffer zone requirements. The EPA argued that *Bt* pollen poses no significant risk (US EPA, 2001).

Monsanto's Anti-CRW Bt Maize

A more recent case from the US, which led to further conflicts over regulatory science, helps to extend our narrative. In 2002 Monsanto sought approval for a *Bt* maize product that offers protection against Corn Root Worm. Insect resistance was particularly controversial in this case because the variety produces a relatively low dose of the *Bt* toxin -- giving it greater potential to encourage insect resistance. Environmental NGOs argued for a 30% refuge requirement (UCS, 2002). The EPA's advisors concluded that the evidence on which to base a decision was lacking and that a more stringent 50% refuge would be appropriate (SAP, 2002).

When the EPA came to its decision it accepted Monsanto's proposal of a 20% refuge. The agency noted that 'there are no registered microbial or PIP products for the control of this organism'. With this comment it implied a relatively less stringent norm for the acceptability of resistance in this case. However, Monsanto was asked to revise its IRM plan in consultation with its critics and the product was authorised on a time-limited basis with a 'further research' requirement (US EPA, 2003).

Non-target harm was also contentious in this case. Industry-funded tests found no evidence of harm to non-target insects and an initial evaluation by the EPA found that the product 'results in less impact on non-target invertebrates than conventional pest management practices'. In response, however, NGOs argued that there was a need for caution (UCS, 2002). The EPA's advisors also systematically questioned the evidence for safety and made several recommendations (SAP, 2002). Once again their arguments drew upon the work of EcoStrat and UCS. As a condition of registration the EPA required Monsanto to undertake 'appropriately designed field monitoring during the initial years', in order to test long-term effects (US EPA, 2003).

In sum, the EPA basically accepted Monsanto's data as adequate to register anti-CRW *Bt* maize. However, at the same time it tried to accommodate critics by imposing extra requirements on commercial use. Environmental NGOs opposed registration, but they also acknowledged that the data requirements in this case were more stringent than had been the case for earlier high-dose *Bt* crops. Some of the EPA's advisors responded to the decision with sarcastic characterizations of the EPA's approach as 'register now, test later'. One SAP member argued: 'The EPA called for science-based regulation, but here that does not appear to be the case…' (cited in Powell, 2003).

EU Regulation of *Bt* Maize

From the outset the EU took a very different approach to regulating GMOs. As outlined above, in the mid 1980s the US Government judged that GMOs were not a novel category of organism and that they would not be a source of unique risks. On this basis they declared that existing legislation was sufficient. EU policy makers reached the opposite conclusion and decided that GMOs created a need for new regulations. Starting in 1990, GMOs in the EU were regulated under the Deliberate Release Directive 90/220 (the Directive). This legislation required member states to ensure that GMOs would not cause 'adverse effects'. It also established an EU-wide approval procedure for commercial use.

In the EU, also unlike the US, there was well-organised opposition to GM products as early as 1997. In 1996 the European Commission approved a Monsanto GM soybean for use in animal feed and processed products. US soybean shipments then provided a target for organized opposition to the technology. Opponents accused governments of 'force-feeding us GM food'. NGOs successfully encouraged, and to some extent coordinated, a widespread public backlash and consumer boycott. In the late 1990s major supermarket chains in Europe decided to exclude GM ingredients from their own-brand products (Levidow and Bijman, 2002). Then, in June 1999, the EU Environment Council imposed an unofficial *de facto* moratorium on the authorisation of new GM products (FoEE, 1999).

Insect Resistance to Bt

In 1997, despite objections from most member states, the European Commission (EC) approved the first *Bt* maize product for commercial cultivation in the European Union. At this time, largely because of ongoing debates in the United States, insect resistance was already recognised as a potential problem and companies were developing IRM strategies for use in Europe for commercial reasons. When they applied for product authorisation, however, the same companies argued that insect resistance was an 'agronomic problem' and not an 'adverse effect' on the environment. Using this argument they were able to claim that insect resistance was not covered by the Deliberate Release Directive. The EC agreed and on this basis approved Ciba-Geigy's *Bt*-176 maize in early 1997 (EC, 1997).

Despite this apparent success, however, companies became more cautious about insect resistance as they faced widespread protests against GM crops and more focussed criticism of their IRM strategies. For example, in a subsequent application Monsanto included a plan to monitor its *Bt* maize for insect resistance during commercial use. The EC's approval decision for this product mentioned this plan even though it had previously judged that insect resistance was not covered by the Directive (EC, 1998). Companies also planned further research on the high dose/refuge strategy. For example, Novartis (formerly Ciba-Geigy) commissioned entomologists at the University of Milan to establish a baseline of prior susceptibility to *Bt* in insect populations.

Even though there was generally more criticism in Europe of the scientific and normative basis for authorising products, insect resistance remained a minor issue there compared to the US. There were are a number of reasons for this difference. First, few European farmers bought *Bt* maize seeds, except in Spain, where there was limited protest against GMOs. Other European farmers were deterred by the widespread anti-GM feeling and by the retailers' boycott of GM grain. Second, opponents of agri-biotechnology did not focus on the insect resistance issue, partly because it might be seen as a manageable risk. Instead they emphasised other issues, such as non-target harm and 'GM contamination' of conventional products.

Risks to Non-Target Insects

When companies applied for *Bt* crop authorisation in the EU, their safety claims in relation to non-target harm were based on two types of evidence. They argued that laboratory studies revealed no harm to various insect species and that field monitoring had found no fewer beneficial insects in *Bt* maize fields compared to conventional maize fields. However, these claims were undermined in 1997 when Swiss scientists reported laboratory results showing harm to lacewing, a beneficial predator insect (Hilbeck et al., 1998a, 1998b). This research involved a 'tritrophic' experiment (one involving three levels of the food chain). It suggested that lacewing were harmed when they ate corn borers which had themselves ingested a *Bt* toxin. The researchers argued that more research should be done on indirect causes of non-target harm. They also argued that tritrophic research raised doubts about the value of the direct toxicity tests that the industry were using to test *Bt* toxins in plants.

As had occurred with the Monarch studies in the US, a debate over the relevance and adequacy of the lacewing experiments followed. Industry representatives questioned whether the results had any implications for commercial field cultivation. The EU's Scientific Committee for Plants (SCP) also criticised the research, and in doing so scrutinized research that produced evidence of risk more stringently than research that did not. For example, questions were raised about the high mortality rate of control insects in the lacewing research, but not about even higher mortality rates in other studies, particularly when the researchers reported no evidence of non-target harm (Riddick and Barbosa, 1998). The SCP therefore appeared to single out the lacewing research for criticism and ignore the weaknesses of other studies (SCP, 2000).

As it had in the US, the non-target harm issue also led to a wider debate about the baseline of acceptable harm. From the outset regulators assumed the comparator of conventional agriculture. According to the EU's Scientific Committee on Plants, any harm to non-target arthropod insects 'will be less than that from the use of conventional insecticides' (SCP, 1998). One member portrayed this as a purely scientific issue:

> 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, Chairman, SCP Environmental Sub-Committee, June 1998).

Not surprisingly critics targeted those assumptions. When the same issue was raised a few years later, the same respondent implied that a more stringent norm might be appropriate:

> Safety should be understood as a relative absence of harm, which in turn depends upon a definition of acceptable 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, June 2002)

Throughout the late 1990s, to accommodate the wider public controversy, regulators in EU member states delayed the regulatory process by citing results from experiments that indicated potential risks. These experiments were no less realistic than those that showed no evidence of harm. At the same time regulators moved away from simply accepting conventional agriculture as an obvious norm against which to compare *Bt* crop agriculture. The European Commission also funded more ecologically-informed research on non-target harm (DG Research, 2001, 2003). To some extent these delays and changes anticipated more stringent regulatory criteria.

Significant changes were made to the EU's regulatory regime in 2001 when the Deliberate Release Directive was revised. Particularly important changes involved the 'adverse effects' criteria. For example, environmental risk assessment was broadened to include 'risk to human health and the environment, whether direct or indirect, immediate or delayed'. The new legislation also required companies to submit monitoring plans to confirm any assumptions made in their risk assessments (EC, 2001). More detailed risk assessment guidelines mentioned insect resistance (EC, 2002). Some member states proposed mandatory monitoring for non-target harm in 2003, going beyond the companies' proposal to monitor for insect resistance only (EuropaBio, 2002); the former issue was still unresolved by early 2005.

Transatlantic Interactions and Networks

In this paper so far we have described conflicts within the US and the EU associated with the regulation of Bt maize. In relation to insect resistance and non-target harm, in both jurisdictions, there was pressure for higher standards of risk assessment and regulatory oversight. Having analysed each jurisdiction in turn, in this section we focus on transatlantic interactions and networks involved in the standard setting processes.

F2 Screen and Insect Resistance

Detection at an early stage is one of the main problems associated with assessment (and management) of insect resistance. Using conventional methods, by the time any resistant insects are found resistance genes can be widespread in an insect population. To overcome this problem some US entomologists developed a more sensitive test called the F2 screen. This involves interbreeding insects over two generations and testing their progeny for rare resistance alleles (Andow and Alstad, 1998). This new test was a potential replacement for the discriminating dose test, which is widely used by companies. Significantly, the F2 screen emerged at the same time as some EU member states began to demand earlier detection of possible insect resistance through 'active monitoring'. In response to this demand, scientists based at INRA (National Institute for Agricultural Research) in France adapted the test. It was also recommended by a working group of EU regulatory officials and then by the relevant EU scientific committee (SCP, 1999). Although they had no direct means to implement or enforce this recommendation, this illustrates how a US development was taken up in the EU.

From 2003 onwards an EU-funded research project used the F2 screen to test insects from maize fields on both sides of the Atlantic. No resistance was found and the researchers concluded that it 'is probably rare enough in France and the northern US corn belt for the high-dose plus refuge strategy to delay resistance to Bt maize' (Bourguet et al., 2003). Likewise, some US university projects took up the new technique. In one example lab tests were used to induce increases in resistance in corn borers. This occurred but not enough for corn borers to survive on *Bt* maize (Huang et al., 2002, for other related research see Tabashnik et al., 2003). In practice, howver, companies have continued to use the discriminating-dose test, despite the SCP (1999) recommendation to adopt the F2 screen test. This is partly because the latter is more laborious and expensive, but some critics argue further:

> I think the deeper reason is that they don't really want to find resistance because in their minds it will automatically mean that failure is around the corner… If you use cheap methods, you'll never find it, and it [any greater resistance] becomes a customer satisfaction problem. (Interview, SAP member, September 2003)

Regardless of whether or not companies have such motives, the F2 screen is an example of a more sensitive test, originally developed by US scientists, which was taken up in Europe by

scientists and expert advisors. It illustrates both the pressure for higher standards and transatlantic dynamics.

EcoStrat and Non-Target Harm

As outlined earlier, non-target harm became a dynamic area of debate in the late 1990s with new research and an emerging US-EU network of critical entomologists playing an important part. A European entomologist, temporarily based in the US, developed the tritrophic test that eventually identified harm to the lacewing (Hilbeck et al., 1998a, 1998b) -- her project was funded by the Organisation for Economic Cooperation and Development and the Swiss National Science Foundation. As the validity of the lacewing results was being debated, the project leader set up the EcoStrat consultancy. European pressure groups then contracted EcoStrat to identify weaknesses in the evidence for the safety of *Bt* maize (EcoStrat, 2000). These developments then had implications in the US. On the basis of EcoStrat's European work, Greenpeace contracted further studies which criticised regulatory oversight by the US EPA (EcoStrat, 2001). It was this EcoStrat critique, more so than the lacewing research, which was taken up in the US. In particularly, the EPA's own Scientific Advisory Panel criticised the EPA for applying a double standard to evidence of safety and risk.

'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: 54).

Transatlantic links were particularly important for US environmental groups during the debate about the lacewing research because few US scientists were willing to make public criticisms along these lines. As a result US environmentalists looked to European scientists. One commentator said:

> We need someone like Angelika Hilbeck because most agricultural scientists in the US are unwilling to write reports for NGOs. We operate in a socially different environment here, where US academics are unwilling to be seen as NGO consultants. Their colleagues fear that strong criticism of safety claims could lead regulators to restrict GM crops. (interview, US NGO scientist, April 2002)

Following the intervention by EcoStrat, however, more critical US scientists began to engage with the non-target harm issue. Some extended the critique and argued that risk research on *Bt* crops must 'consider the ecological complexity of agroecosystems'. They drew an analogy to past mistakes and the rapid adoption of agrochemicals in the 1950s. They argued that at that time ecologically based management practices had suffered, and adverse effects were ignored, thus limiting the management options for farmers. They also warned against 'the acceptance of yet another silver bullet for pest management' (Obrycki et al., 2001a: 359).

In an interview, and speaking in relation to risk in general rather than any specific risk, a UCS representative tried to clarify the practical meaning of 'more stringent' regulatory standards:

> More stringent standards pertain to a wider range of risks evaluated, more than to the quality of evidence submitted…. Over seven years the EPA has learned more about what questions to ask, but it hasn't clarified the data requirements, nor criticised the data which it receives. There is no improvement in the quality of studies being done… (interview, Union of Concerned Scientists, October 2002).

At the same time, such NGOs saw public funds as a means to improve the quality of regulatory science:

> Scientists who receive risk-assessment grants from government agencies want to publish journal papers, so they will have higher standards… Scientists on the SAP could also push the agency to raise standards. But this would be a slow, slow process (email, Union of Concerned Scientists, August 2003).

Regulatory Standards: Types and Changes

What types of regulatory standards can be identified in the case of *Bt* maize? Drawing on our earlier discussion, we can identify three types of regulatory standards, as summarised in Table 1. Each type links new knowledge to framing visions of the social and natural order (cf. Jasanoff, 1993). First, there are regulatory standards implicit in normative judgements, which can favour some agricultural cultivation methods over others. A good example is the initial decision to compare the non-target impacts of *Bt* crops against conventional (chemical) agriculture rather than less intensive forms. Second, there are regulatory standards associated with risk assessment, such as the testing methodologies that have been accepted as appropriate or judged as inadequate for identifying potential harm. These in turn have depended on models of causal pathways. Such standards are also implicit if regulators simply regard particular tests as acceptable, but they become explicit if written down in guidance. Third, there are regulatory standards associated with risk management measures. These more clearly assign institutional responsibility for potential effects. Standards of this kind are usually made explicit as a statutory condition of product authorisation. This category includes the spatial specification of non-*Bt* refuges used to delay insect resistance, for example.

What changes in regulatory standards can be identified? In the area of normative judgements, there have been important changes. For example, in the EU it was argued initially that insect resistance was acceptable because it was only an 'agronomic problem'. Although companies did not officially change their view, they began to submit monitoring plans under European legislation, and in this way began to act as if insect resistance is an 'adverse effect' on the environment. Similarly, in the US it was argued initially that insect resistance is acceptable because individual *Bt* toxins are dispensable. Over time this argument was undermined by the argument that insect resistance must be avoided because *Bt* toxins are a public good.

There have been similar changes to normative judgements in relation to non-target harm. In both the US and the EU it was initially argued that non-target harm is acceptable if it is no greater than that which is associated with chemical insecticides. By making this argument its proponents were assuming that the use of chemical insecticides is the appropriate comparator against which to assess the impacts of *Bt* maize. They also assumed that *Bt* maize would only replace conventional maize in areas previously sprayed with insecticides. However, this comparator has become less acceptable and impacts of *Bt* maize are increasingly compared more with those of other agricultural regimes, particularly non-chemical ones. Developments have also shown that in practice *Bt* maize is cultivated more widely and does not simply replace conventional maize in areas previously sprayed with insecticides.

In the area of risk assessment, changes in regulatory standards are seen in the emergence of new research questions and methodologies. In many cases the optimistic assumptions of regulators and others were recast as issues that require further research and in some cases the development of new test techniques. For example, in relation to non-target harm, the tritrophic lacewing experiments contributed specific data and highlighted the limits of direct toxicity tests. The direct toxicity test had been appropriated from the testing of agricultural chemicals and it was not designed to examine biological pathways. In relation to insect resistance, the F2 screen emerged as a more sensitive test method, compared to the discriminating dose test. More generally, US and EU regulators treated research that indicates

harm more rigorously than research that indicates safety, but later they were put on the defensive in relation to this double standard.

Finally, there were also some changes in regulatory standards in the area of risk management. The insect resistance problem, for example, led to a debate over refuge requirements and specifications. Over time the EPA moved towards actually specifying refuge sizes, thus leaving behind the idea of 'unstructured refuges', which it had previously regarded as adequate to control insect resistance. Changes in regulatory standards in relation to non-target insects are less clear, however. Although buffer zones were proposed in the US by environmental NGOs in 1999, the EPA did not make them mandatory. Across the Atlantic some EU member states proposed mandatory monitoring for non-target harm from *Bt* maize.

This preliminary analysis therefore shows that many regulatory standards became more stringent over a relatively short period. Most of the evidence for this comes from the US rather than the EU, where the regulatory procedure was suspended between 1999-2002. It also shows how regulatory standards of different kinds are related. As normative judgements about unacceptable effects became more stringent, this in turn created pressure for more sensitive methods to test for such effects. In the area of risk assessment, evidence of safety and risk was variously criticised on the grounds that the methods were not sensitive enough or did not adequately simulate realistic exposure or causal pathways. As the evaluation of test methods and results became more stringent, pressure created a context more favourable to ecological perspectives. Also, when they evaluated test results for making risk management decisions, regulators increasingly applied more conservative assumptions about the limits of those methods. More stringent risk management measures were ways to manage the uncertainties associated with potential risks and detection methods. The controversy in general led to more public funds to support more rigorous research.

Explaining Changes in Regulatory Standards

Regulatory Science: Mutual Shaping of Context and Content

Earlier sections of this paper have identified and described changes in regulatory standards in the US and the EU. How can these changes be explained? Before the public controversy over GMOs and subsequent trade conflict, there had been little critical discussion of regulatory science and few opportunities for critics to generate such a debate. In this context regulators ignored or denied relevant unknowns about potential risks. Later, however, transatlantic networks of critical scientists and NGOs used the public controversy in Europe to generate a critical debate about the regulation of GMOs. By citing novel hazards, they raised concerns about the normative and scientific basis of regulation. In this new context, regulatory officials engaged with more critical views and in some cases accommodated them. They did this partly by changing the regulatory standards associated with risk assessment and risk management.

This case illustrates, therefore, what can happen when the relatively 'private' world of regulatory science is opened up to greater public scrutiny (see Irwin et al., 1997). In the case of *Bt* maize, various optimistic assumptions were made by the biotechnology industry these were taken up by regulators. Critical scientists and NGOs later challenged these and turned them into issues requiring further research and/or control measures. This happened in all three areas discussed above -- normative judgements, risk assessment and risk management -- often in interlinked ways. Further research clarified some issues but was also interpreted as highlighting additional sources of uncertainty. There were then further arguments about whether experiments adequately simulated conditions in agricultural fields. These processes illustrate the provisional nature of regulatory science.

Contextual features of this case include new technology, public controversy, trade conflict and transatlantic networks of critical scientists and NGOs. The significance of transatlantic networks is seen particularly clearly in the role played by the EcoStrat consultancy. As outlined above, following its critique of regulatory standards in Europe, EcoStrat was commissioned by an NGO based in the US to critique the US EPA's handling of *Bt* maize risks. The EPA's Scientific Advisory Panel then took up elements of the EcoStrat critique and helped to translate them into more direct pressure on the EPA. In this way US critics appropriated European arguments and used them to shape regulation of *Bt* maize in the US.

Our case also confirms the importance of the relationship between the composition of expert advisory bodies and regulatory science (Jasanoff, 1990; Irwin et al., 1997). Starting in the late 1990s, US expert bodies began to include more critical scientists who took up arguments from NGOs and European scientists. In particular they challenged the EPA's double standards applied to evidence of risk and safety (e.g. SAP, 2000; NRC, 2000). More critical peer review of this kind was linked to the changing context of the risk debate and to the changing composition of expert bodies. In the EU system some member states and their expert advisors played a peer review role that was functionally similar to that of US expert bodies.

Drawing on the above examples, we can also derive insights into the links between funding sources and standards of regulatory science. In both the US and the EU, regulatory conflicts led to more publicly funded risk research, which was more academic in origin. This was set against earlier research that had been mostly conducted or funded by companies and standards became more stringent in various ways. For example, the EPA began to evaluate a wider range of risks whilst at the same time considering test methods that were more refined and of higher-quality As a result, public funding influenced both the breadth and quality of regulatory science.

More generally this case illustrates the mutual shaping of the context and content of regulatory science. Content influenced the context, particularly as critics of agricultural biotechnology used new evidence of risk to undermine optimistic assumptions about safety. This led to changes in expert judgements and regulatory science more generally. Following the public backlash in Europe and the transatlantic trade conflict, the new context influenced the content of regulatory science in various ways, particularly by generating more plural forms of advisory expertise and introducing more publicly funded research. More stringent agri-environmental norms and novel methods of testing more complex uncertainties were also outcomes. These dynamics illustrate the hybrid character of regulatory science, linking its content and context (Irwin et al., 1997).

US-EU Trade Liberalization and Trade Conflict

US-EU trade liberalization was an important context within which the regulation of GM products was shaped in the mid 1990s. We outlined earlier the roles played by the Transatlantic Business Dialogue and the Transatlantic Economic Partnership in promoting regulatory harmonisation. These groups planned to undertake a pilot project on the simultaneous assessment of a GMO in the US and the EU in the late 1990s. However, the public controversy over GMOs in Europe blocked that agenda and led instead to a trade conflict. The 'trading up' perspective helps to highlight the relationship between these inter-jurisdictional dynamics and regulatory standards.

As mentioned earlier, Vogel argues that trade liberalisation and trade conflict can create opportunities for NGOs and others to campaign for higher standards. This is one of many possible mechanisms for trading up. Although the TEP Biotechnology Working Group did not directly attract the attention of NGOs, it was part of the EU-US New Transatlantic

Agenda (NTA), which did attract such attention. Multi-sectoral trade liberalisation was central to the 1995 agreement on the NTA. NGOs feared that the TABD was a force for 'levelling down standards and they criticised the exclusion of NGOs in the NTA/TEP process. Agricultural biotechnology is just one area in which the Transatlantic Business Dialogue, the New Transatlantic Agenda and the Transatlantic Economic Partnership were linked in the late 1990s.

As Vogel (1997: 61-62) notes, however, 'Any effort to harmonize regulations in… visible and emotional areas is likely to prove highly divisive, if not fruitless'. Moreover, publicly sensitive areas, such as food and environmental safety, create more opportunities for NGOs. European consumer and environmental groups, which had already raised concerns about trade liberalisation and NTA/TEP process, played a central role in raising public awareness about GM crops and foods in the late 1990s. They encouraged the public backlash that eventually led to the unofficial *de facto* moratorium. As part of a campaign strategy, they targeted US shipments of maize and soybean that might contain GMOs, thus highlighting trade liberalisation as a threat. As well as a specific development to be contested, agricultural biotechnology was therefore attacked as an example of neo-liberal globalisation and its problems -- undermining government sovereignty, removing consumer choice, polluting the environment and so on.

How did these developments influence regulatory standards? In essence a controversial technology was linked with a controversial trade liberalisation process and actual transatlantic shipments of GM products. This context provided a resource for critics of safety claims and NGOs were able to reframe and re-shape the content of regulatory science, especially for *Bt* maize. Although supermarket blockages of GM soya products were an important barrier, the EU's regulatory barriers to GM maize were at the centre of the US-EU trade conflict. In this politically charged context, scientific criticisms of safety claims gained a higher profile in the public debate. Critics of lax regulations in the US received more attention than before.

Thus the 'trading up' perspective draws our attention to dynamics that might otherwise remain hidden. However, trading up literature tends to focus on explicit and formal standards, such as product specifications or the 'burden of proof' for risk or safety, while our analysis has focused on a less formal standard-setting processes and regulatory standards which often remain implicit. Another difference is that our analysis has linked changes in regulatory standards with trade conflict, and not trade liberalisation, which has remained an elusive goal thus far. For these reasons, we use the trading up literature in novel ways.

Conclusion: Linking Perspectives

In this paper we have analysed changes in regulatory standards for one product in two jurisdictions: *Bt* maize in the US and the EU. We have shown that more stringent regulatory standards were adopted, particularly in the US, in at least three areas: normative judgements, risk assessment and risk management (see again Table 1). Public protest in Europe over GMOs led to a transatlantic trade conflict and a context was more favourable for NGOs and networks of scientist to press for higher standards. NGOs also linked their concerns about GMOs and the broader trade liberalisation agenda.

In the introduction to this paper, we criticised commentators who take official rhetoric at face value. In particular, they explain this trans-Atlantic conflict in terms of 'sound science' versus the 'precautionary principle'. As we have shown, such stereotypes ignore the conflict around regulatory science, both within and across jurisdictions. We have drawn attention to trans-Atlantic interactions and networks that helped actors in each jurisdiction to appropriate developments in regulatory science emerging elsewhere.

Theoretically, this case has helped us to extend analytical perspectives on 'regulatory science' (particularly Jasanoff,1990 and Irwin et al., 1997). The *Bt* maize case shows what can happen when the 'private' world of regulatory science is opened up to greater scrutiny. More generally it illustrates how the context and content of regulatory science can mutually shape each other in practice. We have shown this by analysing how regulatory standard-setting processes underlie and frame regulatory science. In the case of *Bt* maize, new research results were used to change the wider context. Early moves towards market approval and trade liberalisation were undermined by a public backlash in Europe and trade conflict. This in turn led to more critical approaches to regulatory science, more public funding for risk research, and a greater role for sceptics of safety claims in peer review and advisory processes.

We have also linked analytical perspectives on regulatory science with 'trading up' (Vogel, 1995, 1997). Trading up led us to look at how conflicts around trade liberalisation can create opportunities for NGOs to campaign for higher standards. In parallel, perspectives on regulatory science helped us to understand that higher standards can take more subtle forms than is usually acknowledged in the 'trading up' debate. Thus this case study illustrates how STS analyses can usefully draw on and enrich perspectives from political science.

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TABLE 1

Types and Changes:
Regulatory Standards in the Case of *Bt* Maize

	Insect Resistance	Non-Target Harm
Normative Judgements	Early: Insect resistance to *Bt* is an 'agronomic problem' and not an 'adverse effect' on the environment. More stringent: *Bt* is a public good and should be protected as such. Insect resistance threatens this.	Early: The impacts of *Bt* should be compared against the impacts of using chemical insecticides. More stringent: The impact of *Bt* is unacceptable if it causes more harm than non-chemical control methods.
Risk Assessment	Early: The discriminating dose test can be used to test for insect resistance. More stringent: The F2 screen should be used to test for insect resistance because it is more sensitive than other methods. Other issues: Recessive or dominant trait? Baseline of susceptibility? Changes in susceptibility?	Early: Direct toxicity tests can be used to test the impact of plant *Bt* on non-target insects. More stringent: Tri-trophic tests should also be used to test for more subtle impacts of plant *Bt* on non-target insects. Other issues: How to conduct field monitoring? The role of toxic pollen and anthers?
Risk Management	Example: Non *Bt* maize refuges (specifying area and distance from the crop) as part of a strategy to manage insect resistance. Other issues: Engineering high dose *Bt* gene expression in the maize stalk. What contexts require a refuge?	Example: Planting buffer zones to limit the flow of pollen to milkweed plants where it might impact on non-target insects. Other issues: Engineering low dose *Bt* gene expression in maize pollen.