

Biopolitics in the EU and the U.S.: A Race to the Bottom or Convergence to the Top?

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This paper examines the circumstances under which economic globalization has led (and not led) to a convergence in the regulation of agricultural biotechnology in the European Union (EU) and the United States. While the EU has taken a precautionary approach to regulating biotech products, the U.S. has decided that these products are no different from those made using more traditional methods. As such, the U.S. government has implemented no novel legislation or risk assessment procedures to regulate them. These varying regulatory responses pose an interesting puzzle for scholars who are interested in examining the impact of economic globalization on domestic regulatory institutions and policy outcomes. Despite the fact that agricultural biotech products were developed for highly competitive and globally integrated agri-business markets, the paper argues that biotechnology regulation has followed very different paths in the two polities with the EU mimicking the environmental politics model and the U.S. remaining largely nonadversarial in its approach. We investigate why this has occurred by focusing on differences in the domestic political economies surrounding biotechnology issues in the two regions. The paper then examines why the U.S. biotechnology policy mode recently has shown signs of gravitating toward the EU model, signifying a potential for convergence to the top. Although no new statutes have been enacted or rules adopted yet, there are noticeable changes in the regulatory climate. The paper argues that these changes can be attributed to developments in the domestic political economy, especially the StarLink episode and how this opened the “policy window” for the pressures of globalization to influence the potential ratcheting-up of U.S. standards.

Background

This paper examines why the regulation of agricultural biotechnology in the European Union (EU) and the United States (U.S.) has diverged and, why in the last three years, the U.S. is showing signs of moving toward the EU regulatory model. Given that multinational enterprises (MNEs) dominate the agricultural

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biotechnology industry, we investigate whether and how forces of globalization have influenced regulatory divergence and convergence.

In recent years, technical sounding issues such as the presence of synthetic growth hormones in beef, acceptable decibel thresholds for new aircraft, and risk assessments for genetically modified (GM) foods have become matters of “high politics” between the United States and the European Union. Perhaps nowhere has the intensity of these regulatory disputes been greater than the one forming over GM foods. In keeping with its own approach to environmental regulation, the EU has applied the “precautionary principle”¹ to regulate GM foods/agricultural biotechnology² and has adopted a number of directives aimed at ensuring consumer safety. By contrast, the U.S. has decided that GM products are no different from those made using more traditional methods. Consequently, the U.S. government has neither enacted new statutes nor implemented new risk assessment procedures to regulate GM products. Further, the U.S. has delegated the lead regulatory role to the business-friendly U.S. Department of Agriculture (USDA). Although working from the same set of basic scientific facts, the British Medical Association has called for an indefinite moratorium on GM foods, while the U.S. National Research Council (1989, 2000) has labeled GM foods as a safe food source.

These diverging policy debates and regulatory responses to biotechnology were developed and have largely been sustained despite the technology’s promotion by large multinational enterprises (MNEs) and the globalized nature of agricultural markets as well as a growing movement led by both domestic and transnational nongovernmental organizations (NGOs) against their use. Given this background, this paper examines two empirical questions. First, why have two polities with broadly similar social, cultural, and economic structures taken such different approaches to regulating a new technology? Second, why has the U.S. shown signs of inching toward the European model of regulation over the past three years? Our comparative case study adds to the theoretical understanding of how, and the extent to which, economic globalization as a structural force influences the policy trajectories of political systems. We argue that while market competition and NGO activism can create pressures on polities to converge, such pressures are always filtered through domestic institutions and political processes. Thus, while upward convergence can and occasionally does occur through globalizing processes, it rarely changes core policy approaches, and is piece-meal in nature.

Globalization and Domestic Policy Agendas

Globalization is a multifaceted phenomenon with economic, political, cultural, and social dimensions (Appadurai, 1996; Falk, 2000). The most talked about dimension, economic globalization, can be conceptualized as a set of processes that are leading to the increased integration of factor, intermediate, and final product markets, coupled with the increasing salience of MNEs’ value-chains in cross-border economic flows (Prakash and Hart, 1999, 2000). Because of their high salience in cross-border flows (UNCTAD, 2002), MNEs arguably have greater clout in influencing domestic regulations, thereby abetting regulatory races-to-the-bottom across borders (Spar and Yoffie, 2000; Drezner, 2001). However, under certain circumstances economic integration can also lead to the “trading up” of regulatory

¹ On different versions of the precautionary principle see Soule (2000).

² Biotechnology is “any technique that uses living organisms or substances from those organisms to make or modify products, improve plants or animals, or develop micro-organisms for specific uses” (Persley and Doyle, 1999:1). It allows for the transfer of selected genes between organisms and perhaps more importantly between species.

(product not process) standards if the dominant regional economy (Germany in the EU and California in the U.S.) supports stringent standards (Vogel, 1995).

Complicating this picture further, scholars have recently argued that globalization also empowers a counterbalancing force, NGOs, many of which believe governments should not conform to MNE-preferred regulatory standards (Falk, 2000). They often seek global acceptance of norms such as sustainability, the precautionary principle, and transparency that firms may not always support.³ These groups, domestic as well as transnational, operate within the state-centric system by influencing governments as well as by directly influencing firms, consumers, and policy discourses (Gereffi, Garcia-Johnson, and Sasser, 2001).

Many scholars suggest that a global civil society and a corresponding global politics—organized social life and politics that are autonomous of the state and outside the state-centric system—are starting to emerge (Rosenau, 1990; Lipschutz, 1992; Wapner, 1995; but see Clark, Friedman, and Hochstetler, 1998). Realizing that their strength lies in numbers, domestic NGOs have incentives to coordinate their strategies across borders. The Internet has reduced the costs of organizing collective action as demonstrated by the mobilizations against the failed MAI agreement (Kobrin, 1998) and the WTO Seattle meeting. Many NGOs are quite media savvy and often manage to outmaneuver their corporate opponents. Their expertise in both generating and interpreting information is noteworthy (Comor, 2001). Evidence suggests that TV news networks and the printed press have increased the coverage of NGOs, their actions, and their interpretations (Berry, 1999; but also see Smith, 2000).

Given this background, it is not surprising that there are multiple perspectives about the power of MNEs to force convergence in domestic regulatory agendas, structures, and policies. Kobrin (1999) and Ohmae (1991) are key proponents of the hypothesis positing convergence in the wake of globalization. Structural Marxism as well as development economists such as Rostow also propounded some sort of a convergence thesis. Thus, convergence theories have been examined in various disciplines. Arguments against convergence and the continuation of differing national styles of regulation and policymaking, however, also abound (Berger and Dore, 1996; Boyer and Drache, 1996; Pauly and Reich, 1997; Kitschelt et al., 1999).

Scholars of international regimes and international political economy (Chayes and Chayes, 1993; Victor, Raustiala, and Skolnikoff, 1998; Raustiala, 2000; Hauffler, 2001) emphasize how increased international rule-making, both intergovernmental and private, influences the regulation of domestic actors. Using a somewhat different logic, Vogel (1995) has argued that market integration creates incentives for states with lax regulations to adopt more stringent product standards of the dominant regional economy (the California Effect). Contrarily, students of comparative political economy (Boyer, 1996; Streeck, 1996; Hall, 1999) highlight the continuing idiosyncrasies of national regulatory practices and institutions. Oftentimes, these debates center on misunderstandings about what convergence entails. As we view it, convergence is the process of becoming more alike rather than the state of being exactly the same. If one employs, implicitly or explicitly, the latter absolutist definition of convergence, there are usually a slew of facts from which one can draw to make a case for continued divergence. The question scholars should be asking is not whether regulatory systems have become exactly the same,⁴ but rather have domestic regulatory systems become more alike as a result of

³ Of course, businesses often support universalization of other norms such as consumer sovereignty (though not for GM foods—as will be discussed subsequently) and market-based economies.

⁴ Convergence has many facets to it: instruments, institutions, goals, processes, and outcomes (Bennet, 1991). Our primary focus is on regulatory approaches on core issues: labeling of GM products and segregating GM and non-GM products.

international or transnational pressure. For the reasons described above, the development of biopolitics in Europe and the U.S. offers an excellent case in which to study the interactive effects of domestic and international variables.

We draw on Kingdon's (1984) agenda-setting model to explain why the regulation of biotechnology has developed so differently in the two polities and how international pressures have come to affect, albeit subtly, the regulatory climate in each. Kingdon argues that domestic policy agendas are shaped by three separate process streams: the political, problem, and policy streams. The problem stream is determined by the extent to which the current situation in a particular issue area is perceived to be getting worse. The political stream includes interest group politics and the composition of the government and legislature, as well as party politics. The policy stream for its part is made up of possible solutions to perceived problems. Normally these three streams work in isolation from one another. However, at certain moments a so-called policy window opens—usually in response to a change in the problem or political stream—in which preferred policy solutions can be matched to policy problems. Using this general framework, the first part of the paper examines why, despite pressure from MNEs and NGOs for harmonized regulation (the former seek minimal regulation while the latter favor ratcheting up), the regulation of agricultural biotechnology in the EU and the U.S. has followed such different policy trajectories.⁵ We locate the explanatory variables in this section of the paper mostly within Kingdon's political stream, or what we call the domestic political economy.⁶ We define the domestic political economy, our independent variable, as the relative strengths and relationships of actors who engage in the domestic policy debate about the use of GM products. This is not to argue that pressures from foreign markets, NGOs, or MNEs are unimportant in shaping the actions of governments. They are indeed important but their impact is felt only to the extent that they impact the domestic political economy. The weakness of the biotech industry, the cultural importance placed on small-scale farming, and recent food safety disasters have greatly affected the political economy surrounding the biotech industry in Europe. These factors coupled with anti-biotech consumer activism led to the definition of GMO regulation as an environmental issue in Europe. Once the terms of the debate had been set, the European Commission's Environment Directorate General (DG) logically became the lead regulatory body. In the U.S., by contrast, the strong presence of the biotech industry, a farming sector focused on price competition and exports, and a public that is not particularly anxious about the safety of GM products has caused biotech to remain a largely technocratic issue. Further, because the institutional structures to regulate biotechnology were decided in the 1980s, a period marked by concern about the decline in U.S. competitiveness and how excessive regulation contributes to it, industry-friendly USDA became the lead agency for biotech regulation. A lack of organized and sustained opposition from major U.S. environmental groups to this regulatory mode, and a belief that biotechnology is a frontier technology in which the U.S. still had a competitive advantage, contributed to this permissive regulatory approach.

The second part of the paper examines why the U.S. is showing signs of inching toward the EU's biotech policy mode in terms of the core issues of labeling and the segregation of GM and non-GM crops, thereby signifying a possible move toward a

⁵ Although these new techniques have been used in the pharmaceutical and agricultural industries, transatlantic disputes are over the latter only.

⁶ In terms of alternative explanations, the epistemic community perspective is arguably relevant given the technical nature of biotechnology policy debates. Similar to Raustiala (1997), we find that although epistemic communities were perhaps influential in getting elite attention to the issue of GM foods, they were not influential enough in shaping regulatory outcomes desired by NGOs. Further, there is an epistemic confusion about the dangers from GM foods, with anti-biotechnology experts clashing with pro-industry experts (often from conservative think tanks) on this subject.

weak “convergence to the top.” We provide evidence from developments at the federal level and the state level, as well as the changed U.S. position toward a key international agreement, namely, the Biosafety Protocol (CHM, 2000). We focus on the role of a critical unanticipated development (a domestic shock) (Baumgartner and Jones, 1993; Sabatier and Jenkins-Smith, 1993), the StarLink corn controversy. We argue that this event created the political space necessary for the U.S.-based anti-biotech NGOs to change the tenor of the debate by significantly altering the problem stream (on agenda-setting see Baumgartner and Jones). Once this “policy window” was created, the biotech policy mode in the U.S. began to respond to the pressures from foreign markets on U.S. exporters as well as to the norms of consumer empowerment and transparency. Although new laws and regulations have yet to be enacted at the federal level (at the state level, new laws have been enacted) and the United States Trade Representative (USTR) continues to threaten the EU with WTO action, U.S. regulators and biotech firms now seem more amenable to stricter policy solutions in the regulation of biotech products, many of which were first implemented by the EU. Thus, while globalizing processes influence domestic policy agendas, they primarily only do so by working through extant institutional frameworks. As will be seen, the policy stream seems to be particularly susceptible to influences from the outside as MNEs seek to find common rules by which to operate in multiple national jurisdictions.

The paper proceeds as follows. In the first section we compare biopolitics with environmental politics to illustrate differences in the modes of biotechnology policymaking in the two polities. Following from the differing domestic political economies, we argue that biotechnology regulation in the EU has followed the adversarial mode of environmental politics while in the U.S. it has remained cooperative in nature and is generally not considered an environmental issue. The second section investigates why this has occurred by focusing on differences in the domestic political economies surrounding GM products in the two regions. The third section examines why the U.S. biotechnology policy mode shows signs of gravitating toward the EU model, signifying potentially some convergence upwards. We trace developments in the domestic sphere and how a domestic shock has created the political space necessary for globalization pressures to ratchet up U.S. standards. Finally, in the last section, conclusions and issues for further research are examined.

Biopolitics Versus Environmental Politics

This paper seeks to understand the different trajectories of biotechnology regulation in the U.S. and the EU. To better illustrate these differences, we compare biopolitics with the more established environmental politics in both systems. While biotechnology has become an environmental issue in the EU and has followed a more contested mode of policymaking, it has largely been defined as an agricultural, technocratic, and national competitiveness issue in the U.S., thus allowing the government to engage in a more cooperative policymaking style.

Environmental Politics in the U.S. and the EU

An important feature of U.S. regulatory politics, especially environmental politics, is the adversarial nature of the political economy surrounding industrial regulation. Put more simply, uneasy government–business relations are a hallmark of most U.S. regulatory policy fields (Chandler, 1981; but also see Lindblom, 1977). Though such adversarial relationships manifest themselves in many ways across different countries and issue areas (Kollman and Prakash, 2001), they typically exist where governments are willing and able to enact and enforce stringent legislation over the objections of industry (Lundqvist, 1980; Vogel, 1986).

It is clear that U.S. NGOs have not yet succeeded in extending these adversarial relationships to biotechnology policymaking. Until recently there had been no news-grabbing biotechnology accidents that would create political space for NGOs to redefine the policy problem and aggressively use the judicial system. And because the biotech industry has had a very favorable regulatory climate, it has not sought recourse within the judicial system to halt, delay, or derail the rule-making processes.⁷ As will be discussed subsequently, recent controversies, especially over StarLink corn, have increased judicial activism by NGOs, thereby creating a less permissive regulatory climate for the biotechnology industry.

To a certain extent comparing U.S. policymaking, environmental or otherwise, with that of the EU⁸ is a bit like comparing apples and oranges. The European Union is a supranational or intergovernmental body whose policymaking processes differ significantly from those found in sovereign states. Majone (1995) has argued that the EU is, in fact, almost exclusively a regulatory state, which, because of its limited power to tax, can only have a minimal effect on distributive or redistributive politics. Until ten or fifteen years ago, its influence over member states' regulation was also limited to a number of specific policy areas. However, as the pace of economic integration increased in the run-up to the completion of the internal market in 1992, the demand for common regulatory rules also greatly increased. It is not surprising therefore that the Single European Act, which was signed in 1986, granted the EC the legal competency to pass environmental legislation. These legal competencies have been expanded with the adoption of the Maastricht and Amsterdam treaties in 1992 and 1997, respectively. Consequently, the EU has come to play a dominate role in most areas of its member states' domestic environmental regulation. Certainly in the case of GMO regulation, the EU has become the locus of legislative activity although some member states have chosen to adopt additional regulation. As such, it makes little sense to compare U.S. GMO regulation with that of individual member states despite some of the incongruities involved in making U.S.-EU comparisons.

The EU still has little authority over the implementation of the policy that it adopts. This task is largely left to the member states and their own administrative bureaucracies. Although the European Commission, the executive arm of the Union, does have the ability to bring member states before the European Court of Justice for noncompliance with its laws, EU competencies remain focused on policymaking rather than policy enforcing. The main lines of EU environmental policy are set by the Commission's Environment Directorate General which is equivalent to an executive department or ministry. The Environment DG is responsible for proposing environmental legislation in the EU system. The adoption process is a complicated one that involves the Council, the European Parliament, and the Commission, and that varies according to the type of policy being debated. Although the intergovernmental Council is still the most powerful actor in the adoption process, the Parliament has gained considerable influence over final policy outcomes since 1986 through provisions adopted in the single European, Maastricht, and Amsterdam treaties. In the co-operation and co-decision procedures, under which the vast majority of environmental legislation is adopted,

⁷ Interestingly, key U.S. firms leveraged this "adversarial legalism" (Kagan, 1991) to ensure that the Bush administration does not sign the Convention on Biological Diversity (CBD). For an excellent account of how various domestic institutions in the U.K. and the U.S. led to these countries' divergent responses to the CBD see Raustiala (1997).

⁸ The term European Union officially applies to the three pillars of European integration that were constructed when the Maastricht Treaty came into force in 1993. The European Community, which is just one of these pillars, is the only body that has international legal recognition. It is thus the European Community and not the European Union that signs multilateral and bilateral agreements. Although legally the distinction between the two should be kept, this article follows the common practice of using EU to refer to all components of this umbrella organization except in referring to those pre-1993 periods of time when the EU did not yet exist.

the Parliament has the power to amend the Council's initial common positions.⁹ Although the Council can adopt or reject these amendments in either procedure, under co-decision the Council's rejection leads to the formation of a conciliation committee between the two bodies. The joint text that emerges from this conciliation process must be agreed to by both the Parliament and the Council in order to become law (Hix, 1999).¹⁰ The Parliament has used this power to increase the stringency of a number of the Commission's initial proposals in the environmental area including those pertaining to the regulation of biotechnology.

The legislation that has come out of this somewhat fragmented process has been surprisingly stringent and increasingly complex. The relative success of the EU in this policy area can be attributed to several factors. First, at important junctures environmental policy within the Union has been pushed by a small group of environmental "leaders," states (Germany, Denmark, Netherlands, and Sweden) that have sought to transfer their own stringent regulations to the community as a whole. Oftentimes they have done so at the urging of domestic industry groups who feel competitively disadvantaged by these demanding environmental standards. Stringent standards have also been supported by firms that want to sell their green technologies in other European markets. Lastly, the Commission has been encouraged to pursue its environmental agenda because of the popularity of this policy field among European citizens.

The stringency of EU environmental policy and the independence of the Environment DG within the Commission, however, should not be exaggerated. As many environmental groups have pointed out, the European Union began its life largely as a neoliberal experiment designed to decrease barriers to trade within the common market. Liberal economic goals still figure prominently within the culture of the Commission. The Environment DG has often run up against and lost important battles to the Trade, Agriculture, and Enterprise (formerly Industry) DGs. Indeed, in the case of GMO regulation, the Environment DG has faced severe criticism from the Research and Health and Consumer Protection DGs. As will be seen below, it largely has been successful in winning these latter battles.

The application of the precautionary principle within EU environmental policy is illustrative of the uneven influence the Environment DG has within the Commission. Although environmentalists were successful in getting the precautionary principle enshrined in the Maastricht Treaty as one of the core principles of environmental policy, it has never been well defined and has been applied erratically. In an effort to clarify its position, the Commission issued a communication on its use in 2000. This rather short document rejected some of the more absolutist interpretations of the precautionary principle by linking its use to the proportionality principle and the use of cost-benefit analyses. At the same time, however, the Commission reiterated its ability to invoke the precautionary principle to regulate before scientific proof of environmental harm has been established (McCormick, 2001:84–85). The communication has in fact done little to clear up the confusion surrounding this controversial principle. Indeed it seems its application is only viable when strong public sentiment exists to support regulation as is the case with global warming and GMO regulation. Despite this spotty history, the EU has promoted the precautionary principle in a number of multilateral environmental forums and, in general, has been more comfortable using this principle to shape its regulatory practices than is true of EPA in the U.S.

⁹ In general, under both of these procedures, the Council takes its decisions by qualified majority votes and the Parliament by simple majority votes.

¹⁰ For an in-depth treatment of these different adoption procedures and their effect on legislative outcomes see Tsebelis and Garrett (2001).

Biopolitics in the U.S. and the EU

As noted previously, the U.S. has enacted no new statutes to regulate biotechnology products and the U.S. government has largely acted in concert with U.S.-based MNEs to ensure minimum levels of regulatory hurdles. In part, this was due to the Reagan-Bush era in which these decisions were made, that was marked by a belief that minimal regulatory oversight is necessary to foster U.S. competitiveness in this critical emerging technology. Further, the revolving door among key regulators and the biotech industry (for details see Verzola, 2001) ensured that the industry had (and has) an adequate voice in influencing the regulatory framework (Ferrara, 1998). Within the existing statutory framework, three federal agencies with sometimes overlapping jurisdictions are expected to ensure that GM products are safe to grow (U.S. Department of Agriculture, USDA), eat (Food and Drug Administration, FDA), and be released into the environment (EPA). The USDA, which has a reputation for being business-friendly, was chosen by the government as the lead regulatory agency. This particular regulatory framework was in no way pre-ordained by the structure of U.S. federal bureaucracy. In fact in 1983, the EPA drafted a proposal suggesting that it become the lead regulating agency of biotech processes under the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Control Act (EPA, 1983).¹¹ While this proposal did not suggest that new legislation be passed in order to regulate GMOs, it did suggest that current risk assessment procedures were inadequate and that new ones needed to be developed. The White House rejected this proposal and set up a working group in which the EPA and other federal agencies participated. In 1986, they issued a Coordinated Framework for the Regulation of Biotechnology that outlines the regulatory procedures still used today (Vogt and Parish, 1999).

Established by Abraham Lincoln, the USDA is charged with serving the farming population, including the promotion of agricultural exports (USDA, 2000). Because U.S. farmers increasingly rely on biotechnology for key crops such as corn, soybeans, and cotton, the USDA has been a key proponent of agricultural biotechnology (Glickman, 1999). In fact, the USDA's Agricultural Research Services undertakes active research in biotechnology and owns several patents that have been commercialized. This makes the USDA a beneficiary of the royalties (albeit not a significant proportion of its total budget) that flow from biotechnology patents.¹² As this discussion suggests, there is an obvious conflict of interest in the way the regulatory and promotional aspects of agricultural biotechnology are institutionally organized within the USDA. Within the USDA, the Animal and Plant Health Inspection Service (APHIS) is the lead agency for biotechnology regulation. Under the authority vested by the Federal Plant Pest Act, it approves field-testing of GM crops. Since 1987, APHIS has approved over 5,000 field trials on about 28,000 sites (Foudin, 2000).

Before any GM crop can be marketed, the APHIS needs to approve a petition for a determination of "nonregulated status," that is, to certify that the crop is not a pest. This petition is published in the *Federal Register* which provides interested parties with the opportunity to express their views on how the GM crop may impact the environment and/or health safety of humans and animals. On this count, the approval process is quite open and subject to public scrutiny. Two other federal agencies, the

¹¹ From the mid-1970s to 1984, the National Institutes of Health's Recombinant DNA Advisory Committee was the key federal agency for biotech regulation. A lawsuit, however, forced the Reagan administration to rethink the regulatory framework (Vogt and Parish, 1999). Monsanto, with significant investments in biotechnology, was worried that consumers may be uncomfortable with the new technology, and therefore actively lobbied for government regulation (business-friendly) to assuage/forestall public concern (Eichenwald, 2001). An important learning is that businesses may not oppose regulations per se, but only those that shrink the market and/or make them uncompetitive (Levy and Prakash, 2003).

¹² We owe this point to Dr. Arnold Foudin of the USDA.

Food and Drug Administration (FDA) and the EPA, are involved in regulating biotechnology. Under the authority vested by the Federal Food, Drug and Cosmetic Act, the FDA's Department of Health and Human Services regulates foods and food additives (except meat and poultry). In May 1992, the FDA issued a policy outline stating that GM and non-GM foods will not be treated as separate entities:

[N]ew techniques are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued by traditional plant breeding. The agency is not aware of any information showing that ... foods developed by the new technique present any different or greater safety concerns developed by traditional plant breeding. (*Federal Register*, 1992:22991)¹³

The Federal Food, Drug and Cosmetic Act requires labeling in cases of "material" changes such as changes in the nutritional composition or inclusion of allergens that are made to food products. The FDA has taken the position that genetic engineering does not constitute a material change unless proven otherwise. Thus, unlike the EU, the FDA does not require labeling or pre-market safety studies for GM foods (recent developments will be discussed subsequently). As a result, unlike the USDA, the FDA is not deemed as a critical regulatory agency for biotech regulation.

The EPA is involved in biotechnology regulation because it regulates pesticides (under the Federal Insecticide, Fungicide, and Rodenticide Act) and sets tolerance levels for pesticide residues in foods (under the Federal Food, Drug and Cosmetic Act). Because many GM crops contain pesticides/herbicides, they require an EPA's pre-market approval. Critics believe that this calls for long-term safety studies which are currently not required. Although never adopted, the EPA has proposed rules that would regulate pest-resistant GMO plants in the same manner as pesticides. In general, the EPA has voiced greater concern about the potential risks of the release of GMOs into the environment than the USDA or FDA; however, it has only rarely turned these concerns into concrete action.

As is typical of EU regulation, multiple agencies at multiple levels of government are responsible for formulating and enforcing biotechnology regulations in Europe (*Belgian Biosafety Server*, 2000; OECD, 2000a). Unlike in the U.S. where there are independent regulatory agencies to ensure food safety (i.e., USDA, FDA, EPA), the EU has no such institutional apparatus. New regulations adopted by the EU do, however, specifically outline the procedures that need to be followed in order to use GMOs in field trials or to bring GMO products to the market. The EU Commission's Environment DG has become the lead agency responsible for drafting the horizontal legislation governing these procedures. The most important of these regulations include Council Directive 90/219/EEC (on contained use of live GMOs such as GM crops) and Council Directive 90/220/EEC (on field trials and marketing of live GMOs).

Together these directives outline the application process GMO products must undergo to be used in field trials or put on the market in the EU. Unlike in the U.S., these procedures include fairly stringent risk assessment studies whose results must be sent to the Commission as well as to the governments of all member states. The approval process works as follows: first the member state where the petition has been filed has to approve the marketing of a GM product. If approved, the

¹³ In fact, the FDA created hurdles for voluntary labeling. It requires that dairies wanting to label their milk as free of bovine growth hormone have to include a disclaimer on the label that no significant difference is shown between hormone treated and hormone free milk. Similarly, it requires grocery stores wanting to make this claim to provide verifiable paper trails that the milk suppliers did not use any hormones. In January 2001, the FDA (2001) issued draft rules on voluntary labeling laying out what kinds of claims would be acceptable. It seems amenable to allow labels that indicate presence of GM ingredients, but not amenable to allow claims about the absence of GM ingredients. However, NGOs are keen to have the latter kinds of labels and not the former.

proposal is forwarded to the European Commission where other member states are invited to comment. If a member state(s) has/have objections, the issue is decided by a qualified majority vote in the Council of Ministers. Once approved, the GM product can be marketed within the EU unless a member state temporarily bans it under Article 16 (the “safety clause” under 90/220/EEC). This ban is then deliberated upon by the EC’s Scientific Committee which may or may not uphold it.

The EU has frequently revised and added legislation to this general framework. In December of 2000, after three years of negotiations, the Council adopted a revised version of the 90/200/EEC Directive in which registers will be established in each member state listing where GMO crops have been planted. Additionally, all marketing permits for GMOs will now expire after a ten-year period at which time new applications and new risk assessments have to be submitted if the product is to remain on the market (*ENDS Daily*, 2000a). The passage of this revised Directive was supposed to end the unofficial three-year moratorium on the approval of GMO products which all member states unofficially agreed to in the face of public pressure; two and a half years later, however, no new marketing permits have been issued (Byrne, 2000a). In addition to requiring these special market permits, the EU has also established a fairly comprehensive GMO labeling scheme that has no equivalent in the U.S. The first labeling requirements were laid out in the 1997 Novel Foods Regulation (Directive 97/258/EC) that mandates all GMO food products and foods derived from GMO products be labeled as such. Similar legislation exists for GM plants and GM seeds. Finally, the Commission recently has introduced a set of proposed rules to improve the traceability of GMOs and GMO-derived products so that marketed goods can be properly labeled. These new rules would set a rather stringent—one percent—GMO content threshold level for labeling (*ENDS Daily*, 2000b).¹⁴

The two paths taken by the EU and the U.S. in the area of biotech regulation could hardly be more different. The U.S. has passed no new legislation for the regulation of GMOs and has largely adopted the opinion that products created by gene-altering processes are not fundamentally different from those made using more traditional means. The lead regulatory agency, the USDA, is well known for being (agri)business-friendly. As such, the agency that was most likely to treat the regulation of biotechnology in an adversarial manner, the EPA, has played only a minor role in these regulatory decisions. As outlined above, quite the opposite has happened in the EU. The Environment DG has taken the legislative lead and has aggressively pursued novel legislation that is very much based on a strict interpretation of the precautionary principle. While American regulators have couched the biotech debate in the scientific language of risk assessment and cost-benefit analyses, their counterparts in Europe have emphasized more emotive issues such as food safety and the threat to traditional farming practices (Byrne, 2000b).

To understand why European and American responses have diverged so widely, we examine the different domestic political economies of biotechnology in the two regions and how these have affected the agenda-setting process in each system. Once institutional choices were made to regulate biotechnology, certain institutional features reinforced the differences in the policy choices made in the two regions.

¹⁴ Other Directorates General within the Commission are responsible for additional sectoral legislation relating to GMO regulation. The Enterprise DG and the Agriculture DG are responsible for specific product legislation such as Council Directive 93/114/EEC (on food additives), Council Directive 93/41/EEC (on medicinal products), and the European Parliament and Council’s Regulation 258/97 (on novel foods and novel food ingredients—that is, products that may contain GMOs or GM ingredients). The Energy and Transport DG is responsible for the safe transportation of GM products while the Health and Consumer Protection DG is responsible for dealing with technical issues affecting human and animal consumption.

Explaining the Differences

We argue that despite the susceptibility of biotechnology regulation to such globalizing pressures as international agriculture markets, promotion by large MNEs, and protest from NGOs, the early phases of the policy debate were largely structured by the domestic political economy surrounding the issue. Thus, differences in the kinds of groups involved in shaping the domestic agenda, the relative strengths of these groups, the issue linkages these groups were able to make, and their relationships with regulatory authorities seem to be key to understanding why two such different regulatory modes developed in the U.S. and the EU. An important determinant of the agenda-setting process in most democracies is public sentiment. Indeed, the difference in public perceptions of biotechnology across the two shores of the Atlantic is stark. Although reliable longitudinal data are not available, multiple polls suggest that Europeans are far less supportive of biotechnology than Americans. For example, Environics, an environmental polling firm, asked 1,000 citizens in 25 countries about their views on using biotechnology to grow pest-resistant crops. Country-wide support levels for agriculture biotechnology were as follows: China, 79%; U.S., 78%; India, 76%; Germany, 54%; France, 52%; Britain, 36%; Spain, 29% (*Washington Post*, 1999). We attribute the differences in public opinion to a variety of factors, especially different economic structures and recent histories with food safety regulation that, in turn, led to various institutional responses.

The most obvious difference can be found in the size of each region's biotech sector. According to a 1997–98 Ernst and Young survey of the "life sciences sector," U.S. biotech firms earned about \$18.6 billion (\$3.1 billion for European firms) in revenues, invested \$9.9 billion in research and development (\$2.2 billion for European firms), and employed 153,000 people (39,000 in Europe) (OECD, 2000b). By early 1999, the U.S. had approved forty GM crops for commercial marketing as opposed to nine approved by the EU with none being approved during the moratorium of the last four and half years.

Differences in the structure of the two region's agriculture sectors also need to be taken into account. In the past four decades, the agriculture sector in the U.S. has become increasingly concentrated and industrialized. It has emerged as a major exporter of agricultural commodities by virtue of becoming a low-cost supplier. Since 1975, export revenues have accounted for 20%–30% of U.S. farm income (USDA, 2001). Over the past decade, U.S. agriculture exports have made up about 13%–14% of the world's total agricultural exports. With growing competition from China and Latin America, U.S. agriculture producers have had to work hard to maintain this position. One reason for this success is its reliance on large-scale modern technology, including biotechnology. Approximately 56% of cotton, 52% of soybean, and 35% of corn grown in the U.S. use GM seeds. Acreage under GM crops has grown from 6 million in 1996 to 72 million in 2000 (Foudin, 2000). In Europe, by contrast, the GM crop acreage is almost negligible. In 1999, 68% of the globe's GM crops were grown in the U.S., whereas less than 1% were grown in EU member countries (Jones, 2000).

Additionally, to a much greater extent than is true in the U.S., the family farm in Europe has consciously been protected against the potentially devastating effects of the world market under the auspices of the EU's Common Agriculture Program.¹⁵ Europeans have come to justify these protectionist practices for cultural reasons and out of a concern for the darker side of the mass production techniques (such as biotechnology) used in the U.S. (Byrne, 2000b). These values-based arguments can be attributed, in part, to the fact that the European family farm is perhaps the last

¹⁵ Arguably, this protection is not effective given the decline in the number of family farms. On the other hand, the decline most likely would be steeper had the CAP not been in place.

repository of biodiversity in that region that may be destroyed by GM-based agriculture. By contrast, the U.S. has large tracts of wilderness that preserve biodiversity and so rely little on the family farm to undertake this function. As a result, supporting organic farming is a national policy objective in many European countries. In October 2000, as a part of a comprehensive sustainable development plan, Belgium's prime minister set a goal to increase the number of organic farms by 60 percent a year for the next four years, with the aim of having at least 4 percent of the country's agricultural land farmed organically (*Daily Grist*, 2000). Germany's Chancellor Schroeder also wants to increase the share of organic food in German farm output from the current 2.5 percent to 20 percent (Mitchner, 2001). It is thus not surprising that many of the trade disputes that have arisen between the U.S. and the EU in the past decade have in some way involved agricultural issues.

Of course, this begs an explanation for U.S. opposition to labeling even outside the United States. If U.S. firms were major exporters of GM crops to the EU, this opposition could be understood. But for soybean, the major markets for U.S. agriculture exports lie outside the EU.¹⁶ Thus, U.S. opposition so far can be explained by the fear that there may be a convergence-to-the-top instead of a race-to-the-bottom, whereby EU labeling standards may be accepted as de facto standards by countries outside Europe as well. As we discuss subsequently, economic globalization in the form of pressures from importing markets is creating incentives for many U.S. exporters (such as Cargill and Archer Daniels Midland) to demand some sort of verifiable methods of segregating GM and non-GM crops.

This is not to say that European MNEs are shunning biotechnology. As indicated previously, biotechnology has been extensively used in pharmaceutical (by European MNEs) and agriculture as well as other industries. Interestingly, European MNEs active in agricultural biotechnology sell primarily to the U.S. StarLink corn which has been in the news recently is manufactured by Aventis, a European MNE. Since biotechnology applications in pharmaceuticals have yet to be debated vigorously, this industry is not being scrutinized or opposed on this count. In fact, European pharmaceutical firms have conspicuously maintained silence on the raging debate over the morality and usefulness of biotechnology lest they become the next targets of anti-biotechnology groups.

Recent food safety disasters in Europe have served only to accentuate the European public's discomfort with GM foods. Although the European public was quite skeptical about their food regulatory institutions before the recent outbreaks of BSE mad cow and foot and mouth diseases (Pollack and Shaffer, 2001), these incidents have been a key driver in the recent revisions of European biotech regulation that have ratcheted up standards further. This mistrust is accentuated by the institutional deficit in terms of a lack of "independent" (Shapiro, 1997) regulatory agencies such as the EPA, FDA, or the USDA in the EU or most member states. Because European countries have historically tended to regulate core industries through nationalizations, independent regulatory agencies have never been used extensively. With the privatization of most of these state-owned enterprises, European governments have increasingly turned to independent agencies to enhance government oversight capabilities (Majone, 1996). In the wake of the recent food safety catastrophes, the EU has decided to follow this trend and is in the planning stages of creating an independent food safety agency (*ENDS Daily*, 1999).

To sum up, the weakness of the biotech industry, the cultural importance placed on small-scale farming, and recent food safety disasters have greatly affected the political economy surrounding the biotech industry in Europe. Because consumers in Europe have come to view GMOs as potential pollutants, the EU's Environment

¹⁶ GM soyabean exported to Europe is used as animal feed and soybean oil is exported. Because very little of GM soyabean is used for human consumption, it has not become an arena for U.S.–EU trade dispute (Victor and Runge, 2002).

Directorate General logically became the lead regulatory body on this issue. This strong public reaction and its antecedent causes go a long way in explaining Environment DG's aggressive approach to regulating GMOs. In the U.S., by contrast, the strong presence of the biotech industry, a farming sector focused on price competition and exports and a public that is not particularly focused on food safety concerns has caused biotech to remain a largely technocratic issue regulated primarily by industry-friendly USDA.

Biopolitics Across the Atlantic: Toward Convergence?

Normally, our examination would end here. But starting in 1999, there has been a subtle but noticeable change in the policy agenda surrounding biotechnology issues in the U.S., signifying movement (but not a drastic change) toward some sort of convergence with EU standards, especially regarding labeling and segregation of GM crops. Further, as the passage of the revised EU rules for releasing GMOs into the environment demonstrates, the Europeans are likely to keep updating and strengthening the regulations controlling the use of agricultural GMOs. Indeed the political will for implementing greater food safety regulation has only increased in Europe in the wake of the recent outbreaks of mad cow and foot-and-mouth diseases on the Continent.¹⁷

We posit that this international pressure is beginning to have an effect on the regulatory climate for agricultural biotech products in the U.S. However, these international influences do not work in a straightforward manner and are always filtered through Kingdon's domestic agenda streams. Thus, we explain recent changes in the U.S. regulatory climate by examining developments in the domestic political economy (political stream) and the problem and policy streams. We then show how they have created the political space for pressures generated by globalization to influence the U.S. policy agenda and perhaps to ratchet up U.S. regulation. This influence from the outside is intriguing because international pressures did not seem to have much impact on the policy agenda-setting process and outcomes before 1999 despite the global marketing of GM products.

What exactly has changed in the U.S. regulatory climate since 1999? We argue that three key changes have occurred in the U.S. approach to regulating agricultural GMOs in the past three years: (1) an increase in the number of court cases challenging the marketing and release of GMOs into the environment; (2) the introduction of bills in both Congress and state legislatures calling for more stringent regulation of GMOs; and (3) the USDA's and the FDA's review of their GMO policies and their about-face on recommending labeling for GMO products. Although these changes do not represent revolutionary shifts in policy, taken together they do signify a trend toward a transformation of the regulatory climate.

The first change has been the mushrooming of legislative activity that has occurred since 1999 at both the federal and state levels. Many bills have been introduced in the U.S. Congress and state legislatures that call for more stringent regulations and mandatory labeling. The surge in legislative activity began in the 106th Congress with the introduction of several bills.¹⁸ This interest has

¹⁷ In Germany, where the outbreak of BSE has been particularly severe, political consequences forced both the Agriculture and Health Ministers to resign. The Agriculture Minister was replaced by a prominent member of the Green Party, Renate Kunast. Additionally, the Ministry was given new competencies and renamed the Ministry of Agriculture and Consumer Protection. Two weeks into her job, Kunast broke off talks with biotech companies in Germany aimed at breaking the three-year moratorium on the approval of new GMO products, saying the time was not right to broach this subject.

¹⁸ These were: H.R. 3266 (Brown), H.R. 3377 (Kucinich), H.R. 3883 (Holt), H.R. 5095 (Tierney), H.R. 5591 (Kucinich), S.18 (Harkin)/H.R. 983 (Baldacci), S. 908 (Dorgan)/H.R. 1612(Pallone), S. 1126 (Mikulski)/H.R. 2055 (Pallone), S.1281 (Dubin)/H.R. 2345 (DeLauro), S.1868 (Durbin)/H.R. 3526 (Pallone), S. 2080 (Boxer), S. 2106 (Ashcroft), S. 2315 (Moynihan), S. 2480 (Collins), S. 2692 (Mikulski), S. 2760 (Harkin), S. 2838 (Hutchinson), and S. 3184 (Durbin) (Vogt, 2000).

continued in the 107th Congress with the introduction of 50 bills (for a detailed listing of the bills see Thomas, 2000).

There has been significant legislative activity at the state level as well. In 2000, 13 bills were introduced in various state legislatures. In 2001, 130 pieces of legislation were introduced in 36 states. Ninety-three of these bills focus on such issues as regulation of GM crops, including bans or moratoriums on their use (for details see Pew Initiative on Food and Biotechnology, 2002). Maryland (HB 189) has barred the introduction of GM crops while North Dakota (HB 1388) has barred the introduction of GM wheat for two years. In addition, bills were introduced in several states to place a moratorium on GM crops. These efforts include proposals in Massachusetts (HB 2207), Montana (HB 211), New York (A 5156, A 5741, S 3016), South Dakota (HCR 1011), and Vermont (HB 247, SB 79).

Maine (LD 1266) requires manufacturers or seed dealers of GM plants to provide written instructions on how to plant, grow, and harvest the crops to minimize cross-contamination of non-GM crops. Maine passed another bill (LD 1733) authorizing voluntary use of a biotech-free label for foods that do not contain GM ingredients. In addition, 22 pieces of legislation were introduced in 10 other states (Colorado, Hawaii, Massachusetts, Michigan, New Hampshire, New York, Oregon, Rhodes Island, Vermont, and West Virginia) for either the voluntary or mandatory labeling of all food products generated through biotechnology.

North Dakota (SB 2235) passed a bill requiring the segregation of GM crops from non-GM crops. In addition, 22 bills were introduced in Hawaii (HCR 202, HCR 95, HCR 99, SB 1562, SCR 118), Iowa (HF 147, HF 257, HF 734, HF 741, SF 431, SF 454, SF 539, SF 580), Massachusetts (HB 3385, HB 178), Maine (LD 1266), Minnesota (HF 150, SF 1203), North Carolina (HB 1426), Oregon (HB 3426), and South Dakota (HCR 1010) requiring some sort of restrictions on the sale and use of GM crops (Pew Initiative on Food and Biotechnology, 2002).

The second major change to occur in the U.S. has taken place in the judicial arena as biopolitics appears to no longer be immune from adversarial legalism. In early 1999, the Center for Food Safety (2000) initiated legal action against the FDA demanding that Monsanto's genetically engineered Bovine Growth Hormone (rBGH) be taken off the market. The CFS suit was prompted by Health Canada's report (the Canadian equivalent of the U.S.FDA) that the FDA had failed to investigate studies that indicated that the oral feeding of rBGH led to a 25 percent risk increase of mastitis (udder infections) in dairy cows.

In December 1999, a coalition of small farmers and farm groups filed a class action suit against Monsanto accusing the company of marketing GM seeds without properly testing and giving farmers false guarantees about the marketability of GM crops. Further, Monsanto and nine other companies are accused of forming an international cartel that has conspired to control the world's market in corn and soybean seeds (CMHT, 2001). In December 2000, a class action suit on behalf of U.S. farmers was filed against Aventis alleging that the company failed to take precautions to ensure that StarLink does not enter the human food supply chain (CMHT, 2001).

Still the anti-biotechnology coalition has refrained from introducing the kind of adversarialism into the policymaking process that marked the early battles fought over environmental policy issues. While biotechnology for the first time is being portrayed as a new generation of pollution and a public health issue (very similar to their strategies in framing environmental debates), most groups are asking for rigorous screening and safety protocols rather than outright bans on the use of biotech products. The reason, ironically, lies in the short-term perspective that industry has adopted. Because of their huge investments in research and development, biotechnology companies have been pushy in seeking to market

their products.¹⁹ Consequently, they have been less willing to invest in long-term impact studies, field trials, and farmer education. Thus, framing the debate in terms of benefits and costs makes the anti-biotechnology alliance look reasonable (not as neo-luddites) and puts business on the defensive.

Second, the anti-biotechnology movement has come to realize that although the American public is becoming concerned about biotechnology, the problem has not been sufficiently radicalized to ignore economic implications of restrictive regulations. Importantly, unlike adversarial environmental politics where regulators sided with them, the anti-biotechnology alliance has found that regulators continue to be (reluctant) allies of the industry. Because commercial farmers and agri-business have invested large sums of money in biotechnology, they are unlikely to meekly succumb to the demands of the anti-biotechnology coalition.²⁰

The third change has occurred within U.S. regulatory agencies themselves which have begun to reexamine their regulatory deficiencies particularly in the area of labeling. The USDA has acknowledged that although it is supposed to be an independent regulatory agency, its promotional functions may clash with its regulatory functions. Thus, to remove any accusation of conflict of interest, former Secretary Glickman (1999) announced a review to ensure that the USDA maintains a credible regulatory process. In May 2000, the Clinton administration declared (and the Bush administration has not rescinded) that the USDA, the FDA, and the EPA would review agricultural biotechnology regulations (White House, 2000). In response, the FDA published draft rules in January 2001 that require firms to notify the FDA 120 days in advance before they market GM foods (*Federal Register*, 2001) and encourage firms to voluntarily consult the FDA.²¹ They also specify the safety test data that should accompany the notification (Vogt and Parish, 2001).

After opposing the labeling of GM foods for almost a decade, in January 2001, the FDA (2001) issued a new set of rules in its draft on voluntary labeling of GM foods. This change is not surprising because recent consumer studies commissioned by the FDA (2000) suggest that U.S. consumers are becoming anxious about the long-term impact of GM foods. A poll conducted by the Pew Initiative on Food and Biotechnology in January 2001 also indicates that about 75 percent of Americans want to know if their food has been genetically altered (MSNBC, 2001). Additionally, in response to threats from export markets, the USDA published draft rules for public comments that require exporters, *inter alia*, to segregate biotech and non-biotech crops; a policy solution that has been widely adopted in other countries to deal with public discomfort over GM foods. This document published in the *Federal Register* (2000) acknowledges that many importers of U.S. agricultural products want GM-free crops and U.S. firms need to respond to this market demand. As stated above, we posit that both domestic and international factors are needed to explain these subtle policy shifts that have taken place in the U.S. over the past three years. While events in the international arena have influenced U.S. domestic actors' stances toward GMO regulation, this influence always works through the prism of domestic political institutions, processes, and past policy

¹⁹ It is estimated that only 1 in 10,000 GM seed gets approved for field trial. It takes about 10 years and \$300 million in R&D investment to create a commercial GM product (Vogt and Parish, 1999).

²⁰ On the other hand, U.S. farming population is dwindling, mainly because of economic reasons. Thus, long-term viability of relying on the farming lobby to support biotechnology remains in question.

²¹ Arguably, the USDA's recent regulatory effort reflects its attempt to shield the biotechnology industry. Even prior to the stock market slide, the regulatory uncertainty and a potential consumer backlash prompted investment banks to lower ratings for leading biotechnology firms. Not surprisingly, then, Monsanto, Astra Zeneca, and Novartis decided to spin off their biotech divisions (Pollack and Shaffer, 2001). By proposing stricter regulation, particularly in the area of product labeling, the USDA hopes that consumer and investor confidence in biotechnology will be restored.

legacies. It is for this reason that Kingdon's agenda-setting model is still appropriate for examining the policy outcomes of regulatory fields that are shaped by international rule-making.²²

We begin by examining international factors. By the late 1990s, it was becoming increasingly clear that consumers in key U.S. agriculture export markets were extremely distrustful of GMO products and the U.S. MNEs that market them. A number of well-publicized attacks on fields where GMO crops had been planted in Europe and India did a great deal to publicize the issue to consumers across the globe (Depledge, 2000:160–61). Consumers in Europe and parts of Asia began insisting that U.S. MNEs be required to segregate and label GM seeds and foods so that they could choose to avoid them if they wished. These calls for labeling have been translated into concrete legislation in a growing number of countries. By June 2001, most governments in Europe, Brazil, China, India, Australia, New Zealand, Russia, Israel, Ecuador, Paraguay, Thailand, Indonesia, Hong Kong, Pakistan, Egypt, Algeria, Saudi Arabia, Sri Lanka, South Africa, Ethiopia, and Ghana had adopted mandatory labeling and other types of restrictions on GMO agriculture products (OCA, 2001).

The impact of this consumer protest and move toward mandatory labeling abroad was first felt by the U.S. MNEs that were often the targets of these protests, particularly Monsanto. As the manufacturer of GM corn, soybeans, and cotton, Monsanto has aggressively marketed GM food crops across the globe throughout the 1990s usually by ignoring requests for the segregation and labeling of GM foods and seeds. These tactics have been widely criticized by environmental and consumer groups in Europe and Asia. In response to this consumer backlash, a number of firms in Europe including McDonalds and McCain Foods (which supplies French fries to fast-food restaurants) have asked their contract farmers to produce non-GM crops. Monsanto eventually withdrew GM potatoes from the market. These developments not only hurt the sales of biotech MNEs but also influenced their stock prices. In 1999, the value of Monsanto's shares fell by 25 percent (Chase, 2000: 3D).

These dramatic events throughout 1999, mainly induced by NGO pressure, caused Monsanto and other U.S. MNEs to change their positions on establishing an international agreement regulating the trade and transport of GMOs. Talks for such an agreement, a Biosafety Protocol to the Convention on Biological Diversity (CBD), had been under way since the mid-1990s. After initially opposing such a treaty in the 1980s, Monsanto paid lip service to supporting these negotiations in the 1990s but always pushed for a very weak agreement. Its influence was felt at the negotiations in Cartagena, Columbia, in early 1999. Although the U.S. did not ratify the CBD, it actively participated in the negotiations as an observer through its five allies that have signed the CBD (the so-called Miami group). The U.S. blocked a proposed treaty that would have required exporters of GM products to obtain advance permission to distribute these products from importing countries. It also would have required that GM products be segregated and labeled. Although the U.S. government and MNEs wanted a treaty to boost confidence in the new technology, U.S. negotiators made it clear they were not going to sign a treaty they felt hampered the marketing of GM products (Pollack, 2000).

By the time negotiations for the Biosafety Protocol resumed in January of 2000 in Montreal, both the U.S. negotiators and Monsanto were willing to agree to a much stronger treaty than was the case just a year before. As outlined above, the increase in consumer protest against GMOs and corresponding action by large

²² Beginning October 2002, under the USDA's National Organic Program, 3 types of organic labels have been introduced: "100 percent organic," "organic," or "made with organic." The use of GMO ingredients is prohibited for any kind of organic label (USDA, 2003). This is an important policy shift given that USDA has maintained that GM crops are no different from non-GM crops.

restaurant retailers had caused Monsanto to change its decade-long opposition to any form of labeling as well as the use of the precautionary principle in regulating GMOs. The agreement that was signed in Montreal, which became known as the Cartagena Protocol, requires shipments of GM crops to be labeled and allows importing countries to reject these shipments based on the precautionary principle.²³ Although U.S. negotiators allowed the inclusion of the precautionary principle, they also insisted that import bans that are not based on scientific data are susceptible to WTO rules against discrimination (Alden, 2000:11).²⁴ Thus, where the line is to be drawn between precaution and discrimination remains unclear. Still, this agreement, which was praised by both Monsanto and Greenpeace, signifies a major shift in U.S. trade policy and for the first time acknowledges the legitimacy of EU labeling standards and use of the precautionary principle in the regulation of GM products.

Despite this activity at the international level, very little change occurred in the U.S. domestic arena until late 2000. Indeed the most critical change occurred due to an unexpected development—the StarLink corn episode—that opened up a “policy window,” thereby creating opportunities for the anti-GM coalition to redefine the biotechnology issue within the U.S. context. This incident took place in September 2000.²⁵ A laboratory testing on behalf of a coalition of anti-biotech groups, Genetic ID Testing Company based in Fairfield, Iowa, discovered that taco shells sold under the Taco Bell Shells label of Kraft Foods contained traces of GM corn. This particular corn, StarLink, produced by Aventis Crop Science, had been approved by the EPA for animal use but not for human consumption.²⁶ Faced with a public outcry, Kraft recalled all taco shells. Within two weeks of this incident, Safeway, a major U.S. grocery chain, found StarLink in its house brand of taco shells. At the urging of the EPA, Aventis “voluntarily” canceled its marketing license for StarLink. With the help of the USDA, Aventis sought to purchase back StarLink corn from the farmers.

StarLink contains a bacterium gene that produces a protein, Cry9C, that kills the corn borer caterpillar. Under the Insecticide, Fungicide, and Rodenticide Act, the use of such a pest-resistant crop needs the EPA’s approval. In 1998, the EPA approved StarLink for use in animal feed only.²⁷ Though Aventis required farmers to sign an agreement that the StarLink corn would be sold exclusively as animal feed, many farmers in fact never signed the agreement. Due to slack monitoring, Aventis nonetheless sold StarLink to them. Some farmers also claim that though Aventis told them that the corn was not approved for human consumption, the company alluded that the approval would come shortly. Importantly, as alleged in a class action suit filed against Aventis, farmers are claiming that they were not

²³ Exporters need a prior consent of importers for shipping GM seeds that will be introduced in the environment. Although they do not need such consent for shipping GM crops meant for consumption, they are required to label them if they contain GM products. Because of the backlash against GM crops, and the consequent lower price that exporters realize for GM crops, this effectively means that exporters have incentives to segregate GM and GM-free shipments so as to get higher prices for non-GM crops (Cosbey and Burgiel, 2000).

²⁴ Unlike the WTO’s ruling on the beef hormone case where the status of the precautionary principle was ruled as “less than clear,” the Protocol establishes the precautionary principle as the principle of international environmental law. On these counts, it corresponds to the EU approach to GMO regulation (Cosbey and Burgiel, 2000).

²⁵ We do not consider the Monarch butterfly episode to have had the same impact, although it received a lot of media coverage. For one, it did not result in the recall of food products or other mass-produced items. Further, the Monarch butterfly study has been extensively criticized on methodological grounds. As a result, key sections of the biotech epistemic community do not think much of it.

²⁶ Subsequent to the StarLink episode, Aventis asked the EPA to approve StarLink for human consumption but, much to the dismay of the food industry, was turned down (Kaufman, 2001).

²⁷ The FDA also has jurisdictional responsibilities because StarLink contains a protein that could cause allergic reactions in humans. The StarLink episode thus led to finger pointing among the federal agencies, each trying to lay blame for lax regulation at the doorstep of others.

adequately educated about planting restrictions, specifically, to have a 600-foot buffer to prevent genes of StarLink from contaminating non-GM crops (Federal Register, 2000). In November 2000, the Cry9C protein was discovered in another corn hybrid produced by Garst Seed Company (a subsidiary of European MNE, Advanta BV) licensed by Aventis to produce and distribute StarLink (Kaufman, 2000b). The anti-biotech groups have pointed out that if normal planting procedures are not followed by educated and technologically savvy U.S. farmers, how would firms ensure that their instructions are followed by often illiterate farmers in developing countries.

Only after this domestic shock occurred did the problem stream in the U.S. begin to change. Stories on biotech regulation have begun to appear regularly in the *New York Times*, the *Washington Post*, *USA Today*, and even on the CBS Evening News. A standard search on Lexis-Nexis found that 81 articles were published about GMO-biotechnology in the year 2000, 33 articles in 1999, 8 articles in 1998, while no articles were found for 1997 or 1996. Additionally, starting in 1999, well-resourced consumer and environmental groups have begun to pay more attention to biotech issues and have questioned the U.S.'s comparatively lax regulatory regime since.²⁸ Prior to that, the anti-biotechnology crusade in the U.S. was led by groups/activists (such as Jeremy Rifkin) that were generally perceived as being extremist and their arguments lacking scientific validity. Thus, the quality of actors opposing relatively lax GM rules in the U.S. has changed.

This change in the problem stream, which was only tangentially touched off by events occurring outside U.S. borders, has opened up the political space for a wider debate about GMO regulation. It is here that we see the very obvious influence of international rule-making. In particular, the policy stream, which seeks to match solutions to problems, has been greatly shaped by the rules and regulatory principles adopted at the international level and by foreign governments. The legislative, judicial, and inter-agency debates that have opened up in the U.S. since the Starlink episode have centered around the core issues of the segregation of GM products and labeling and, to a lesser extent, the use of the precautionary principle. The hesitant moves made toward the European model show that the political stream in the U.S. is still greatly influenced by a strong biotech industry and an agriculture sector geared toward price competition. Still, the changes in the tenor of debate have clearly been shaped by the recent events that have occurred at both the domestic and international levels.

Conclusions

Several scholars have examined the issue of convergence of regulatory policies and institutions in a given issue area. Our study is unique because it examines both divergence and convergence in the regulatory approaches of the U.S. and the EU in a given issue area: agricultural biotechnology. We contend that the domestic political economy is the key mediating variable in shaping the regulatory approach of a polity. It is precisely because domestic structures and processes remain important that Kingdon's model of agenda-setting has proven so useful. Globalization pressures impact regulatory policy in as much as they influence the domestic political economies; convergence or divergence is not inevitable. The domestic political economy can serve to reinforce policy divergence across polities or move them toward convergence. In short, the evidence presented above

²⁸ An example is the Turning Point project (Turning Point, 1999), an alliance of groups including Greenpeace, Friends of the Earth, Humane Society, U.S. Public Interest Research Groups, Rural Vermont, Center for Food Safety, Council for Responsible Genetics, International Forum on Globalization, and Native Forest Network. This alliance has taken out full-page advertisements in major national newspapers on the dangers of biotechnology.

supports the contention made at the beginning of the paper that the effects of globalizing processes on domestic regulatory styles are contingent and uneven.

The assertion that the pressures exerted by globalization forces are refracted through domestic institutions and political processes and therefore have uneven effects is perhaps not terribly surprising; although the tenor of the current debate sometimes obscures less absolutist interpretations such as these. The findings in this paper, however, can help us go beyond this somewhat obvious conclusion by identifying the specific circumstances under which globalization affects domestic regulation, the extent of these effects as well as what in particular is vulnerable to change.

In the early stages of the agenda-setting process surrounding biotechnology regulation, the two very different problem and political streams significantly shaped the manner in which the U.S. and the EU sought to regulate the new technology. Although it is obvious *ex post* that the divergent regulatory paths would lead to trade problems, neither side paid much attention to these risks. Instead each polity adopted legislation that was very much a function of their respective political economies such as Kingdon's model would suggest. By creating a favorable regulatory climate in the U.S. context—bestowing the USDA rather than the EPA with major regulatory authority—the U.S. government ensured that regulators would support rather than hinder U.S. biotech firms. On this count, this paper argues against the notion of a borderless world where MNEs do not have national identities (Ohmae, 1991) and supports scholars such as Pauly and Reich (1997) who argue the opposite.

It was not until markets for agriculture GM products became well established that governments and MNEs began calling for harmonization, the U.S. asking that rules be set aside while the EU insisting that its regulations be respected. The battle that has ensued began in the late 1990s and, until 2000, was mostly waged in European and Asian markets and in intergovernmental bargaining forums. By late 1999, U.S. MNEs, particularly Monsanto, began to feel the effects of this transnational pressure as markets for certain GM products began to dry up and NGO activism began to tarnish their reputations. Although this transnational pressure in and of itself was not enough to significantly change the regulatory environment in the U.S., it played a key role. Indeed one of the lessons to be drawn from this case seems to be that national governments will become more vulnerable to pressure for convergent change when key MNEs are being targeted within international markets.

The pressure from international markets increases the need to harmonize U.S. policy instruments across borders. In our case this phenomenon has most obviously been illustrated by the example of labeling and segregation of GM products. For these reasons, it seems to be the domestic policy stream (i.e., how solutions are matched to problems) that is most susceptible to outside pressure for convergence. Even here, however, this pressure has been refracted through the pre-existing institutions and processes of the domestic political economy. The U.S. government has still not made labeling of GM food products mandatory at the federal level; it has, however, drawn up guidelines for firms to do this voluntarily. Additionally, several states have adopted these instruments in their own legislatures.

As we have emphasized throughout the paper, the impact of outside pressure for convergence, while significant, is still contingent on the political space provided by the domestic political economy. Its role in influencing policy outcomes is evidenced by two facts, that it took a domestic shock, the Starlink episode, to open up the policy window necessary to bring about these changes,²⁹ and that U.S. NGOs continue to act in a relatively non-adversarial manner rather than try to push the

²⁹ Such shocks have been critical in influencing U.S. environmental policy debates. For example, Love Canal led to the Superfund legislation in 1980 and the Bhopal disaster led to the Emergency Planning and Community Right to Know Act in 1986. This raises another set of issues beyond the purview of this paper: what accounts for the varying capacities of institutions to respond to different categories of shocks.

biotechnology discourse over into the adversarial mode practiced in Europe. Thus, the domestic factors, particularly those found in Kingdon's political stream that were influential in the early stages of the regulatory field, are likely to play a lasting and significant role on domestic policy outcomes.

Where does the GMO case fall on the convergence continuum? Is this weak convergence or strong convergence? Is this an idiosyncratic case of weak convergence or is this a typical outcome for regulatory disputes between the U.S. and the EU? To assess these issues, one should examine the extent to which either party's "core positions" on the definition of a policy problem, the use of certain policy instruments, and the institutional structures used to address the problem have changed. High convergence implies changed core positions. In biotechnology, the core issues are labeling and segregation. At this point, convergence is weak because neither party has formally compromised on its core position. However, we find weak convergence to EU standards because some U.S. states have enacted labeling laws, the federal government has watered down its opposition to labeling, and there is a surprising shift in the U.S. position on the biosafety protocol.³⁰

EU and U.S. comparisons are interesting precisely because examples can be found from across the divergence–convergence continuum. In the area of anti-trust, U.S. and EU policies continue to diverge. This divergence has resulted in several high-profile disputes including the EU's rejection of the GE-Honeywell merger over U.S. objections. Similarly, the regulatory dispute over beef hormones is characterized by continued divergence even in the face of a WTO ruling against the EU. By contrast, the successful negotiation of the worldwide ban on most ozone-depleting substances is a case of strong convergence between an initially reluctant EU and a more enthusiastic U.S. The cases of GMO regulation, fisheries management, and mining in the Antarctic represent cases of weaker convergence. Our argument suggests that these differences across cases can only be explained by examining how international pressure for change is filtered through and sometimes subverted by the domestic political economy.

When upward convergent change has occurred between the U.S. and the EU in the environmental sphere, it has tended to be of the "weak ecological modernization" variety.³¹ There has been a ratcheting up of rules but not to the highest standards and generally without dramatically changing how the core issues are being defined in individual polities. In some ways, the EU's acceptance of the carbon trading model for climate change policies indicates the acceptance of "weak ecological modernization," albeit in a continuing atmosphere of policy divergence between the U.S. and the EU. The dispute over acceptable levels of airplane noise is also likely to end with a settlement characterized by weak ecological modernization as the two parties continue to negotiate over a "balanced regulatory approach" under the auspices of the International Civil Aviation Organization (United States Mission to the European Union, 2002).

While our findings go some way in pinpointing the circumstances under which international pressure causes domestic policy change as well as the extent of that change, as can be seen from the preceding discussion more research in this area is

³⁰ In the beef hormone case, there is continued divergence. The core EU position is that it will not allow the import of hormone-treated beef—labeling is not a core issue for the EU. In the face of U.S. pressure, if the EU allows import of labeled hormone-treated beef, then the EU would have compromised its core position, and the convergence would be high and toward U.S. standards.

³¹ As the anonymous reviewer correctly pointed out, trends toward convergence to the EU model serve the interest of MNEs. A convergence toward such "weak ecological modernization" (Hajer, 1995; Bernstein, 2001) helps MNEs by reducing market and regulatory uncertainties. "Weak ecological modernization" implies that economic growth and environmental sustainability can be mutually supportive. As a result, businesses, governments, and moderate environmental groups can work together on environmental policy issues. For a review of the debate on "ecological modernization" see the special issue of *Environmental Politics* (2000, vol. 9, 1), especially the review article by Mol and Spaargaren (2000).

needed. To the extent that upward convergence was achieved in the regulation of GMOs, it occurred in Kingdon's policy stream in which policy instruments are matched to policy problems. The U.S. government is likely to make concessions to the EU on labeling without changing how the problem of GMO regulation is defined in the U.S. and without changing the institutional structures erected to deal with GMOs in the U.S. Given the need for common rules in international markets, it seems quite logical that policy instruments would be more vulnerable to change than domestic policy institutions or core aspects of how an issue is framed. This hypothesis should be tested in other cases.

Our results also suggest that political scientists need a more sophisticated understanding of how the interaction of norms and material interests influences agenda-setting processes. The GMO case indicates that NGOs have numerous tools available to them to target MNEs and manipulate regulatory outcomes. Anti-biotech NGOs have waged a multi-pronged attack which has included directly targeting biotech firms by distributing negative information about firms' business practices, lobbying key retailers such as McDonald's restaurants to reduce the demand for GM foods, influencing intergovernmental forums in an effort to establish stricter trade regulations, and linking the norms of precaution, consumer sovereignty, and transparency to their demands for the segregation and labeling of GM products.

The interaction of norms and market integration seems to be more complicated and intertwined than characterizations of "globalization from below" (norm driven, NGOs) and "globalization from above" (market driven, MNEs) would suggest. In the biotech case, norms such as transparency and consumer sovereignty seem to be winning out over the influence of U.S. MNEs and the support of their government. The success of these norms is no doubt linked to the strength and political savvy of the NGOs that are promoting them. However, it is interesting to note that these groups and the governments that support them (in particular the EU) have used one of the key principles used by MNEs to promote economic globalization, namely, transparency. Economic globalization does not influence the agenda-setting process by power and money alone, it also creates the potential for the use of ideas. Once a norm has become widely pervasive, all groups are equally able to use it to their advantage. As such, it has been difficult and increasingly untenable for U.S. MNEs to deny consumers the "right-to-know" what they consume by labeling GM products.³² More research is needed on the synergy between norms and the behavior of market actors.

To conclude, upward regulatory convergence may be possible particularly in instances where NGOs can successfully put pressure on MNEs, but this process is seldom complete. Convergence, in terms of either races to the bottom or races to the top, is not inevitable; the domestic political economy can sustain regulatory divergence as well as help facilitate increased convergence. National policy agendas surrounding biotechnology regulation have been influenced by international forces but only to the extent that the domestic problem streams have made room for these issues and only in a manner dictated by domestic politics. What political scientists have been slower to recognize is the more direct effect that NGOs can have on MNE policies and behavior. Along with studying the influence of NGOs on state policy, political scientists should also focus on how they influence MNEs directly.

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³² On the subject of "strategic framing" by NGOs see Legro (1996), Keck and Sikkink (1998), and Price (1998).

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