CONSTRUCTING A TRANSNATIONAL POLICY PARADIGM IN THE EUROPEAN UNION: THE CASE OF GMO RISK REGULATION

Grace Skogstad

Introduction

Two distinct paradigms have developed in the European Union (EU) and the United States (US) with respect to the regulation of genetically modified organisms (GMOs), products of modern biotechnology.[1] These paradigmatic differences were fully apparent in the complaint the US brought to the World Trade Organization (WTO) in 2004 against EU policies affecting the approval and marketing of genetically modified (GM) crops. Defending its besieged biotechnology policies, the EU made a number of arguments. First, the technologies which produce GMOs are new and GMOs therefore cannot be treated as "like" or "equivalent to" their non-GMO counterparts; second, determining GMOs' advantages and risks is `scientifically complex' and their long-term consequences--to human, animal and plant life and health, as well as the environment– are `relatively unknown'; and third, the `inherent characteristics' and potential risks of GMOs `require them to be subject to rigorous scrutiny' to ensure they do not cause harm (European Communities 2004: 5, 1 and 3). By contrast, the US government's submission to the WTO articulated an alternate epistemic understanding of GMOs. It stated that the current products of biotechnology are simply `the latest technique' –and the most `precise' technique--of many centuries of genetically engineering plants in order to improve their productivity and functionality, stressed the benefits of GMOs with no mention of any potential harms, and argued GMOs had a `proven safety record' (United States 2004: 4, 9). Its own

domestic regulations do not view GM foods as novel; indeed, their `substantial equivalence' to non-GM foods exempts GM foods from pre-market regulatory approval in the United States.

Besides the divergence of its epistemic framework from that in the US, another feature of the EU GMO paradigm is noteworthy. It, and the regulations based upon it, are controversial not only across the Atlantic but within the European Union itself. Indeed, the contestation that surrounds the regulations based on the EU GMO paradigm, and the unwillingness of some member states to implement and comply with these rules, denote the failure of the EU GMO epistemic framework to acquire the `taken for granted' quality that marks a Kuhnian/Hall paradigm.

Its divergence from the US model and its controversy provoke a question about the EU GMO paradigm that is at the centre of this book. To what degree are both features of the EU GMO paradigm attributable to its transnational scope: that is, its applicability across all European Community/EU member countries? How does the institutional context within which transnational paradigms are constructed in the EU bear on their constituent elements and the likelihood of consensus around paradigmatic elements? How have transnational actors, both within and outside the EU, through their strategic interactions and discourses within this institutional context, shaped the development of the EU's GMO risk regulation paradigm?

To answer these questions and to address the role and impact of transnational actors and transnational institutions in paradigm development, the chapter begins theoretically in Part I where it conceptualizes policy paradigm development as a conflict-prone exercise in knowledge-making. It posits that the apparent settlement of epistemic controversies at a given juncture need not end controversy about their legitimacy. The act of inscribing knowledge claims in public policies and institutional procedures is thus usefully distinguished from the subsequent process

of acceptance of these same knowledge claims as legitimate, including by competing epistemic factions. Part I also demarcates the factors important in accounting for why some knowledge claims prevail over their competitors at a given point in time: `the positional advantages,' resources, and legitimacy of competing discourse factions; the fit between competing factions' epistemic ideas and the broader normative context; and systemic-wide events that intersect with knowledge-making activities in sectoral policy arenas. Arguing that transnational paradigms are prone to a hybrid character, it argues that this characteristic, as well as the positional advantages and discursive strategies of competing epistemic coalitions, make it difficult to settle epistemic controversies in transnational paradigm development, contribute to their ongoing controversy, and handicap societal acceptance and legitimation of paradigmatic knowledge claims.

Parts II and III of the chapter discusses the development of the current EU GMO paradigm. Part II focuses on the initial period of EU GMO paradigm construction from the late 1980s through to the mid-1990s when an episteme that emphasized the novelty and risks of GMOs succeeded in displacing its rival episteme that presented GMOs as neither novel nor riskier than traditional plants to become the basis for regulating GMOs in the EU. This outcome is attributed to both the positional advantage of the GMOs-as-novel-and-risky coalition, as well as the fit of its ideas with polity-wide goals and norms. Part III examines the subsequent evolution of the EU GMO paradigm after it lost legitimacy in the late 1990s. This account stresses the impact on GMO paradigm development of two systemic developments. The first was a crisis of legitimacy in transnational governance within the EU; its effect was to weaken the authority of unelected state actors, in particular at the EU-level, and to strengthen that of non-state actors speaking on behalf of consumer interests. More specifically, this systemic crisis strengthened the authority of a transnational advocacy coalition opposed to GMOs who

successfully linked knowledge claims of GMOs novelty and risks to the need to strengthen norms of transparency, accountability and public participation in policy-making. The second systemic development was global/WTO rules; they lent legitimacy to the claims of a pro-biotechnology coalition that GMO risks were scientifically knowable. In the EU context of systemic policy goals of competitiveness and market integration, these two competing discourses had to be reconciled and the result was a GMO paradigm that was a synthesis of the two competing discourses.

The incorporation of the premises of an episteme into public policies does not necessarily end controversy around the constitutive ideas of the paradigm, and Part IV documents and addresses why the EU GMO risk regulation paradigm continues to be contested. Part V concludes by drawing lessons for conceptualization of policy paradigms and theories about their development from the continuing controversy around EU GMO knowledge-making. Throughout, the analyses draw on primary documents, interviews with European policy-makers, and secondary literature.

I. Transnational Policy Paradigm Development

Theorizing about transnational paradigm development begins with the observation that paradigm construction is an exercise in `knowledge-making': that is, it entails `constitut[ing] social order by molding the underlying epistemic frameworks that guide the definition of social problems, the classification of social kinds [ontological frameworks], and the evaluation of social behaviors' (Miller 2007: 331). Not surprisingly, then, paradigm development is often seen to be the work of epistemic communities of technical experts; decision-makers turn to them to classify social phenomena, particularly when there is uncertainty around their meaning, and to prescribe

appropriate courses of action with respect to them (Haas 1992). Indeed, communities of experts have been credited with considerable influence in the construction of epistemic consensus around transnational paradigms, for example with respect to capital accounts liberalization (Chwieroth 2007) and central bank independence (McNamara 1998).

Knowledge-making activities are, however, neither an exercise solely for professionally trained experts nor one devoid of conflict. Others besides professionally or scientifically trained experts also claim possession of knowledge. This possibility is enhanced in policy domains where expert knowledge is continuing to be built. Moreover, efforts to meld political authority and expert authority (Miller 2007: 332) often falter as disagreements emerge across experts, and between them and non-experts, on the `truth status of knowledge claims' (Ibid: 330). Such disputes over credible knowledge claims appear in the domestic arena, but they are especially likely to bedevil transnational policy paradigm construction. Understandings about what constitutes credible knowledge—and the respective role of experts, state actors and even citizens in its constitution—are entangled with values, historic contingencies, and the bias of institutional settings: all factors which are likely to differ more across countries than within them and thereby to yield different national discourses about knowledge (Gottweis 1998; Jasanoff 2005). One should therefore not be surprised to discover cases (like GMO risk regulation) where attempts to privilege one set of knowledge claims over another, or even to synthesize them--the stuff of transnational paradigm development—have proven contentious.

What shapes the outcome of a contestation of epistemic frameworks at a given point in time? To answer this question, the analyses here turn to the persuasion and powering dynamics of the coalitions that line up behind competing epistemes, looking at both the discursive fit of their epistemic ideas with the broader normative context, and their positional advantage within

the transnational institutional framework. Normative and epistemic frameworks in the wider (regional or global) polity give the discursive advantage to social and political actors who deploy their resources (of information and public and media support, for example) strategically and frame their epistemic discourses in ways that resonate with other ideas and norms in good standing in the polity (Cortell and Davis 2000; Checkel 1999). The transnational institutional setting—with its decision-making norms and rules for pooling and delegating political authority—determines whose epistemic claims get a hearing and have influence, and, as well, the possibility for consensus-building around competing knowledge claims. At the same time, there is still likely to be an element of contingency in the outcome of contestation over epistemes/paradigms, as developments exogenous to the policy domain intersect with knowledge-making activities in unanticipated ways (Hall 1993; Schmidt 2001; Garzon 2006).

As with a domestic policy paradigm, the knowledge claims that triumph initially as the scripts for transnational policy-making are likely to be particularly consequential. Analysts have documented the dynamics of `positive feedback' that lend resilience to the ideas that initially constitute public policies and give them an advantage over their competitors (Pierson 2000, 2004). Even in the face of controversy over their appropriateness, any deviation from embedded ideas will be resisted not only by their promoters but also by earlier opponents who have subsequently configured their behaviour to be consistent with the inscribed episteme (Ibid.). Paradigm change thus normally hinges upon changes in institutional decision-rules that either shift resources to proponents of alternate epistemic frameworks, or, alternatively, create the conditions for incumbent political actors to alter their epistemic assumptions (Hall 1993; Howlett and Ramesh 2002). In the case of transnational paradigms, whose scope of application, as embedded in public policies, extends across a number of countries, changes to their epistemic

scripts will also ordinarily require the support of multiple political actors. Changes will thus usually be difficult.

While the high threshold of consensus needed to change transnational policy paradigms can lend them further resilience, it does not necessarily end controversy around them. The institutional framework within which they are developed is likely to make transnational paradigms hybrids of competing knowledge claims and this hybrid character can ensure continuing controversy insofar as no epistemic community is fully satisfied with the outcome. Even when inscribed in public policies, policy paradigms may thus fail to be internalized as consensual knowledge. The broader normative and epistemic context, particularly when it is in transition, can continue to be discursively deployed by strategic actors to undermine the legitimacy of the inscribed paradigm.

In explaining the constitution of the EU GMO risk regulation paradigm over time, and the controversy that surrounds it, the discussion below draws attention to changes in the structural and normative context of decision-making in the EU. Institutional and normative changes have enhanced the role of non-state transnational actors and shaped their resources and strategies for advancing their competing claims of good governance for risk regulation. Looking first at structural changes, formal institutional changes have led to a larger role for the European Parliament, alongside the Council of Ministers and the European Commission, in EU policy-making. Informal changes, intended to bolster the legitimacy and effectiveness of decision-making by unelected officials in transnational structures, have given non-governmental actors a greater role in transnational policy development in the EU. This development is EU-wide (Risse-Kappen 1995; Kohler-Koch and Eising 1999; Pollack 2005; Eberlein and Grande 2005) but a crisis of legitimacy in risk regulation for food product safety in the late 1990s has made it

particularly prominent in EU GMO risk regulation. At the same time, structural changes in the global political economy have granted the World Trade Organization regulatory authority, including over matters of food safety and trade. These global institutional changes heighten the role of the WTO, as well as extra-EU (especially North American-based) private and public actors, in the EU GMO policy process.

Along with this change in the institutional context towards even greater transnational political activity, transnational GMO paradigm development in the EU has also been shaped by a shifting normative context. In the EU, `input legitimacy' norms have gathered strength; they stress democratic procedures, public participation, and attentiveness to public concerns in policy formulation (Scharpf 1999: 7). These norms sit uneasily alongside `output legitimacy' norms that stress effective policy outcomes and grant authority to experts, including scientific, to define the common good in a way that is consistent with external standards of appropriate behaviour (Scharpf: ibid). Output legitimacy norms dominate in the WTO, where scientific experts are viewed as authoritative on matters of GMO risk regulation. In the context of governing by transnational policy networks, the result of efforts to reconcile this tension between input and output legitimacy norms is a hybrid GMO risk regulation paradigm that does not fully satisfy either of the knowledge-making communities that have formed around GMO risk regulation.

The discussion now turns to the early stage of constructing the EU GMO paradigm when two truth claims about GMOs tangled.

II. Phase I of Constructing the EU GMO Paradigm

GMOs are created by recombinant DNA (rDNA) techniques that involve transferring a particular gene from one organism to another in order to create a new organism with a desirable

trait. GM corn varieties, for example, are inserted with genes from a microbe (bacillus thuringiensis or Bt) that is toxic to predatory insects; other GM plants are inserted with genes to make them resistant to pests. If scientists can agree on what the techniques of rDNA entail, they, society and governments have not always agreed on whether GMOs are novel, what their risks are, the balance of their risks to benefits, and, consequently, whether and how to regulate GMOs risks.

In the 1970s and 1980s, as GM plants were developed first in the laboratory and subsequently tested in field trials in Europe and the United States, two knowledge-making claims or discourses emerged about GMOs. The first, described as a scientific rationality paradigm (Isaac 2002), rested on the knowledge claim that any risks that GMOs present can be controlled. To the question—what is the difference between a product created by genetic engineering technologies, and one produced by other means?—its answer was `nothing—or at least nothing to merit specific legislation to regulate them.' This epistemic view presented genetic engineering as a key technology of future industrial competitiveness and prosperity, and urged a regulatory framework which did not discriminate against it and allowed the benefits of biotechnology to be fully exploited (Cantley 1995). Advanced by the biotechnology industry and many scientists, this epistemic discourse around GMOs prevailed in the United States where it became the basis for a regulatory framework that relied on existing laws to control any risks posed by GM products (United States, 1985, 1991; Jasanoff 2005: chapter 2).

The second epistemic discourse stressed that the process of genetic modification was a novel one and that GMOs posed unique risks to the environment, human health and society (Gottweis 1998: 249-54; Toke 2004; Jasanoff 2005).[2] Vigorously advanced by national Green parties and environmental groups in the EU, it was particularly influential in Germany where it

was supported by the Green and Social Democratic parties (Jasanoff 2005: 58-61; Gottweis 1998**)** but it also gained credence in the United Kingdom and in the European Union.

In the EU, the first epistemic view that rDNA posed no significant novel hazards and hence there was no need for special legislation to regulate products of biotechnology, took hold initially in the early 1980s. It did so under the influence of scientists, the biotechnology industry, a number of member states and those within the European Commission then responsible for biotechnology policy (Gottweis 1999: 73; Cantley 1995:530). Nonetheless, the second discourse—of GMOs as novel and risky—largely won out by the early 1990s. The evidence was Directive 90/220, the Deliberate Release Directive, which specified procedures to authorize GMOs for licensing and sale in the EU. Directive 90/220 singled out GMOs for regulatory oversight on the rationale that the release of GMOs into the environment could have `irreversible' effects and so `action by the Community relating to the environment should be based on the principle that preventive action should be taken' (Commission of the European Communities, 1990). The Directive required member states to undertake a case-by-case assessment of the potential risks to the environment of a new GMO prior to its authorization for cultivation and commercial marketing in their country. Because GMOs might also have risks to human health, a risk assessment of each GMO's impacts on human health was also required.

Why did the epistemic understanding of GMOs as novel and risky, and therefore in need of rigorous regulation, prevail in this initial stage of developing the EU GMO paradigm? The answer is found in first placing the GMO debate in the wider context. EU polity-wide goals of a single internal market, to which member states had committed themselves in the 1987 *Single European Act*, threatened to be derailed when member states like Denmark and Germany launched national initiatives to regulate biotechnology. Their legislation raised the real

possibility of divergent GMO regulatory standards across member states, and, as Directive 90/220 stated explicitly, made an EU-wide regulatory framework necessary in order to avoid `unequal conditions for competition or barriers to trade [in GMO products]… thus affecting the functioning of the common market' (Commission of the European Communities 1990; see also Cantley 1995).

Once the need for an EU regulatory framework became evident, factors of positional advantage, resources of political support, and the ability to capitalize on the broader normative context of public scepticism about GMOs, influenced which knowledge claims around GMOs won out. After 1985, those in the European Commission who appeared to have earlier prevailed in eschewing the need for GMO specific legislation lost their positional advantage as a cross-national network of Green parties and environmental groups found allies for their knowledge claims (of GMOs as risky) in the three institutions whose support was needed to pass EU-wide legislation: the European Parliament, the European Commission, and the European Council of Ministers (Gottweis 1998: 245). The European Parliament, whose rejection of Commission legislation could only be over-ruled by unanimity within the Council of Ministers, argued in a 1987 report that there were `special risks associated with genetic engineering methods' and there were, to date, no `reliable scientific methods for assessing the medium and long-term effects of the irreversible release of GM organisms into the environment' (as quoted in Cantley: 543, 542). A proposal in the Parliament for a five-year ban on the sale of certain products of genetic engineering was defeated by a single vote (Ibid.). In the European Commission, the Environment Directorate, which had acquired legislative responsibility for environmental legislation around GMOs, laid the epistemic groundwork for what eventually became Directive 90/220. It linked the precautionary regulation of hazards of genetic engineering to market

harmonization, and argued that public mistrust of genetic engineering warranted a common regulatory framework to allow the European biotechnology industry to succeed (Gottweis 1999: 79). These views resonated with countries like Germany, Netherlands and Denmark in the Council of Ministers and, as noted earlier, with the European Parliament (Cantley 1995; Gottweis 1999; Patterson 2000; Gaskell and Bauer 2001; Gaskell et al. 2001). The biotechnology industry, which opposed singling out GMOs for regulation, was too weak and poorly organized to counter this argument effectively (Greenwood and Ronit 1992; Cantley 1995: 559).

The political struggle over truth claims around GMOs and whether/how they were to be regulated in the EU was an exercise in mutually constituting political and expert authority. Those who argued GMOs were novel entities with unpredictable risks, as well as those who argued the opposite view, sought to mobilize scientific arguments to support their position. As Gottweis (1999: 77) observes, `Political reasoning was… always supported by reference to scientific arguments, while scientific reasoning inevitably relied on arguments from the political discourse.' Scientific arguments could not settle the controversy around GMOs' risks, but reference to broader norms of environmentalism appeared to assist the discursive coalition that emphasized the risks and novelty of GMOs. The `environment', Gottweis (Ibid: 69) argues, had become `a core value in the political arena' and this normative context lent legitimacy to environmental groups and Green Parties and their GMO skeptical arguments.[3]

As a compromise among competing truth claims, Directive 90/220 failed to settle the controversy over GMOs. It was not fully satisfactory to those who thought genetic engineering was a largely unpredictable and difficult-to-control technology, and who believed assessment of GMO risks should also include their social, economic and ethical risks (Gottweis 1998: chapter 6). Nor did its requirement to assess every GMO's risks appease those who argued that there

were no scientific grounds to treat GMOs differently than their non-GMO counterparts. The latter—the biotechnology industry and branches within the European Commission responsible for industry and research--worried that the onerous regulatory framework would stifle the competitiveness of the European biotechnology industry.[4]

Industrial competitiveness goals and lobbying by a now better organized biotechnology industry led to initiatives in the European Commission over 1993-1994 to streamline the EU GMO approval process and to harmonize it with international practice (Commission of European Communities 1994; Cantley 1995: 647-651). After 1995, global rules under the rubric of the World Trade Organization clarified what international practice entailed. The WTO Sanitary and Phytosanitary (SPS) Agreement, implemented in 1995, requires that health and safety measures, such as those for GM products, be based on scientific assessments of risks. It also requires food and safety measures to be based on international standards where they exist and mandates the Codex Alimentarius Commission (Codex) to establish such international standards. Countries that adopt Codex standards are deemed to be in compliance with the SPS Agreement and WTO law. The WTO has very strong powers to enforce the SPS Agreement. Countries that are found to be in violation of the SPS Agreement–for example, by erecting barriers to entry of a food product from another country--are required to bring their measures into conformity with the Agreement or face WTO-imposed sanctions from the exporting country.

Efforts commenced to harmonize the EU GMO regulatory framework on international epistemic principles. The major legislative initiative in this regard was the 1997 Novel Food and Novel Food Ingredients Regulation. It allowed the manufacturer of a novel (GM) food that was judged to be substantially equivalent to an existing food to produce only a scientific justification for the claim and not a risk assessment of the GM food (Commission of the European

Communities 1997). This regulation, consistent with Guidelines issued by the OECD in 1993 and endorsed by the United States, stated that GM foods that were `substantially equivalent' to an existing food or food component could be treated in a similar manner with respect to their safety. The Novel Food Regulation appeared to mark a shift away from the epistemic premise that genetic engineering was an inherently risky process. However, another of its provisions, requiring novel foods to be labelled, also suggested the resilience of the idea of GMOs as risky. Before further steps could be taken towards US paradigmatic principles, a crisis in the legitimacy of the EU with respect to food product safety regulation altered the institutional and normative context of EU GMO paradigm development.

III. Phase II: Paradigm Development in the Wake of a Systemic Legitimacy Crisis

From 1997 onward, a handful of EU member states began to ban the import and cultivation of GM products within their country, despite these products having been approved for EU-wide marketing by EU level institutions.[5] No new applications for GMO release in the European Union were approved after October 1998, and in June 1999, member states in the Council of (Environmental) Ministers formally announced that they would not approve any new GMOs until Directive 90/220 was reformed. The suspension of GMO authorizations signalled a loss of legitimacy of the transnational GMO regulatory framework and indeed, of the EU as a transnational decision-maker in this policy domain.

The short-term cause of the loss of the regulatory framework's legitimacy was the European Commission's approval of, first, a GM soya in April 1996, and then a GM maize (corn) in early 1997 against the wishes of member states. The Commission had acted—legally--on the advice of an EU committee of scientific experts that concluded the products posed no

risks. Not all experts, however, agreed with this claim, and this division of knowledge claims, publicized by the media, allowed environmental, consumer, and other organizations that were critical of GMOs to mobilize public opposition against GM products (Murphy and Levidow 2006: 3). Public opposition to GMOs led some member states (Austria, Italy, Luxembourg and France) to ban the EU-approved products in their country, and other member states to support their fellow EU-members' actions by subsequently refusing to abide by the existing EU GMO regulatory framework.

What had caused an already sceptical European public to become even more leery of GM products? The answer is found in the successful discursive strategies of transnational consumer and environmental groups, as well as members of the European Parliament. They were able to interpret simultaneous developments in other policy arenas in a manner that reinforced their own truth claims about GMOs and undermined the knowledge-making authority of national and EU scientific experts and regulators (Bernauer and Meins 2003; Ansell et al. 2006). Three developments in the broader context were particularly important in creating opportunities for strategic actors to reinforce the public's already negative opinion of GM foods and their worries about GMOs' environmental risks (on public opinion, see Eurobarometer 2001: 26; on the importance of these developments, see Jasanoff 2005; Ansell et al. 2006; Pollack and Shaffer 2009).

The first development was the BSE or `mad cow' debacle. [6] National and EU regulatory authorities had earlier relied on the advice of scientists that the disease found in animals was first, unrelated to animal feed produced from rendered animal parts, and, second, could not be transmitted to humans eating beef. In March 1996, a month before the Commission approved the sale of the GM soy over member state objections, the British government announced that it had

earlier erred in saying there was no threat to consumer health. Consumer and environmental groups successfully framed the regulatory lapse as evidence of government failure, of scientists (on whom national and Commission regulators had relied for faulty advice about the safety of eating meat from BSE-infected cattle) turning a blind eye to consumer safety, and of the risks of industrial farming methods and its technologies (Chambers 1999; Gaskell and Bauer 2001; Jasanoff 2005). Consumer groups adroitly used the EU's mismanagement of the BSE crisis to enhance their legitimacy as champions of consumer interests.[7] The European Parliament used the crisis to force a major re-organization of responsibility inside the European Commission for food safety issues—including for GM foods—that left it in the hands of a Consumer Directorate (Skogstad 2001).

Further, the BSE debacle, in conjunction with other food safety crises, helped to change the normative context of risk regulation in the EU by lending vigour to the precautionary principle. As incorporated in the 1997 *Treaty of Amsterdam*, the precautionary principle obliges governments to act to avoid harm in the event of scientific uncertainty and not to wait for a risk to be confirmed by scientific evidence (Commission of the European Communities 2000). The principle signals that `doubt and uncertainty concerning the safety of a product can justify recourse to protective measures' (Noiville 2006: 309) and shifts the burden to GMO advocates to demonstrate that they pose an acceptable or no risk.

The second development in the institutional and normative context was economic globalization within the WTO regulatory framework.[8] In December 1996, just before the EU approved for licensing a GM maize developed by the American biotechnology company, Monsanto, the United States, supported by Canada, challenged the ban on hormone-fed beef that the EU had implemented in 1985 with wide popular support. By 1998, the United States and

Canada had successfully argued before the WTO that the SPS Agreement (discussed earlier) prohibited the import of American hormone-fed beef. The beef hormone dispute was followed by a second trade action by the United States against the EU. In the wake of its de facto moratorium on GM product approvals, the United States, supported by the two other major exporters of GM products, Canada and Argentina, first threatened to, and then, in 2003, launched a formal challenge to the EU's de facto moratorium.[9] The complainants argued—eventually successfully—that the SPS Agreement required that imports of foods and plants (like GM products) be restricted only when a scientific risk assessment demonstrates that they are unsafe.

These American-led globalization developments were differently framed by GMO-opponents and GMO-proponents. For anti-GMO activists, these events represented an effort by the US to use WTO rules to enforce its `industrial model' of agriculture on the EU. Environmental groups, like Greenpeace and Friends of the Earth, and later organizations representing small farmers, argued that the United States, as the world's major producer and exporter of GM seeds, animal feed, and foods, was seeking once again to undermine EU public policies.[10] Anti-GMO activists were able to make resistance to biotechnology `a surrogate for resisting America's imperial power' (Jasanoff 2005: 8; see also Ansell et al. 2006). For Commission officials, particularly trade officials, and the organization representing the biotechnology industry, Europabio, these trade disputes and economic globalization required closer harmonization of the epistemic principles of EU GMO regulatory framework with those in the global trading regime. Closer alignment was needed both to avoid trade frictions and to ensure the competitiveness of the EU biotechnology industry.[11]

The third contextual development that intersected with the GMO debate was ongoing European political and economic integration. By the late 1990s, criticisms of the democratic

deficit of the EU had made norms of transparency, accountability, and public participation crucial to the legitimacy of EU-level governance (Eriksen and Fossum 2000; Horeth 1999; Majone 1999, 2000). The significance of these input legitimacy norms (Scharpf 1999: 7)—and the need for the EU to adhere to them--was explicitly recognized by the European Commission in its July 2001 White Paper on Governance. Referring directly to the biotechnology and food safety crises, the White Paper acknowledged that `a better informed public increasingly questions the content and independence of the expert advice that is given.' It also stated that a wider range of inputs `beyond the purely scientific' was needed as was overcoming the opaqueness of expert committees (Commission of the European Communities 2001a: 35). This perception, that `the confidence of the European consumer in science and politics is totally gone'[12] and had to be restored, shaped both the process and content of EU GMO regulatory paradigm development in the late 1990s and early 2000s.

Recognition on the part of EU decision-makers of the EU's only `partial' legitimacy (Ansell 2006: 343) resulted in a prominent role for civil society groups in the transnational policy networks that attempted to build a consensus on EU GMO regulatory governance (Skogstad 2003; Abels 2005; Borrás 2006; Kurzer and Cooper 2007). By virtue of their legal authority over decision-making, the European Commission and the European Parliament were central nodes in these transnational networks. Besides bilateral meetings of civil society groups with individual MEPs, there were also monthly meetings organized by an MEP that brought together Commission officials, MEPs, and representatives of the biotechnology industry, environmental groups and other civil society actors. Commission officials in responsible directorates (health, environment) engaged in extended deliberations with civil society groups too in an attempt to forge a compromise between two competing knowledge claims: those of the

biotechnology industry (and most scientists) who stressed the ability to scientifically determine and manage whatever risks GMOs posed, and those of environmentalists and consumers who were much more skeptical of the benefits of GMOs and more risk-averse. The two responsible Commissioners linked the need to provide the European public with `a high level of protection for human health and the environment based on science' to goals of ending the de facto moratorium on licensing GMOs so as to allow society `to profit from the benefit of these new technologies.'[13]

Interviews with state and non-state actors who were insiders to the policy deliberations provide insight into shifts in discursive strategies that took place as a result of the social learning that Hall (1993) describes as characterizing paradigm development.[14] For its part, the biotechnology industry learned that with public opinion running overwhelmingly against GMOs, it could not simply dismiss the concerns of consumers and environmentalists about the risks of GMOs. For their part, anti-GMO activists, like Greenpeace, recognized that their preference for a ban GMOs (on grounds of their risks) could not be sustained and that they could still largely accomplish that goal by making GMO licensing conditional on labeling these products. For both competing epistemic factions, mandatory labeling of GM products to give consumers `the right to know,' and also thereby the means to reject GM products, was the social learning that enabled compromise on a regulatory framework whose objective was to re-commence GMO licensing in the EU.

In short, much as during the first phase of GMO risk regulation paradigm development, the outcome of efforts to restore legitimacy to the EU transnational GMO regulatory framework was shaped by the institutional and normative context of transnational policy formulation. This context enabled strategically positioned actors to advance their competing knowledge-making

claims but it also gave them incentives to moderate their claims sufficiently to enable agreement on the rules under which GMOs would be licensed for sale in the EU.

As reflected in the regulatory reforms implemented over the period 2002-2004, the compromise was a hybrid of competing knowledge-making claims about GMO risks and their knowability. On the one hand, the original epistemic claim of genetic engineering as a novel and risky technology persists and is extended. Every GM seed/plant must undergo a scientific risk assessment in order to confirm that it poses no environmental or human health risks (Commission of the European Communities 2001b**)**. Similar provisions apply to GM foods (Commission of the European Communities 2003a). In addition, new precautionary measures were implemented to require long-term monitoring of the cumulative long-term effects of GMOs, and traceability provisions require GM products to be tracked from `farm to fork' in order to enable their removal from the market place in the event of a safety issue (Commission of the European Communities 2003b**)**.

On the other hand, there are simultaneously clear efforts to strengthen the authority of the epistemic claim that GMOs' risks are knowable and can be ascertained scientifically. Although decision-makers in EU institutions have the final say on whether to authorize GMOs for licensing, the task of assessing GMO risks no longer resides with Commission-appointed scientific committees. Instead, it is delegated to an independent scientific body, the European Food Safety Authority (EFSA).[6] The allocation of responsibility for risk assessment to EFSA's scientific committees was, argues Chalmers (2005: 654), an effort to allow independent scientists to `frame the debates' around GMO risks.

The hybrid GMO paradigm, with its effort to synthesize competing knowledge claims around GMOs, did not, however, ensure its legitimacy.

IV. Phase III: GMO Paradigm Internalization and the Legitimation Gap

Controversy continues around GMOs in the EU, constituting evidence that the epistemic principles within the existing GMO regulatory framework-- that scientific experts can ascertain the risks of GMOs, and that GMOs are not inherently risky—have yet to acquire legitimacy and a `taken for granted' status. Public opinion surveys show that the majority of the European public continues to view plant biotechnology with skepticism and to see GM foods as neither useful nor morally acceptable (Gaskell et al. 2006; European Commission 2008: 66).[15] The antipathy to GMOs varies across member states, stronger in some countries than in others.[16] A handful of EU member states continues to be reluctant to approve the licensing of GMOs, despite the advice of EU advisory scientific committees that they pose no risks to the environment or human health. And further, despite the WTO ruling their behaviour illegal (as discussed further below), some member states continue to ban GMOs in their country (Skogstad 2008).

GMO risk regulation in the EU illustrates that disputed knowledge-making claims can plague policy paradigms and weaken their legitimacy. This conundrum appears to be especially problematic for transnational policy paradigms that are the outcome of transnational politics and governing structures. Although national decision-making bodies can face difficulties in legitimizing policy paradigms when there has been considerable societal discord around them, the legitimacy of democratically elected national governments is not itself usually disputed. National governments can usually rely on this reservoir of diffuse public support even when they enact policy decisions with controversial epistemic and normative claims. The same situation does not necessarily hold for transnational governing institutions like the EU that necessarily rely on delegated authority and in so doing clash with popular democratic norms of control and

accountability (Skogstad 2008). The endemic competition between national governments and transnational structures of authority in the EU weakens the incentives of national governments to support unpopular EU-level decisions (Tiberghien 2009).

The possibility for political and expert authority with respect to GMO risk regulation to be melded in the European Food Safety Agency has been undermined by contestation around its advice and very role. The GMOs that have been licensed for import into the EU have been approved by the European Commission, acting on the advice of scientific committees in EFSA, but without the consent of a qualified majority of member states. Not surprisingly, then, both member states and environmental groups (Friends of the Earth Europe 2004) have questioned the integrity of EFSA`s scientific opinions, including what they view as its failure to recognize the uncertain state of scientific knowledge of GMO environmental risks (Levidow 2006). The European Commission has taken steps to enhance the authority of EFSA's knowledge-making role, for example, by requiring it to work more closely with member states' scientific experts, to explain in detail when its opinion differs from that of member states' experts, and to take a longer term precautionary approach of the environmental and health effects of GMOs (AgraFocus 2006: 36). Only time will tell whether such initiatives will shore up the authority and legitimacy of EFSA and the scientific premise on which it relies: that is, that GMO risks are knowable.

Time will also tell the impact on EU GMO paradigm development of the WTO ruling in *European Communities-Biotech Products*, the dispute between the European Union and the world's major exporters of GM products (World Trade Organization 2006). The United States, Canada and Argentina challenged both the EU's 1999 suspension of authorization of new GMOs and some member countries' bans on GMOs which had received EU-level approval. They

argued these actions were illegal in the absence of scientific risk assessments to support such bans. The EU defended its actions on the grounds of the scientific uncertainty of GMO risks and argued it needed time to assess those risks: `The science necessary to assess the risks…and in particular any long term, indirect, or delayed effects, has had and is having a hard time to catch up with the rapid development of new GM products. The science traditionally used in risk assessment is deterministic (some say reductionist) by nature, and that means that it had a difficult time to apprehend all the properties of highly complex organisms, the interaction between organisms, and the full picture of the ecosystems and agroecosystems that might be affected' (Commission of the European Communities 2004: 4).

The WTO panel did not agree. It issued a ruling consistent with the scientific rationality paradigm; that is, that the risks of GMOs are knowable and can be ascertained scientifically. The fact that scientific information and data on GMO risks were still limited did not justify the long-term suspension of approval of product-specific measures. The precautionary measures in the SPS Agreement can justify only short-term measures. Nor could member state bans on specific GM products be justified; EU-level risk assessments had been conducted on these same GMOs, and so relevant scientific evidence was not insufficient. The WTO ruling appears to lead to the conclusion that, after a certain point in time, a country has to decide whether a product is safe or not, regardless of the degree of uncertainty surrounding it (Poli 2007; Franken and Burchardi 2007).

V. Conclusion: Drawing Lessons for Transnational Policy Paradigms

The case of EU GMO risk regulation provides a number of insights into the questions at the fore of this text. First is how best to conceptualize policy paradigms. The analyses here have

highlighted the epistemic principles of paradigms, recognizing that cognitive and normative ideas are usually entangled. Ontological ideas about what GMOs are—how novel, how risky—are closely linked to normative ideas about their desirability (GMO Compass 2010). Sectoral paradigmatic ideas do not `float freely' of either their agents (Risse-Kappen 1994) or their context. They need to have a cultural match with acceptable norms and epistemic understandings in the broader society.

Analyses elsewhere suggest that the EU's distinct (from American) food culture helps to explain its attitudes towards techniques of modern agriculture, including plant biotechnology (Echols 1998). Consistent with Tony Porter's argument in Chapter 3, the EU GMO case also suggests the entanglement of ideational and material factors. GMO regulatory paradigms cannot be isolated from their environmental context, including the systems of agricultural and food production in which GMO crops are raised and consumed. The EU's structure of small scale agriculture, balancing traditional and increasingly organic farming, it is argued, has had a bearing on epistemic and normative beliefs about GMOs (Gaskell et al. 2002: 373-374; Toke 2004). For example, Kurzer and Cooper (2007b) find anti-GMO sentiment in Europe to be strongest where an alliance of organic farmer associations and environmental and consumer associations has coalesced around the potential harms of agricultural biotechnology to the environment, farming, culinary traditions, and health and food safety. In short, rather than epistemic communities of scientific experts having authority across national contexts (Drori et al. 2003), the process of mutually constituting expert and political authority is heavily conditioned by features of the local material and normative context.

Second is the matter of how paradigms change and to whom persuasive discourses must be made. In terms of processes of change, EU GMO risk regulation lends support to Hall's

(1993: 280) characterization of paradigm change as `more sociological than scientific' and to Vivien Schmidt's reminder that the `bottom up communications of the public' are important to paradigm development. Transnational environmental groups, like Greenpeace and Friends of the Earth (Europe), as well as other transnational organizations representing farmers, were particularly successful in their bottom up communicative discursive interactions with the European public. Along with transnational groups representing European consumers, this anti-GMO coalition also had some success in their coordinative discursive interactions with the policy actors (state and non-state) who adhered to an alternate paradigm of the novelty/risks and desirability of GMOs. Although the latter were not persuaded to adopt the anti-GMO paradigmatic principles, they were persuaded of the need to adjust their strategies (on labeling GM products, for example) in order to make GMOs more acceptable to the public and hence to move it closer to the pro-GMO understanding of GMOs as not inherently risky and as beneficial to society.

Third, further to how paradigms change, the GMO case suggests the stickiness of initial knowledge-making claims. Early cognitive ideas (of GMOs as novel with unique risks) have persisted. Top-down initiatives at the EU level that portended an evolution away from these ideas in the mid-1990s were thwarted by a systemic-wide crisis in EU regulatory governing. As noted in the Introduction to this book, crises are often understood to be moments that engender transformative change by facilitating discourses of paradigm failure. The failure of the EU GMO regulatory framework took place against a broader crisis in the authority and legitimacy of transnational state officials. It entailed a failure of the cognitive assumption that regulators—including transnational regulators--could be trusted. This lesson, and the consequent alteration of ideas about acceptable risk regulation procedures, lent vigour to the discourse of those who had

initially succeeded in inscribing their epistemic claims about GMOs' novelty and risks in EU legislation.

Fourth, and further to the above, EU GMO risk regulation indicates how developments in other policy sectors, and their timing, can spill over to affect sectoral policy paradigms. Widespread acknowledgement of regulatory failure in food safety policies (the BSE crisis) at the very time the first imports of GMOs were arriving in the EU stopped in their tracks paradigmatic-changing initiatives toward de-regulating GMO licensing. Theories of policy paradigm development thus need to be attentive to developments in neighbouring policy sectors, as well as those in the broader normative and institutional context, that can undermine, or alternatively, bolster, the legitimacy of alternate ideational frameworks.

Fifth, the diffuse legitimacy of political authorities appears to affect the legitimacy of policy paradigms, particularly those whose development has been riddled with controversy over epistemic and normative claims. The weak legitimacy of the EU's supranational governing institutions has undoubtedly handicapped their capacity to shore up support for the GMO risk regulation paradigm. More generally, as compared to domestic policy paradigms, transnational policy paradigms are likely to face larger obstacles to their inscription as legitimate templates because they cannot draw on the reservoir of diffuse support that national democratic governments usually enjoy.

Finally, the EU GMO case sheds some light on another question addressed in this collection: does the EU represent a special case of transnational paradigm development, with limited lessons for understanding the possibilities and dynamics of transnational paradigms elsewhere? It may well. Incentives to develop transnational paradigms are arguably stronger in the EU than they are across countries that are less economically and politically integrated. Strong

incentives—to maintain the common market--explain the persistence of efforts to build a consensus on the constitutive principles of the GMO regulatory paradigm, even while efforts to bridge the EU and US GMO regulatory paradigms have languished. At the same time, its political architecture—with multiple veto players, norms of horizontal accountability of member states to one another, popular democratic norms, and supranational institutions with weak legitimacy—make consensus-building on paradigms difficult in the EU, and arguably more so than across countries with fewer veto players and weaker democratic norms. Still, Porter's attention to an EU paradigm in both accounting and vehicle safety standards in the preceding Chapter suggests that there is no one politics or model of policy paradigm development in the EU. In policy domains that do not witness a high degree of mobilization of transnational advocacy groups, where knowledge claims are settled, and/or where private actors comprise the crucial transnational actors, transnational paradigm development in the EU may well look similar to that across other jurisdictions.

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[1] The terms European Community (EC) and European Union (EU) are both used, with EC referring to the pre-1992 period and EU to the union following the 1992 Maastricht Treaty. The terms `GMOs, plant biotechnology, genetic engineering and genetic modification are used interchangeably.

[2] These risks have been more fully elaborated over time and include environmental risks are to non-target insects that feed on the GM crop and find it toxic, and to the wild relatives of GM plants that may be overwhelmed more resilient GM plants; the health risks, to humans who consume GM plants and foods and have an allergic or toxic reaction; and the social and economic risks are from dislocation and loss of jobs from the technology.

[3] Cantley (1995: 666) reports data that show that environmental organizations were the most trusted group on biotechnology in polls conducted in 1991 and 1993, with 52.6% and 60.8% naming them in answer to the question `Who do you trust most to tell you the truth about biotechnology?' The data are Eurobarometer data. Public authorities were trusted by 20.4% and 16.8% in 1991 and 1993 respectively, and industry by 6.0% and 5.6% respectively.

[4] In 1999, 69% of GM crops were grown in the U.S. and only .03% in Europe (Directorate-General for Agriculture 2000: Table 1.2).

[5] Italy, France, Luxembourg, Greece and Denmark were the five countries that effectively started the de facto moratorium on GMO approvals.

[6] BSE was linked to feeding livestock cow meal that was composed of rendered remnants of other (including diseased) animals.

[7] Eurobarometer data show that in 1999, Europeans trusted consumer (55%), medical (53%) and environmental (45%) organizations more than they did national public authorities (15%); as reported in Jasanoff (2005: 87).

[8] Another structural contextual change is the emergence of a global environmental regime based in the United Nations Environmental Program. The Cartagena Protocol on Biosafety, negotiated by the signatories to the 1992 Convention on Biological Diversity, adopted in December 2000, and into effect since September 2003, applies to trade in living modified organisms (LMOs, referred to here as GMOs). The Biosafety Protocol allows countries to restrict imports of LMOs on precautionary grounds. The WTO Panel in the *Biotech Products* dispute refused to consider whether EU regulations were consistent with the Biosafety Protocol because, although the EU was a party to the Biosafety Protocol, the United States was not (World Trade Organization 2006).

[9] American soybean and corn exports to the EU are estimated to have dropped by $1 billion in sales as a result of the EU suspension of GMO approvals (Zarilli 2000: 6-7).

[10] In France, the farm union leader, José Bové, was particularly effective in framing GM products and WTO trade rules as an exercise in seizing control from European farmers and consumers over decisions about what they could grow and eat.

[11] For the Commission view, see Commission of the European Communities (2002).

[12] This comment was made by the EU Counsellor to the United States at a conference on `The Future of Food Biotechnology' held in Washington, D.C. in 2001. See AgraEurope (November 9, 2001).

[13] Joint Statement of the Environment Commissioner, Margot Wallstrom, and Commissioner for Health and Consumer Protection, David Byrne. Press Release, February 2001, Brussels. Trade officials in the Commission publicly warned that the standstill on GMO authorizations made the EU vulnerable to legal action within the WTO. See AgraEurope (November 9, 2001).

[14] The claims made in this paragraph are based on information obtained in interviews with officials in the Commission, the European Parliament, and environmental and consumer organizations, conducted in Brussels in February and December 2001, and October 2003.

[15] GMO Compass (2010) reports Eurobarometer data showing that public opinion on GMOs is improving but in no EU member state does a majority have a positive view of the technology. It concludes `Even the EU's recently overhauled regulatory framework for GMO authorisation and labelling has yet to make Europeans more accepting of food made from genetically engineered plants.' Further, `the public is clearly concerned about potential risks to human health and the environment.'

[16] Opposition to GM foods is stronger in Austria, Germany, Greece and France than in Italy or Spain.