Regulating Risk in a Global Economy:
Law, Politics and the Struggle to Govern Genetically Modified Foods

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Acronyms

APHIS	Animal and Plant Health Inspection Service, US Department of Agriculture
BIO	Biotechnology Industry Association
CBD	Convention on Biodiversity
Coreper	Committee of Permanent Representatives (EU)
DNA	deoxyribonucleic acid
EC	European Community
EFSA	European Food Safety Authority (EU)
EPA	Environmental Protection Agency (US)
EU	European Union
FAO	Food and Agricultural Organization (UN)
FDA	Food and Drug Administration (US)
FDCA	Food, Drug and Cosmetics Act (US)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GATT	General Agreement on Tariffs and Trade
GM	Genetically modified
GMO	Genetically modified organism
GRAS	Generally recognized as safe
IPPC	International Plant Protection Commission
LMO	Living modified organism
NIH	National Institutes of Health (NIH)
NTA	New Transatlantic Agenda
OECD	Organization for Economic Cooperation and Development
OIE	International Office of Epizootics (Office International des Epizooties), now also called World Organization for Animal Health
OLF	Other Legitimate Factors
OSTP	Office of Science and Technology Policy (US)
PIP	Plant-Incorporated Protectant
r-BST	recombinant bovine somatotropin

rDNA	recombinant DNA
SPS	Sanitary and Phytosanitary (Agreement, WTO)
TABD	Transatlantic Business Dialogue
TACD	Transatlantic Consumer Dialogue
TBT	Technical Barriers to Trade (Agreement, WTO)
TEP	Transatlantic Economic Partnership
USDA	United States Department of Agriculture
UN	United Nations
US	United States
WHO	World Health Organization
WTO	World Trade Organization

Chapter 1

Introduction:

Biotechnology, Risk Regulation, and Transatlantic Discord

In 1992, the United States (US) Food and Drug Administration (FDA) approved the first genetically engineered food – Calgene's Flavr Savr Tomato – for sale and marketing in the United States. Encouraged by a favorable US regulatory system and the lack of serious domestic political challenge, US scientists have subsequently created, farmers have grown, and companies have marketed a wide range of genetically modified (GM) foods and crops. By the end of the 1990s, in "the most rapid adoption of a new technology in the history of agriculture," some sixty percent of processed foods available in US groceries were derived from genetically modified organisms (GMOs).[1] By the end of 2003, the estimate had risen to "between 70 and 75 percent of all processed foods available in US grocery stores."[2] By 2007, approximately 89% of soybeans, 83% of cotton, and 61% of corn grown in the United States consisted of genetically modified varieties, and these figures were rising annually.[3] US farmers also grow genetically engineered canola, potatoes, tomatoes, papaya, squash and sunflowers, among other foods, although to much lesser degrees.[4]

By contrast with the US embrace of agricultural biotechnology, European Union (EU)[5] regulators and publics have taken a far more cautious approach to GMOs, treating genetically modified (GM) foods and crops as different from their conventional

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[1] Hill and Battle 2000. European laws use the term "genetically modified organisms," or foods or crops, while United States (US) regulatory authorities tend to refer to "bioengineered" or "genetically engineered organisms," or foods or crops. We use these terms interchangeably. When we use the more common term "genetically modified" (GM) food, it should be clear that we are speaking of genetic engineering and not conventional modification through the cross-breeding of plants.

[2] Bren 2003. Hill and Battle, in contrast, reported a figure of 60% of processed foods in 1999. Hill and Battle 2000: 5.

[3] APHIS 2007: 1.

[4] Vogt 2005.

[5] The terms EU and EC (European Community) are used interchangeably in this book. The Treaty of European Union of 1992 created three separate "pillars" of activities for the regional block: the traditional EC one, the Common Foreign and Security Policy, and Justice and Home Affairs. The first (EC) pillar covers the regulation of agricultural biotechnology. The term which encompasses all three pillars is the European Union (or EU), which is most frequently used by commentators.

counterparts, and adopting increasingly strict and complex regulatory procedures for their approval and marketing. Unlike in the United States, GM foods and crops face considerable regulatory hurdles in the EU, including requirements for mandatory pre-approval of all GM products, as well as provisions on the mandatory labeling and traceability of all GM products, which have made it difficult and sometimes impossible for US farmers to export genetically modified foods to markets in Europe.

In an age of increasing international trade and economic interdependence, these sharp and persistent regulatory differences have resulted in an ongoing transatlantic dispute where economic interests and social values clash, what some political scientists have called "system friction."[6] By the late 1990s, stricter European regulations and slower European regulatory approval processes for new GM varieties raised potentially serious obstacles to the export of agricultural products from the United States. A potential international trade war loomed.

Throughout the past decade, US and EU representatives have alternatively and concurrently dueled and tried to manage the conflict over their respective approaches to biotechnology regulation. They have formed numerous bilateral networks of government officials, scientists and civil society representatives to engage in extensive bilateral consultations. They have also discussed and negotiated the issues in multiple multilateral contexts, such as before the Organization for Economic Cooperation and Development (OECD), the international food standard setting body, the Codex Alimentarius Commission; the international trade body, the World Trade Organization (WTO); and an international environmental body, the Conference of the Parties to the Convention on Biodiversity, which has resulted in a new Biosafety Protocol. Despite these efforts, the two sides have not fundamentally modified their divergent regulatory approaches and decisions, although there have been changes as we will see. After considerable internal debate and delay, the Bush Administration finally filed a legal complaint before the WTO in May 2003, maintaining that the EU's regulatory decisions over GM crops and foods violated the EU's international trading commitments, which finally resulted in a panel decision issued in September 2006.

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6 Kahler 1995.

Today, the transatlantic dispute over the regulation of agricultural biotechnology has become a global one, illuminating the challenges faced *when national diversity meets economic interdependence*. Most contemporary regulation remains nation-based or, in the case of the European Union, a nation/region-based hybrid. Yet the market for food and for innovations in biotechnology is increasingly global, and companies pursue global strategies. Thinking about regulation only in terms of autonomous national jurisdictions, therefore, is increasingly inaccurate and inappropriate. National regulatory systems do not exist in isolation. They respond to developments beyond national boundaries that have internal effects, and their decisions have external effects over those who have no say in their determination. When conflicts arise among different regulatory jurisdictions, like the United States and the EU, there is no centralized global governmental structure present to impose discipline. Facing such potential and actual conflicts, both states and non-state actors have fostered the development of international regimes, transgovernmental networks of regulators and transnational networks of scientists and activists. Many analysts maintain that it is through a combination of these decentralized networks and pluralistic international regimes that cooperation can be facilitated, deliberation promoted, and conflict diffused. Agricultural biotechnology thus presents the world with a challenge: In an age of global markets, agricultural biotechnology cannot be regulated purely at the domestic level, yet it is unclear how, or even whether, regulation can take place at the global level when states disagree.

In this book we investigate these challenges – regulating risk in a global economy – through the prism of the United States (US)-European dispute over the regulation of agricultural biotechnology, or, as more popularly known, genetically modified organisms (GMOs).[7] The book addresses the interaction of domestic law and politics, transnational networks, international regimes, and global markets in this area. It starts by examining the US and European regulatory differences that gave rise to the conflict, examining the sources of the differences and their impact on the prospects for regulatory convergence or accommodation. It shows how conflicts arise when national regulations become barriers

[7] European laws use the term "genetically modified organisms," or foods or crops, while United States (US) regulatory authorities tend to refer to "bioengineered" or "genetically engineered organisms," or foods or crops. We use these terms interchangeably. When we use the more common term "genetically modified" food, it should be clear that we are speaking of genetic engineering and not conventional modification through the cross-breeding of plants.

to international trade, and how they can become particularly bitter and intractable when, as in the case of GMOs, they concern the regulation of risk to society. It then addresses attempts to reconcile these differences through transnational networks and multilateral institutions – which have, as we shall see, enjoyed a record of at best mixed success over the past several decades. The US/EU dispute, and whether it can be resolved through deliberative networks or international regimes, matters profoundly, we argue, not just for those countries but for the rest of the world, whose regulation of genetically modified (GM) foods and crops is likely to be influenced by the outcome of the transatlantic conflict.

In analyzing the ongoing struggle over the regulation of agricultural biotechnology, we draw upon, and seek to contribute to, rich literatures on politics and law, at both the domestic and international levels. At the domestic level, we ask why the US and EU systems for the regulation of GM foods and crops look as different as they do, and we survey theories of comparative politics that attribute differences in domestic regulation to differences in organized interests, political institutions, culture and ideas, and contingent events, respectively. We also ask about the development of the two regulatory systems over time, drawing on the historical institutionalist literature to understand the conditions under which different regulatory systems are subject to inertia or path-dependence, resisting pressures for change or displaying change only at the margins. We argue that the current "regulatory polarization" between the United States and the European Union cannot be traced to any single factor, but reflects the efforts of domestic interest groups advocating their preferences in specific institutional and cultural contexts, with a significant role played by contingent events on each side. The adoption of starkly different regulatory systems on each side of the Atlantic was not inevitable, we argue, but once these systems were in place, their subsequent development has been incremental, marginal, and path-dependent.

At the international level, we draw upon a growing body of international relations and international legal scholarship that focuses on the promise of regulation through networks and/or international regimes, with a particular emphasis on the prospect of "deliberation" as a new form of decision-making in which governmental and non-governmental actors engage in a collective search for truth and for the best policy. A

growing amount of scholarship has also addressed the roles of so-called "soft" law (which is formally non-binding) and "hard" law (which is formally binding and enforceable) as complementary (and sometimes evolutionary) means for international problem-solving. We address both the prospects and the limits to these approaches, using the GMO dispute as a vehicle. As we will see, a wealth of transnational governmental, scientific, business, and civil society networks have arisen, complementing multiple international regimes that govern aspects of the regulation of GMOs. Yet this growth of international law, networks and institutions has not necessarily led to deliberation, conflict reduction, and regulatory convergence. Transnational and transgovernmental networks have attempted to engage in collective deliberation, we demonstrate, but such deliberation has been frustrated in practice by the existence of sharply different regulatory views and traditions, by the intense politicization of the issue in domestic politics, and by the existence of distributive conflicts between the two sides. Furthermore, the international regimes established to deal with different aspects of GMO regulation can conflict and affect each other's operations, and various actors with starkly different views can "forum shop" among regimes, attempting to harness them strategically to advance their particular goals. Our study shows, for example, how "soft" law regimes can become constrained and stalemated by distributional conflicts, and "hard" law regimes (such as that of the World Trade Organization, WTO) become softened and less certain, when they simultaneously confront a single policy dispute. The result can be the continuation of underlying conflict which simply manifests itself in different venues. Nonetheless, in the end we show that, despite rather entrenched US and European positions, different transnational and international factors have affected domestic politics, institutions and decisions, both through market reactions to foreign and international regulatory rules and practices, and through direct legislative and regulatory change.

The dangers of generalizing broader conclusions from a single case study are well known, and we take care throughout the book to acknowledge the aspects of the dispute that are distinctive to the subject of agricultural biotechnology. We nonetheless embed our study and its conclusions in the broader context of theoretical and policy debates over regulatory conflict, transnational and multilateral governance, and risk regulation for two

reasons. First, this case is one of major public policy import involving revolutionary technologies that could bring significant benefits, yet are also considered (by many) to pose considerable risks. The transatlantic dispute over agricultural biotechnology *matters*, not only farmers and biotech companies that produce GM foods and crops, but also to each of us, for whom it will help determine the food we eat and the clothes we wear.[8] In order to understand the GMO case, however, we need not only to investigate and tell an empirical story (although we attempt to do just that), we need also to ground that story within generalizable theoretical accounts of comparative public policymaking, historical institutionalism, international networks and regimes, international law, and dispute resolution. In one sense, therefore, this book is of "applied theory," using a range of off-the-shelf theories of politics and law to analyze and think critically about one of the vital public-policy issues of our day. At the same time, however, we believe that our analysis of the GMO case has implications for broader theoretical inquiry, providing an important test case for theories of public policy-making, network governance, and deliberation, and generating new and novel insights and hypotheses about the workings of international "regime complexes," forum-shopping among international regimes, and the interaction of hard and soft law. Hence, we seek in this book to borrow from theoretical literatures on domestic and international law and politics, but also to give back to those literatures as well.

Second, we believe the conflict is emblematic of issues that will increasingly arise in the future in an economically globalized world characterized by rapid technological changes whose effects are uncertain. Future technological developments, including agricultural biotechnology, will affect a broad spectrum of concerns, ranging from international competitiveness, trade and investment, research and development, environmental risk, human and animal welfare, consumer notification and choice, the ethics of new research, the relative roles of scientific and political oversight of regulatory

[8] That is, in a world where agricultural trade continues to grow faster than agricultural production, and where the global food distribution system cannot guarantee the segregation of seed varieties, the resolution of the regulatory conflict between the US and EU will facilitate or impede the adoption of agricultural biotechnology, and, in this way, will shape the future of agriculture. The average yearly growth for world agricultural exports since 1951 is 3.6% (since 1980 it is 3.0%). The average yearly growth for world agricultural production since 1951 is 2.5% (since 1980 it is 2.2%). See WTO 2005 (containing a table that lists yearly changes in world agricultural exports and world agricultural production since 1951). See also Josling et al 2004: xx.

approvals, and the impact of foreign and international law and of global markets on national decision-making and local social orders. Understanding how domestic polities have governed the new technology of GM foods and crops, and how international networks and regimes have succeeded or failed in coordinating domestic regulations, is therefore a crucial first step in understanding the regulatory challenges to be faced in the regulation of other new technologies in the years to come.

In this introduction, and in the subsequent chapters of the book, we offer five inter-related arguments about the origins of the dispute, the difficulties of resolving the dispute both bilaterally and multilaterally, the impact of international and transnational developments on domestic regulatory systems, and finally the risks and potential rewards of legal recourse to the WTO. First, the United States and the European Union have adopted starkly different standards and systems for the regulation of agricultural biotechnology. These distinctive regulatory approaches, examined in Chapter 2, have led to increasing trade conflicts and potential legal disputes between the two sides, spurring calls for greater international cooperation. The *causes* of these regulatory differences, we argue, are complex, reflecting underlying transatlantic differences in organized interests, political institutions, and ideas about food and technology, as well as contingent events. Although multiple factors contributed, we show why the best explanation for the differences lies not in innate, or "essentialist" forms of culture (such as US and European attitudes toward food, risk or technology), nor in institutions alone (such as US specialized agencies compared to European political processes), but in the ability of interest groups to frame public perceptions and debates over this technology, and its uncertain costs and benefits, in light of the opportunities provided by these cultural differences and institutional structures, combined with important, contingent events. The stark differences in the US and EU regulatory systems were not preordained, we argue, by the interest-group, institutional or cultural configurations of the two sides; but the differences are real, and the two systems, once in place, have proven increasingly resistant to change, even as friction between them threatened to lead to a global trade war.

Second, we argue that the record of transatlantic cooperation on GMOs has

largely been one of failure, despite hopes for a new type of bilateral collaboration through flexible and deliberative networks of government regulators.[9] Through such networks, both officials and academic analysts believed that US and EU officials might engage in joint analysis and joint deliberation of the core issues of risk regulation, putting aside fixed positions and negotiating tactics in favor of a collective search for better understanding and better policy. Although there have been joint transatlantic meetings of scientists, government officials and civil society representatives, examined in Chapter 3, the record of US/EU regulatory cooperation on agricultural biotechnology has shown only limited evidence of genuine deliberation, or at least of deliberation that has had policy consequences. Deliberation, we argue, is a hothouse flower that flourishes only under restrictive conditions, and the sharp disagreements, intense politicization, and distributive conflicts that characterize agricultural biotechnology have all prevented US and EU policymakers from engaging in a deliberative search for the best policy in this area.

Third, we argue that the record of multilateral cooperation, undertaken within regimes such as the WTO, the Convention on Biodiversity, the OECD, and the Codex Alimentarius Commission, has been similarly limited, characterized largely by strategic maneuvering by both sides to "export" their own standards and their own principles for risk regulation, and to "forum shop" among the regimes most likely to produce each side's favored outcomes. These maneuvers have given rise to overlapping and (sometimes purposefully) inconsistent regimes for trade, the environment, and food safety, whose inconsistencies reflect the conflict between the two sides (Chapter 4). The result is that these regimes can constrain each other's operations, at least as they were initially intended to function. The WTO trade regime, with its "hard" binding rules backed by compulsory dispute settlement, has affected negotiations in "soft law" regimes, such as the Codex Alimentarius Commission, which is to be based on voluntary standards that lead to progressively harmonized regulatory policies. In turn, "softer" regimes (in the sense that third party dispute settlement is not used), such as the Convention on Biodiversity and its Biosafety Protocol, have arguably "softened" the impact of what had been considered "hard" binding WTO rules by signaling to WTO

[9] Slaughter 2004.

dispute settlement panels to tread lightly in this domain, as demonstrated (we argue) by the WTO judicial decision in the GMO case.

Fourth, we maintain that the failures of bilateral and multilateral cooperation are reflected in the ongoing differences between the US and EU regulatory systems for agricultural biotechnology, which continue to differ fundamentally in their respective approaches despite the US and EU's modification of their regulatory frameworks and administrative practices. There has, to be sure, been some domestic change on both sides of the Atlantic, due at least in part to external pressures from international markets and international regimes. On the US side, regulators have increased requirements for trials before the commercial release of many GM seeds so that these varieties, in fact, are treated distinctly from more conventional ones, despite official US proclamations to the contrary. Even in the absence of tightened regulation, moreover, US farmers have demonstrated a reluctance to adopt new GM foods and crops which they fear will be rejected in the EU and other large export markets. In the EU, meanwhile, the Commission and biotech companies have been somewhat empowered by international developments to resume approvals of new GM varieties after a long moratorium and to challenge member state bans against those already formally approved. In both the US and the EU, however, such changes have taken place at the margins of regulatory systems that remain unchanged in their fundamental approaches, reflecting long-standing adaptations to existing regulations by private interests, institutional inertia, and veto players who have managed to impede significant reforms on either side the Atlantic even in the face of considerable pressures for change. In sum, while the story is an ongoing one, the fundamental divergences remain. In some ways, in Europe we have seen much *regulatory reform without fundamental change*, and in the US, (some) *change without regulatory reform* although with little substantive difference in outcomes.

Fifth and finally, in light of the scant record of international cooperation and of regulatory convergence, we suggest that, despite considerable risks, the United States' complaint before the WTO Dispute Settlement Body, analyzed in Chapter 6, has offered the prospect of some clarification and mutual accommodation that had thus far eluded the two sides in other bilateral and multilateral fora. In particular, we show how the WTO has constrained the conflict by channeling it into a "legal" process and thereby deflecting

pressure within the US to aggressively and unilaterally retaliate against Europe, which may have occurred had there been no WTO. The WTO has simultaneously empowered political actors in the EU, including within the European Commission which would like to defend the competitiveness of European biotech research and development, and, in the process, somewhat accommodate US concerns through creating individualized GMO evaluation and approval procedures based on reasoned decisions, even though the procedures are quite demanding in practice.

In the final chapter of the book, we conclude by offering a brief summary of our findings and examining the implications of our study for the future of agricultural biotechnology, in particular for developing countries, as well as the broader implications of the GMO case for the study of international politics and international law. We maintain that in a world of rapid technological change, new conflicts over divergent regulations will continue to arise. New and existing transnational networks and multilateral regimes become sites where the underlying conflicts manifest themselves. In the process, these international regimes affect (and often constrain) each other's operations. Yet, in the end, while international institutions have been demonized by some and dubbed irrelevant by others, we show how they can channel conflict, even when confronted with highly politicized issues in which state representatives engage in strategic maneuvering and little deliberation. We show, as well, how they can empower domestic actors, leading (potentially) to some accommodation of difference and some convergence of practice. We conclude by offering our view that, in the end, the technology will be gradually accepted, but within significant market constraints for GM foods. With the rise of China, India and Brazil as players in the world economy, and as growers of GM products in particular, we examine how the future of agricultural biotechnology may lie in large part in other countries' responses to what was initially a US-European conflict.

The rest of this introductory chapter sets the stage for these arguments, introducing the challenges of genetic engineering and risk regulation and laying out the essential elements of our arguments about the nature of the dispute, the difficulties of bilateral and multilateral cooperation, the lack (thus far) of fundamental US/EU convergence, and the prospects for policy accommodation through the WTO, an

institution that itself has been subject to severe public challenge.

1.1 Agricultural Biotechnology, Risk Regulation, and the Origins of Transatlantic Conflict

Genetic engineering, the process used to create GM seeds, crops, and the foods produced from them, is a technology used to isolate genes from one organism, manipulate them in the laboratory, and inject them into another organism. Supporters of agricultural biotechnology consider such genetic manipulation to be merely the latest step in an ongoing scientific process, from the farmer's "old-fashioned" selection of seeds and Mendelian cross-breeding to the mapping of plant and animal genetic codes. These supporters argue that the characteristics of these new plant varieties offer significant benefits to both producers and consumers. The benefits to producers have been most evident in the "first generation" of GM crops, as new GM varieties can provide greater efficiency and lower costs in agricultural production. As an extensive report of the Pew Initiative on Food and Biotechnology states, "For the most part, this first generation of agricultural biotechnology products consists of single-gene, single-trait modifications made for agronomic purposes, primarily to make crops pest resistant or herbicide tolerant."[10] For example, the predominant genetically modified trait for corn, known as Bt corn, genetically incorporates resistance to the predatory corn borer.[11] The predominant trait for soybeans, such as Monsanto Corporation's Roundup-Ready soybeans, genetically incorporates resistance to the commercial Roundup herbicide.

Direct consumer benefits, by contrast, have been less immediately evident, since the most common GM crops require less maintenance by farmers without enhancing the quality or reducing the price of the product to the consumer.[12] At least in theory, however, GM crops could benefit consumers, including the world's poor, by increasing crop yields, critical for food-scarce regions and thus reducing prices. They could also provide important health benefits by adding vitamins and nutrients to conventional crops,

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[10] Pew Initiative 2004: 3.

[11] "Bt" designates "a gene isolated from the soil bacterium, *Bacillus thuringiensis* (Bt) [which] encodes a pesticide and when this gene is inserted into the plant, the plant can then produce the Bt pesticidal substance." NBII Frequently Asked Questions, available at http://usbiotechreg.nbii.gov/include/FAQRecord.asp?qryGUID=5.

[12] Bernauer 2003: 7.

resulting in products such vitamin A-enhanced rice, "heart-friendly" oil, and iron-enriched wheat.[13] For advocates of GM foods and crops, it is these long-term benefits, together with the short-term cost advantages to farmers, which constitute the promise of agricultural biotechnology. Blocking advances in this technology entails its own risks, they contend, to human life and health, especially in poorer countries.[14] A major study of the FAO in its 2003-04 *The State of Food and Agriculture* concludes,

> Thus far, in those countries where transgenic crops have been grown, there have been no verifiable reports of them causing any significant health or environmental harm… On the contrary, some important environmental and social benefits are emerging. Farmers are using less pesticide and are replacing toxic chemicals with less harmful ones. As a result farm works and water supplies are protected from poisons, and beneficial insects and birds are returning to farmers' fields.[15]

GM supporters maintain, moreover, that the health risks from eating organic foods is much greater than for genetically modified ones,[16] as shown, to give one example, by the e-coli-tainted bagged spinach from Natural Selection Foods that killed at least three people and sickened over two hundred others in the US in the fall of 2006.[17] In fact, the US Centers for Disease Control and Prevention "estimate that each year in the United States, 76 million people get sick, 325,000 are hospitalized, and 5,000 die from

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[13] See Pew Initiative 2004:3 ("The next generation of GE crop varieties will likely include a wider range of desirable agronomic traits, including drought tolerance. Food crops may be modified with traits to improve freshness, taste, and nutrition"). Until they do so, however, there will remain a "legitimacy" gap between the claims of GM advocates and the characteristics of GM products on the market. (Bernauer 2003: 19).

[14] See e.g.,. Sunstein 2004: 31-32 (pointing to Zambians turning down US genetically engineered corn, leaving "2.9 million people at risk of starvation," based on World Health Organization data).

[15] FAO (2003-04: 76).

[16] See e.g. Botkin 1996: 25-27 (maintaining that organic foods are "actually riskier to consume than food grown with synthetic chemicals").

[17] See U.S. Food and Drug Administration, *Spinach and E-coli Outbreak*, http://www.fda.gov/oc/opacom/hottopics/spinach.html (last visited Feb. 7, 2007). The spinach implicated in the outbreak was traced back to Natural Selection Foods LLC of San Juan Bautista, California.

food-related illnesses," so that assuring food safety is rightly a major concern.[18] All the attention given to GM foods, it may be argued, is diversionary, stripping resources from other areas, and thus arguably increasing food safety risks.

Biotechnology's skeptics, by contrast, have raised concerns over food safety, environmental harm, agribusiness power, and ethics, pointing to longer-term uncertainties. Many skeptics question the safety of GM foods, maintaining that they could encourage perverse selection for antibiotic resistance (through the consumption of foods with antibiotic marker genes) or trigger allergenic reactions (though the ingestion of genes introduced from foreign species, such as peanuts). Environmental skeptics raise fears that the technology could lead to monocultures, impairing biodiversity, and give rise to "super weeds" and "super bugs" through cross-pollination and pest adaptation. Skeptics contend that GM varieties could reduce biodiversity and potentially wreak unintended consequences on other species in the food chain as they become widespread. Advocates of small scale agriculture maintain that patented GM seed varieties favor agribusinesses, and threaten the livelihoods of small-scale farmers throughout the world.[19] To the extent pollen from GM plants travel, it could cross-breed with organic varieties, undermining the prospect of alternative GM-free organic agriculture.

Some opponents also raise ethical concerns that complement ones based on risk and uncertainty. They question the morality of mankind's manipulation of genes in the first place, characterized by a statement of Britain's Prince Charles that the production of GM foods "takes mankind into realms that belong to God and to God alone."[20] The genetic engineering of animals provides a clear example of how ethical issues complement environmental ones. For example, faster-growing GM salmon could potentially cross-breed with wild species, eventually wiping them out and degrading

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[18] Vogt 2005: 2.

[19] For a history of international regimes governing seeds, from the treatment of seeds as part of "the common heritage of mankind," to the recognition of some seeds as private property controlled through state-enforced patents, see Kloppenburg 1988. See also Raustiala & Victor 2004. Cf. Sunstein 2006 (noting how "scientists have recently developed an open source technique for genetic engineering, one that is not controlled by the patent system").

[20] Cullen 1999: A1 (citing Prince Charles). See also Thompson 2003: 14.

larger ecosystems.[21] To the extent humans have any ethical obligation to other species,[22] genetic engineering could trigger their destruction. Now that applications regarding genetically engineered animals and products derived from them are proceeding through the US regulatory process, with one GM ornamental fish already being commercialized, debates over ethical concerns could intensify.[23]

Finally, cultural theorists of risk maintain that the management of risk is fundamentally a reflection of cultural "values," and thus raise fundamental issues of democratic control of science. They contend that if they are correct that "risk disputes are really disputes over the good life, then the challenge that risk regulation poses for democracy is less how to reconcile public sensibilities with science than how to accommodate diverse visions of the good within a popular system of regulation."[24] In the case of multiple jurisdictions, the challenge is greater still, namely how to accommodate multiple, conflicting and overlapping sets of regulations, each reflecting a distinctive conception of "the good life." In that context, the spread of GM varieties patented by US-based companies is often seen as one more reflection of US cultural hegemony, and an attack on alternative ways of living.

These debates over risks and benefits have largely been framed in the West, and in particular in the United States and Europe, without taking into account the perspectives and priorities of those in other parts of the world. Proponents in the US and Europe refer to the needs of developing countries, stressing the potential of GM foods to reduce malnutrition and disease. Skeptics point to the biodiversity challenges posed by GM crop monocultures and the adverse social impacts for developing country farmers of widespread use of seeds owned and controlled by US and European multinational companies. In the context of these struggles over defining principles (e.g. science and precaution) and their enactment in formal law, developing countries must balance their

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[21] See Martin 2003; NRC 2002a and 2004; and, more generally, chapter 5 of this volume on the regulatory challenge of transgenic animals.

[22] See Singer 1990.

[23] A transgenic ornamental fish for aquarium has been commercialized, and genetically engineered salmon (containing an introduced growth hormone) could be commercialized soon. Genetically engineered animals could also be used to produce pharmaceuticals, as well as organs and tissues for transplants into humans. Pew Initiative 2004:101. See also NRC 2004 and NRC 2002a.

[24] Kahan, Slovic, Braman and Gastil 2006: 1083-84.

desire for access to European commercial markets and their competition with US and other agricultural exporters, along with local concerns. Although he FAO has noted case studies showing "how biotech can be deployed to help the poor and hungry,"[25] the evaluation of the prospects and risks of agricultural biotechnology for these countries and their constituencies have so far taken a backseat to US-European commercial, regulatory and cognitive framings. We examine the potential for a shift in such framings in chapter 7.

Crucially, we argue in this book, biotechnology regulation concerns the *regulation of technological risk under uncertainty* in an economically and environmentally interdependent world, which, in consequence, pits specific regulatory standards and broader regulatory systems of powerful states against each other. However, from here, supporters and opponents of the US and EU approaches quickly divide. Supporters of the new technology tend to focus on the scientific assessment of its *risks* that can be measured and managed, while skeptics tend to focus on the *uncertainty* that belies the possibility of any meaningful measurement of long-term effects, calling for greater precaution and the recognition of different values underlying risk perceptions.

To start with the concept of risk, it refers to "the combination of the likelihood (*probability*) and the harm (*adverse outcome*, e.g. mortality, morbidity, ecological damage, or impaired quality of life) resulting from exposure to an activity (*hazard*)."[26] In principle, regulators faced with a novel product or process – such as the genetic modification of foods and crops – need to ascertain the potential harm caused by such activities, the probability of such harm, and the costs and benefits of feasible alternatives, in order to take a decision on the legality, illegality, or regulatory conditions for that product or process.

In many ways, such decision-making over technological risk is similar to what

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[25] The first trials of a genetically modified crop variety developed in Africa, a variety of maize resistant to maize-streak virus, a disease carried by insects, may occur soon; see Economist 2007. The FAO has noted case studies showing "how biotech can be deployed to help the poor and hungry." See FAO Newsroom, "Biotechnology at Work," available at http://www.fao.org/newsroom/en/focus/2004/41655/article_41669en.html (noting disease-free bananas in Kenya, pearl millet in India and bt cotton in China; "Yields for insect-resistant cotton are about 20 percent higher than for conventional varieties, and pesticide use has been reduced by an estimated 78 000 tonnes -- an amount equal to about one-quarter of the total quantity of chemical pesticides used in China.") See generally FAO 2004.

[26] Wiener and Rogers 2002: 320, emphasis in original.

Weber identified as "calculation" on the part of the capitalist entrepreneur.[27] The entrepreneur is uncertain of the state of the world, but engages in ventures which involve risk. In making an investment, the entrepreneur must calculate risk under uncertainty. And so it is with regulators and scientists when they assess technological risk. They are uncertain what they know, and there is risk in what they venture. Yet there is a huge difference between them and the entrepreneur. The risk for the entrepreneur is a private one. For the regulator, it is a public risk, one that, in some cases, could be catastrophic.

Skeptics of the technology, in contrast, tend to focus on the *uncertainty* of its effects, insisting that uncertainty is a different concept than risk, and entails not just differences in degree. They point to the classic Knightian distinction that risk is something that one can calculate, while uncertainty is something that one cannot.[28] Taking from sociologists such as Ulrich Beck, some argue that, with such modern industrially produced risks, "the *actual* consequences ultimately become more and more incalculable."[29] They maintain that what one cannot control with GMOs, in particular, are the long-term ecological effects of their adoption, effects that cannot be estimated, modeled or predicted. Skeptics also raise the complementary concept of *ignorance*, in which "not only the probabilities, but also some possibilities may be unknown."[30] That is, the very nature of the possible harm and its magnitude are unknown. They thus focus on the need for considerable precaution regarding the adoption of such new agricultural production processes. Finally, they argue that risk assessments under uncertainty are inherently value-laden, since the perception of risk itself reflects cultural predispositions, including among scientists.[31]

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[27] Weber 1947: 193; Weber 1958: 19.

[28] See Knight 1921 (risk refers to situations with knowable probabilities, while uncertainty refers to situations where only randomness applies, and a decision maker cannot assign probabilities to them).

[29] Beck (1992:171). Beck states that this is "*because* the possible effects become more and more estimable and their assessment takes place more and more in the research process and in interaction with its inherent taboo zones, and determine those zones in the course of results."

[30] Sterlin & Mayer 2000: 39. See also Wynne 1992; Sunstein 2005: 60.

[31] See e.g. Kahan, Slovic, Braman and Gastil 2006.

Leading sociologists such as Ulrich Beck and Anthony Giddens contend that questions of risk regulation have become defining traits of modern society.[32] They theorize "modernity" in terms of the emergence of what they call a "risk society" in which risks are increasingly "manufactured," as opposed to being "natural" or "external" to human activity, in which they no longer consist of personally assumed risks, but become "global" in their potential consequences, and in which the management of risks becomes a defining element of societal conflict and social understanding, including at the global level.[33] As Giddens writes, "Risk is the mobilizing dynamic of a society bent on change, that wants to determine its own future rather than leaving it to religion, tradition, or the vagaries of nature."[34] As Beck puts it, "in advanced modernity, the social production of *wealth* is systematically accompanied by the social production of *risks*. Accordingly, the problems and conflicts related to distribution in a society of scarcity overlap with the problems and conflicts that arise from the production, definition and distribution of techno-scientifically produced risks."[35]

Supporters of the technology, however, maintain that it is an error to focus on uncertainty because science admits for little certainty. Rather, science focuses on degrees of risk that can be tested and reduced. They contend not only that there are potential costs, but also potential benefits from the technology that need to be assessed and compared. In fact, Knight developed the very concept of uncertainty in an attempt to explain "profit" the title of his famous book being *Risk, Uncertainty and Profit*.[36] Were society to attempt to eliminate uncertainty, it would also eliminate great and beneficial technological changes, from the airplane to electricity. As regards agricultural biotechnology, proponents maintain that the GM seeds and foods at issue pose no greater

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[32] Mark. I think we need to include a paragraph such as this in the text, both because it is important literature, and in particularly for some of my/our audience (law and society). Is it best to put it here or elsewhere, such as earlier in the intro?

[33] See Beck 1992 & 1999; and Giddens 1991.

[34] Giddens 2000: 42. See also Giddens 1991 ("the point… is that, in conditions of modernity, for lay actors as well as for experts in specific fields, thinking in terms of risk and risk assessment is a more or less ever-present exercise of a partly imponderable character," at 123).

[35] Beck 1992: 19. Beck (1992: 34) writes, "The center of risk consciousness lies not in the present, but *in the future*. In the risk society, the past loses the power to determine the present. Its place is taken by the future, thus something non-existent, invented, fictive as the 'cause' of current experience and action."

[36] Knight contends that if risk were perfectly calculable in terms of probabilities, then in a world of perfect competition, there would be no profit.

risk than conventional varieties, and offer substantial potential benefits. The United States, they argue, has provided a free laboratory experiment for the world in which GM-derived crops and foods have been grown and consumed for over ten years without any proven harm. Had there been harm to humans, animals or the environment, proponents argue, surely it would have been uncovered in the United States which has the strongest tort-liability system in the world.

Whether or not one accepts the claim that we live in a fundamentally different form of society in which the regulation of manufactured risks is a defining trait, risk regulation requires regulators, in practice, to act in the face of uncertainty regarding the nature and extent of the risks posed by new products and processes. Dynamic technological change raises fundamental questions about how it should be governed. Faced with decisions involving risk under uncertainty, regulators often take *precautionary* measures, regulating or banning certain products or activities in the absence of complete information about the risks posed.

In a review of comparative risk regulation, Giandomenico Majone categorizes four distinct ways in which government regulators in the United States and other jurisdictions have responded to risks, listing them in order of decreasing regulatory severity (or increasing rationality, depending on one's perspective): prohibitions, requirements for the least feasible risk, elimination of only significant risks, and regulation based on cost-benefit analysis. More concretely, regulators have responded to risks (1) by imposing product bans; (2) by setting standards that minimize risk "to the extent feasible;" (3) by enacting requirements to eliminate "significant risks," typically following a risk assessment procedure; and/or (4) by engaging in cost-benefit analysis, prohibiting a product or process only to the extent that one calculates that its risks outweigh its benefits, possibly leaving for a margin of error. Majone maintains that there has been a general trend over time from (what is in his view) the first and least sophisticated to the fourth and most sophisticated approach. Under the first of these approaches, regulators exercise a high degree of precaution by simply banning any product (e.g. food additives) that can be shown to pose some level of risk to human health (e.g. carcinogens). While clearly motivated by a concern for human health, such outright bans ignore the potential social benefits of the banned products, as well as the probability

of risk posed by a given product, which in the case of carcinogens can run the gamut from significant to highly improbable. For this reason, he argues that regulators in the United States and elsewhere have moved over time towards other, less blunt, approaches toward risk regulation.[37]

According to Majone's second principle, regulators are required to set standards that minimize risk "to the extent feasible." This standard is more discriminating than outright prohibition, but it begs the question of technological or economic feasibility, and once again makes no distinction between significant and minor risks. For this reason, Majone contends, US lawmakers, regulators and courts moved during the 1970s and 1980s toward a third approach, in which the goal of regulators was not to eliminate *all* risk but rather *significant* risks. This approach required regulatory agencies to engage in scientific (and typically quantitative) risk assessments as the basis for new risk regulations. Fourth and finally, he contends that this gradual process of policy learning culminated in the use of *cost-benefit analysis* as the basis for all risk regulation. Such an approach involves not only the use of scientific risk assessments as the basis for assessing the risk of a new product or process, but also the economic calculation of the potential costs and benefits of proposed regulations. These regulations would be adopted only if the net benefits offered to society exceeded their costs. In the space of some three decades, Majone concludes, American policymakers, regulators and courts progressed to a sophisticated approach to risk regulation, relying on scientific assessments of risk as well as economic assessments of costs and benefits – "an outstanding, and in many respects unique, case of policy learning."[38]

While a useful heuristic device to understand the range of possible approaches to regulating risk under uncertainty, Majone's classification scheme simplifies a complex US response to risk that today combines elements of all four approaches under different laws and in different areas. Even more importantly for our purposes, this ideal-typical progression fails to capture parallel developments in Europe, where risk regulation took place largely within national contexts until the 1980s, when EU institutions began to play an increasing role in harmonizing risk regulation across the EU's various member states.

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[37] Majone 2003a: 18-26.

[38] Majone 2003a: 26. See also Breyer 1993.

In the EU context, David Vogel and others have argued, Europe's approach to risk regulation has evolved quite differently than in the United States.[39] Whereas the former began with highly precautionary legislation in areas like the environment, consumer protection, and worker health and safety, only to adopt scientific risk assessment and cost-benefit analysis more recently, regulators in Europe have arguably become more precautionary and more risk-averse over time. Vogel writes:

> Between the 1960s and the 1990s, a number of US regulations were more stringent, innovating and comprehensive than those adopted by European countries and the EC/EU. However, since the mid 1980s, this pattern has changed. Now in a number of significant areas of regulatory policy, EU regulations are more stringent, innovative, and comprehensive than those adopted by the US. Prior to the mid 1980s, US policy-makers identified more products and processes as posing unacceptable risks to public health or the environment than did regulatory authorities in Europe. Now the latter regard a number of products and processes as posing unacceptable risks to consumers and the environment that US policy-makers do not. Since the mid 1980s, the political influence of constituencies favoring more risk averse regulatory policies have strengthened in Europe while since the early 1990s it has declined in the US. Likewise, since the mid 1980s regulatory politics and issues have become more politically salient in Europe, while since the early 1990s, they have declined in the US.[40]

In effect, Vogel maintains, US and EU risk regulation resemble "ships passing in the night," with the EU becoming more precautionary and the US less precautionary over time. A central cause of this increasingly precautionary approach, Vogel and others argue, has been the long series of European regulatory failures and crises over the past several decades, including most notably the BSE or "mad cow" crisis discussed in Chapter 2. As we shall see, these crises have weakened public trust in EU regulators and

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[39] Vogel 2001, 2003.

[40] Vogel 2003: xx.

scientific risk assessments, increased support for highly precautionary regulations, and called into question European publics' acceptance of the *legitimacy* of EU regulations and EU institutions.[41] Responding to this crisis of legitimacy, EU institutions have moved aggressively to overhaul EU risk regulation across a range of areas, adopting strict new regulations for products and processes like genetically modified foods and crops and elevating the "precautionary principle" to play a defining role in EU regulation, as examined in Chapter 5.[42]

Other scholars dispute Vogel's "ships passing in the night" characterization of US and EU risk regulation, noting that the purported "flip-flop" in US and EU approaches to risk regulation draws disproportionately from a few controversial issues, such as the use of growth hormones in cattle and the regulation of GMOs. In a wide-ranging survey of US and European risk regulation, Jonathan Wiener and Michael Rogers find a more complex set of outcomes, in which the US is more precautionary in some areas (e.g. nuclear energy, particulate air pollution) while the EU demonstrates greater precaution in others (e.g. GMOs, hormone-treated beef). They contend that "[t]his broader analysis indicates that neither the US nor the EU is a more precautionary actor across the board, today or in the past. Relative precaution appears to depend more on the particular risk than on the country or the era."[43]

For this reason, we resist characterizing either the US or the EU as the more risk-averse in general, i.e., beyond the specific context of agricultural biotechnology. However, we do emphasize the difficulty of biotechnology regulation as a form of risk regulation under uncertainty, which raises central questions regarding the interrelation of conflicting environmental, food safety and trade laws at the domestic, regional, and international levels. As we shall see in detail in Chapter 2, the United States and the European Union have taken starkly different approaches to the regulation of biotechnology. In the United States, the basic regulatory framework was set in 1986 by

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41 On risk regulation and EU governance, see e.g. Neyer 2000; Vos 2000; Joerges 2001b; Vogel 2001, 2003; Abels 2002; Chalmers 2003; Majone 2003b.

42 The literature on the precautionary principle in risk regulation has mushroomed in recent years. For a range of supportive and critical views, see e.g. Bodansky 1991; Cameron and Abouchar 1991; European Commission 2000; Wiener and Rogers 2002; Majone 2003b; Sunstein 2005 (finding the principle in its strong form as often used in the EU to be "incoherent" because it does not take account of countervailing risks from non-action).

43 Wiener and Rogers 2002: 322-23.

executive action, when the Reagan Administration's Office of Science and Technology Policy (OSTP) issued a "Coordinated Framework for the Regulation of Biotechnology" that continues to shape US biotech regulation to the present day. Simplifying slightly, the US regulatory framework is based on the premise that the techniques of biotechnology are not inherently risky and that biotechnology can therefore be adequately regulated by existing federal agencies under existing statutes, obviating the need for new legislation dedicated to genetically modified organisms. The Coordinated Framework established a division of responsibility among three primary US regulators, with the Food and Drug Administration (FDA) serving as the primary regulator of GM foods, the United States Department of Agriculture (USDA) charged with oversight of the planting of GM crops, and the Environmental Protection Agency (EPA) responsible for overseeing the environmental and food safety impact of GM crops that have pesticidal characteristics. Crucially, these three agencies have generally regulated GM foods and crops in terms of the characteristics of the product, rather than in terms of the process by which they are produced, although there has been some interesting changes in US regulatory practice (examined in Chapter 5).

By comparison with the United States, EU regulation of biotechnology was far more decentralized, with a decision-making process in which the key decisions were taken not by a specialized regulatory agency like the FDA, but by political bodies such as the Council of Ministers, Commission, and European Parliament, in an uneasy cooperation with "competent authorities" in each of the member states. The EU has also taken a far more precautionary and stricter approach to biotech regulation, adopting by legislation a specific and increasingly demanding regulatory procedure for the environmental release and marketing of GM foods and crops. According to the terms of a 1990 directive (since amended and elaborated by subsequent legislation), all genetically modified foods and crops are subject to a special authorization procedure, requiring scientific risk assessment by national and/or European regulators and featuring much greater involvement of political officials in the Union's regulatory committees and in the Council of Ministers. In practice, this procedure has led to a much slower approval of new GM varieties in Europe, and in particular to a six-year (1998-2004) moratorium on the approval of GM varieties in the Council. Even officially approved varieties,

moreover, have had to meet additional hurdles, including recently adopted EU provisions for the labeling and traceability of GM crops, the prospect of national-level bans on specific GM foods and crops approved at the EU level, and boycotts of GM products by consumers and retailers.

The causes of these starkly different regulatory approaches are examined in Chapter 2. Surveying the various accounts of GMO regulation in the US and the EU, we identify four classes of explanation for the observed differences. As we shall see, some analysts stress *cultural differences* in European and American attitudes toward food or toward risk, with the US purportedly more risk-acceptant than the EU; some point to *institutional differences* in US and European assessments and management of risk, including the existence of independent regulatory agencies in the US, and the larger number of institutional actors or "veto players" in the EU; some highlight differences in *interest group configurations*, with the US being characterized by a larger and more politically influential biotech sector; and some note the differential impact of *contingent events* such as the European food-safety crises of the 1990s. Against that background, we argue that the very different approaches to GMO regulation that we observe between the United States and the European Union were not determined in any straightforward way by either the institutions or the political culture or the interest-group configurations present on either side of the Atlantic. It was not inevitable that US regulators would adopt a product-based approach to GMO regulation, nor was it obvious from the outset that the EU would adopt the strict, politicized and highly precautionary system that emerged over the course of the 1990s. The best explanation for the observed transatlantic differences, we believe, is multi-causal, lying in the ability of interest groups to capitalize on pre-existing cultural and institutional differences, with an important role played by contingent events such as the European food safety scandals of the 1990s.

In the US case, powerful interest groups, including the biotech industry and farmers' associations, sought a regulatory framework that would treat new GM varieties as substantively equivalent to their conventional counterparts, and in doing so they were able to draw on a supportive institutional and cultural context, including a regulatory system featuring strong and relatively independent government regulators, a diverse consumer protection movement that was divided on GMO regulation, and a cultural

tradition of accepting the use of new technologies in food production. Yet contingent events also played a role, including the preferences of a Reagan Administration that shaped a Coordinated Framework giving primary responsibility to the FDA at the expense of the more precautionary EPA. In Europe, by contrast, pro-GMO interests in Europe were weaker, with a smaller biotech sector and an agricultural community which was slow to take up GM foods and crops and never emerged as a champion of the new technology, and they did indeed encounter an institutional and cultural framework that provided multiple veto points and multiple sources of opposition (on environmental, food-safety, and ethical grounds) to GMOs, resulting in the more demanding, politicized and process-oriented EU regulatory system. The subsequent evolution of the EU regulatory process in the direction of ever-greater precaution, however, is in large part a direct result of contingent events, namely the BSE crisis and other food-safety scandals of the 1990s which undermined public support for the technology and trust in regulators at a crucial time in the introduction of GM foods and crops.

Neither the United States nor the European Union, then, was preordained by its interest-group, institutional or cultural characteristics to adopt the precise regulatory framework that each side adopted when the technology of genetic engineering and the prospect of GM foods and crops emerged as a public-policy issue in the 1980s and early 1990s. By the same token, we argue throughout this book that the respective US and EU regulatory frameworks, once adopted, have proven remarkably resilient in their essential characteristics. The explanation for this resilience, we argue, can be found in historical institutionalist theory, which examines the effects of institutions on politics *over time*, maintaining that institutional choices taken at one point in time can persist, or become "locked in," thereby shaping and constraining actors later in time. Political institutions and public policies, in this view, are subject to "increasing returns," insofar as those institutions and policies generate incentives for actors to stick with and not abandon existing institutions, adapting them only incrementally to changing political environments. These increasing returns may reflect constraints *from above*, in the form of legally binding rules that are difficult or costly for political actors to change, or *from below*, as societal actors adapt to and develop a vested interest in the continuation of

specific public policies.[44]

Insofar as political institutions and public policies are in fact characterized by increasing returns, politics will be characterized by certain interrelated phenomena, including: *inertia*, or *lock-ins*, whereby existing institutions may remain in equilibrium for extended periods despite considerable political change; *a critical role for timing and sequencing*, in which relatively small and contingent events that occur at *critical junctures* early in a sequence shape (that is, provide the institutional context for) events that occur later; and *path-dependence*, in which early decisions provide incentives for actors to perpetuate institutional and policy choices inherited from the past, even when the resulting outcomes are manifestly inefficient. At the extreme, institutions and policies can become *self-reinforcing*, such that the operation of the institution or policy not only resists change, but bolsters its societal support base in such a way that the institution becomes more difficult to change, and more stable in the face of external shocks, over time.

In this context, we argue that the US and EU regulatory frameworks for agricultural biotechnology, while not themselves determined by pre-existing institutional constraints, have since generated significant increasing returns, lending each system considerable resistance to change, and indeed making each system self-reinforcing. In each case, timing and sequencing have proven vital, as the initial regulatory frameworks were adopted at critical junctures that shaped subsequent developments. In the US case, the critical juncture occurred in the mid-1980s, when the introduction of agricultural biotechnology and of GM foods and crops presented policy-makers with a crucial set of choices. In this context, the Reagan Administration laid down a comprehensive regulatory framework within existing statutory authority, with results that came close to the preferences of the biotech industry. The critical juncture in the EU came a few years later, in the context of a European Union with a relatively weakly organized biotech industry, diverse preferences among EU governments, and a decision-making system with a large number of veto points, with the result that the EU's initial regulatory framework laid down a more demanding regulatory procedure closer to the preferences of GM opponents. In addition, a further critical juncture arguably came during the second

[44] Pierson 2000, 2004.

half of the 1990s in the EU, when the BSE and other food-safety scandals strengthened the position of those actors who sought to make the EU's regulatory framework even more restrictive, resulting in the post-1998 moratorium and the subsequent strengthening of the regulatory framework early the following decade.

Just as importantly, in each case the regulatory frameworks adopted have generated increasing returns, both by creating institutional rules that could be changed only with difficulty, and by generating adaptations among interest groups and public opinion that contributed the stability of the two respective frameworks. In the US case, the early adoption of a relatively welcoming regulatory framework contributed to the rapid growth of the biotech industry and the equally rapid adoption of GM crops by American farmers, who have represented the bulwark of political support for the existing framework in the face of environmental and food-safety contention about GMOs. In the European Union case, by contrast, the early adoption of a relatively restrictive regulatory framework, together with the turn against GMOs in public opinion and the subsequent declaration of a de facto moratorium, discouraged farmers from planting GM crops, prompted retailers to resist GM foods, and led to the flight of agricultural biotech investment from Europe, further undermining societal support for GM foods and crops. At the same time, the EU's convoluted legislative process, requiring qualified majorities among the member states in the Council of Ministers and an absolute majority of a European Parliament that has turned largely against GMOs, has created a huge institutional hurdle to the reform of the EU regulatory framework. Hence, the politics of GMOs, which were arguably fluid during the early years of the technology, have become increasingly rigid in both polities, with strong resistance and high thresholds to fundamental change on either side.

Whatever their causes, the stark and persistent differences between the two systems have led to serious transatlantic tensions, as US biotech producers and farmers have found themselves increasingly unable to export GM foods and crops that have been found to be safe by US federal regulators to Europe, or to countries following Europe's example. As a result, the US has brought increasing pressure on the EU to facilitate the approval of new GM varieties, culminating in the bringing of a WTO complaint against the EU in May of 2003. The stark contrast between the US and EU regulatory systems,

therefore, is not simply a compelling case of comparative public-policy analysis. It has become the source of serious transatlantic and international trade disputes, reflective of conflicts over divergent regulatory approaches that we will continue to see in the future.

1.2 The Promise, and Failure, of Transatlantic Cooperation

The relationship between the US and the EU is not, of course, purely conflictual, despite the real and significant differences among them over the regulation of GM foods and crops. While the trade impact of different regulations presents a clear potential for conflict, the US and the European Union remain each others' largest trading partners and sources of direct foreign investment, as well as political and military allies, and these common interests provide a strong incentive for both sides to cooperate to achieve a unified approach to the regulation of GM food and crops – or, failing that, to prevent the GM issue escalating into a full-scale transatlantic trade war. Toward this end, the US and the EU have engaged in efforts at both bilateral and multilateral cooperation on GM issues since the 1990s, seeking common understandings, if not common standards, on the regulation of agricultural biotechnology. These efforts reflected scholarly claims about the promise of transgovernmental networks of regulators and about the ability of international regimes to encourage international cooperation under anarchy. In practice, however, both of these routes – bilateral cooperation among US and EU regulators, as well as multilateral cooperation in various international regimes – have proven relatively disappointing, providing as yet no clear solution to the fundamental differences between the two sides' approaches.

International relations and international legal scholars have pointed to the prospect of international governance through so-called "transgovernmental networks" of lower-level government officials cooperating directly on a day-to-day basis with their counterparts in other jurisdictions.[45] Such networks are now commonplace in the European Union, where national regulators have established formal and informal EU-wide networks in most areas of policymaking, from competition policy, financial

[45] The foundational statement is Keohane and Nye 1974.

services, environmental policy to utilities regulation.[46] By the turn of the century, Anne-Marie Slaughter argued, national regulators had emerged as "the new diplomats," bypassing traditional foreign-ministry channels to cooperate in a "fast, flexible, and efficient" manner with their counterparts.[47] Significantly, we and other scholars have pointed to the transatlantic relationship, and in particular to the 1995 New Transatlantic Agenda and the 1998 Transatlantic Economic Partnership (TEP), as an emerging arena for such regulatory networks, with US and EU regulators interacting directly and fruitfully in areas such as competition policy and data privacy protection.[48]

Some scholars went even further, maintaining that these emerging transgovernmental networks could provide the setting for a sort of international deliberative democracy, in which national experts would meet, set aside their preconceived notions about the national interest, and deliberate together in search of the best available policy in a given issue-area.[49] This emphasis on deliberation derives largely from the work of Jürgen Habermas, whose theory of communicative action has been adapted to the study of international relations and to the study of EU governance.[50] In Habermasian communicative action, or what Thomas Risse calls the "logic of arguing," political actors do not simply bargain based on fixed preferences and relative power; they may also "argue," questioning their own beliefs and preferences, and being open to persuasion and the power of the better argument.[51]

Habermas and his followers concede that genuine communicative action, or argumentative rationality, is something of a hothouse flower, likely to flourish only under a fairly restrictive set of conditions. In international politics, Risse argues, deliberation, or a logic of arguing, are most likely under the following conditions:

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[46] On transgovernmental relations in the EU, see e.g. Wallace 2005: Coen and Thatcher 2005; Eberlein 2005; Eberlein and Grande 2005; and Eberlein and Newman 2006. The so-called Open Method of Coordination, discussed in Chapter 3, is a variant of these networks; see e.g. Heritier 2003; Borrás and Jacobsson 2004; Zeitlin and Pochet 2005; Rhodes 2005; and Rhodes and Citi 2007.

[47] Slaughter 1997, 2004.

[48] Pollack and Shaffer 2001a; Shaffer 2002.

[49] See e.g. Joerges and Neyer 1997a, 1997b; Risse 2000; and the essays in Zeitlin and Pochet 2005; for critical analyses, see Rhodes 2005 and Rhodes and Citi 2007.

[50] Habermas 1985, 1998.

[51] Risse 2000.

- The existence of a common lifeworld provided by a high degree of international institutionalization in the respective issue-area….[or through] conscious efforts by actors to construct such a common lifeworld through narratives that enable them to communicate in a meaningful way.
- Uncertainty of interests and/or lack of knowledge about the situation among the actors.
- International institutions based on nonhierarchical relations enabling dense interactions in informal, network-like settings.[52]

These conditions are by no means satisfied everywhere in international politics; but where they are present, Habermasian scholars predict that international actors will engage in arguing rather than bargaining, presenting their arguments in a common language, such as those of law or science, and proceeding to decisions on the basis of "the better argument" rather than the bargaining power of the respective actors. And indeed, a growing number of studies have pointed to at least suggestive evidence of deliberation within EU regulatory networks, including the EU's Committee of Permanent Representatives[53], comitology committees,[54] and the OMC,[55] as well as internationally.[56]

Faced with a situation of growing economic interdependence, US and EU policymakers in the 1990s onwards engaged in extensive efforts at bilateral cooperation, enlisting networks of scientists, civil-society groups, business representative, and especially government regulators from both sides to exchange views in the hope of fostering better understanding of each other's regulatory approaches. In this context, they identified biotechnology as an area in which structured dialogues might build mutual understanding and trust, provide early warning of disputes, and perhaps contribute to a

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[52] Risse 2000: 19-20.
[53] Lewis 2003.
[54] Joerges and Neyer 1997; Joerges 2001.
[55] Jacobsson and Vifell 2003; Borrás and Jacobsson 2004; Zeitlin et al. 2005; but see Rhodes and Citi 2007.
[56] Risse 2000.

gradual convergence of regulatory approaches to GMO foods and crops.[57] Starting in the 1990s, the US and the EU established a series of working groups on GM foods and crops, bringing together government regulators, scientists, and representatives from business and civil-society groups, in order to deliberate, separately and together, and possibly find common ground.

As we shall see in Chapter 3, however, these groups generally did not produce the level of deliberation desired, or at least any deliberation that has so far had any significant impact on the ongoing transatlantic GMO conflict. US and EU regulators did meet regularly and exchange information and views during the 1990s, but they also brought to the table, and sought to defend, starkly different regulatory approaches, and none of these groups was able to reach agreement on practical cooperation in the approval of GM foods and crops, much less on harmonized regulations. Just as importantly, even if regulators from the two sides had been able to bridge their differences and move towards a common approach, both sides found themselves operating in a highly politicized issue-area characterized by strongly mobilized interest groups and by a volatile public opinion that made it difficult, if not impossible, to engage in any substantive compromise.

1.4 The Move to International Institutions.

The regulation of agricultural biotechnology did not, in any event, remain simply a bilateral issue. By the late 1990s, other countries were adopting their own regulatory approaches to GM foods and crops. The choices made by those countries, and by the various international regimes whose competences touched in one way or another on the issue of agricultural biotechnology, could bolster or undermine US and European positions, and both sides therefore sought to advance their interests through a variety of multilateral regimes such as the World Trade Organization and its Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which addresses trade-related aspects of GM foods and crops; the Cartagena Biosafety Protocol, signed in 2000 as an amendment to the UN Convention on Biodiversity (CBD), which deals with the environmental implications of GMOs; the OECD which examines cross-cutting trade, regulatory, and

[57] For a good presentation of agricultural biotechnology as a promising case for international deliberation, see Murphy 2001.

technological issues; and the Codex Alimentarius Commission which sets "voluntary" food-safety standards for conventional as well as genetically modified foods.

For decades, regime theorists have argued that multilateral regimes could help states to cooperate, by reducing the transaction costs of negotiations, by facilitating deliberative decision-making among states, and by monitoring and facilitating state compliance and implementation of agreed rules, standards and principles. Consistent with the basic tenets of regime theory, the US, the EU, and other countries have undertaken negotiations on many aspects of agricultural biotechnology regulation. Once again, however, successful cooperation – and in particular a resolution of the fundamental transatlantic dispute – has proven elusive, for two reasons. First, many issue-areas in international politics are characterized by stark disputes about the *distribution* of costs and benefits from cooperation.[58] While all parties to a regime may agree about the *desirability* of cooperation, they may and often do disagree about the *terms* of cooperation, which result in unequal benefits and costs for the parties. International regimes may contribute to cooperative outcomes in these situations by facilitating negotiations and establishing common rules, but the presence of distributive conflicts is likely to impede deliberation and foster hardball bargaining, in which each side maneuvers to press for an agreement closest to its own preferences.

In the case of agricultural biotechnology, we argue, the United States, the European Union and other countries share a common interest in avoiding a global trade war, but they differ sharply in their preferred solutions. For this reason, within each of the various multilateral fora that we examine in Chapter 4, the United States has sought to promote what it terms its more "science-based" approach to biotechnology regulation, while the European Union has sought to secure international recognition for its more precautionary approach. Here again, evidence of genuine deliberation is hard to find, in particular where issues ranged beyond the conduct of scientific risk assessments to actual risk regulation policy. The result thus far in each of these regimes has been, for the most part, a series of inelegant and often vague compromises, with no clear victory for either side and with little or no evidence of a convergence of views about the fundamental issues.

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[58] Krasner 1991.

A second, related impediment to cooperation has to do with the inherently cross-sectoral nature of agricultural biotechnology, which implicates numerous ministries and agencies within government, which in turn represent governments in different multilateral regimes in diverse areas such as trade (WTO), the environment (CBD), food safety standards (Codex), and those of a cross-cutting nature (OECD). Within such a "regime complex" in which different institutions offer different opportunities for strategic actors, states frequently engage in "forum shopping," favoring the specific regime or forum most likely to produce their preferred outcomes.[59] The existence of multiple, overlapping regimes with no clear hierarchy among them, moreover, tends to produce legal inconsistencies among regimes reflective of underlying differences among powerful actors, further clouding the prospects for successful cooperation.

This is indeed the pattern we find in the case of agricultural biotechnology. Both the United States and European Union attempted to promulgate universal global standards for agricultural biotechnology that reflected their own. The US stressed "science-based" risk determinations, while the EU promulgated a precautionary approach. They both tried to globalize their own localisms. We find that the United States demonstrates a clear preference for the WTO forum, with its emphasis on trade and its disciplines on the use of non-tariff barriers to trade, while the European Union has shown a preference for the CBD and the Biosafety Protocol, with its greater emphasis on environmental impacts and on the importance of precaution. We also find substantial, and as-yet unresolved, inconsistencies among the various fragmented regimes, which place variable emphasis on the importance of free trade and of environmental protection, with no overarching hierarchy to resolve conflicts among them. For these reasons, none of the various multilateral regimes has yet resolved the fundamental differences between the US and the EU over the regulation of GMOs, which remains fundamentally contested after a decade of multilateral negotiations.

Indeed, one of our novel findings is that the inconsistencies and conflicts among regimes have influenced the nature of the regimes themselves, including the long-standing distinction between "hard" or binding law on the one hand, and "soft" or non-binding law on the other. As we shall see, the reputedly "hard" rules of the WTO have

[59] On regime complexes, see Raustiala and Victor 2004; on forum-shopping, see Jupille and Snidal 2005.

been "softened" to accommodate environmental and health concerns, such as those reflected in the Biosafety Protocol and debates within Codex. The so-called "soft" law mechanisms within Codex, by contrast, have been stalemated or "hardened" whenever matters could have a possible bearing on WTO dispute settlement, as states have sent trade delegates along with food safety technical experts to discuss the adoption of new "voluntary" standards and principles.

1.4 US and EU Regulatory Developments Since 2000: Continuity, Change, and (Lack of) Convergence

Many analysts have expressed hopes that the US and EU regulatory systems might converge, relieving the friction between them, either through joint deliberation or as a result of pressures exerted by international organizations like the WTO, by national and transnational interest groups and public opinion, or by market forces. Many American observers, for example, hoped that the EU, under pressure from the World Trade Organization, might move towards what the US calls a more "science-based" and less "politicized" system of regulation, which would, in turn, facilitate the resumption of approvals for new GM varieties. Many European observers, by contrast, hoped that either public opinion or market pressures would prompt a process of "trading up" in the United States, which might become more precautionary in its own regulations and thus more accommodating of European regulatory choices.

In Chapter 5, we review the impact of transnational political, legal, social and market pressures on EU and US policies toward agricultural biotechnology. We identify the direction and the sources of change and assess the evidence for convergence between the two systems. In the European Union, the period since 2000 has witnessed a root-and-branch reform of the regulatory system for agricultural biotechnology, as the European Commission has sought to reassure the public about the completeness and the rigor of the EU regulatory system, and thereafter resume the stalled approval process for new GM foods and crops. Beginning with the publication of a White Paper on Food Safety in 2000, the Commission has proposed, and the Council of Ministers and European Parliament have adopted, a raft of new legislation regulating every aspect of GM food production "from farm to fork." Among other measures, the EU has

strengthened the original 1990 directive on the release of GMOs into the environment, extending the scope of the regulation to include GM feed as well as products derived from, but no longer containing, GMOs. In addition, the Union has adopted binding legislation providing for mandatory labeling and traceability of all GM foods and crops, as well as a recommendation on the co-existence of GM and conventional crops, and new rules on the approval and cataloguing of GM seeds. The Union's new legislative framework incorporates some elements of US practice and of WTO jurisprudence. Most notably, it requires scientific risk assessment of each GM variety by a newly created independent agency – the European Food Safety Authority (EFSA). The adoption of this strict and comprehensive regulatory framework was aimed, in part, at reassuring the European public about the adequacy of regulatory controls and hence at ending a six-year moratorium on the approval of new GM varieties in the Council of Ministers, which was one of the targets of the US legal complaint before the WTO. The de facto moratorium did indeed end in May 2004 with the approval by the Commission of a new variety of GM maize.

However, the controversy over GM foods and crops shows no signs of abating in the EU. Public opposition to GMOs remains high throughout Europe (including in the 10 new member states that joined the Union in 2004). This opposition has been reflected in the Council of Ministers, which has consistently deadlocked on the approval of new GM foods, leaving the final decision to the unelected European Commission. Although the Commission, for its part, has wanted since 2004 to overturn a series of national bans on specific GM varieties, which the EU's own scientists have argued are not supported by scientific evidence, the Commission's efforts have been rebuffed by the Council, which voted by an overwhelming majority in June 2005 to retain the existing national bans, and which again blocked the initiation of a legal challenge by the Commission in 2007. Moreover, other aspects of the new legislative framework, such as the new labeling and traceability provisions, represent a move further away from the more accommodating US model, so that US soybean trade associations, in particular, feel that the EU system is actually getting worse. Even though the EU has developed a complex framework for the approval of GM crops and foods, whether they will be approved and, in light of the new labeling and traceability requirements, actually marketed, remains in doubt.

For these reasons, we conclude that the EU regulatory system, despite its many modifications over the past half-decade, remains, as it has been, a strict and highly precautionary system. It continues to regulate GM foods and crops stringently on account of the process of their production (their use of genetic engineering), rather than the characteristics of the product. More importantly, in practice, it continues to impede the commercialization in Europe, as well as around the world because of the importance of the EU market for foreign farmers and the overall normative influence of the EU in global politics.[60] In sum, we argue that while the EU regulatory system has been overhauled, EU policies and the practices remain similar in their effects. In this sense, the EU's increasingly complex, Byzantine system for authorizations and marketing of GM varieties, incorporating multiple governmental actors and non-government stakeholders, can be viewed as a Potemkin village. We call this *reform without change*.

In the United States, meanwhile, national regulators had adopted a more flexible, product-oriented regulatory system, while biotechnology companies and farmers had embraced GM foods and crops far more readily than in Europe. By the end of the 1990s, the US faced some pressures for change, leading some scholars to speculate that the United States might "trade up" to the precautionary and process-based European approach.[61] These pressures took the form of three inter-related phenomena: (1) commercial adaptation, which occurs when US firms or farmers voluntarily comply with EU standards in order to gain access to the EU market (e.g., growing only EU-approved GM varieties); (2) political mobilization, which occurs when domestic US interest groups, spurred (at least in part) by events in Europe, mobilize for stricter GM regulations; and (3) policy change, when US authorities adopt stricter domestic regulations, whether to protect Americans from risks or to reassure foreign markets and foreign governments of the safety of US products.[62] A careful analysis of recent US events provides some evidence of commercial adaptation and political mobilization, as well as some modest policy change. However, these policy changes largely reflect an

[60] To the extent that the EU exerts normative influence on third parties, in excess of its market- and negotiating power, such influence might be considered a manifestation of "soft power" – an intriguing claim, but one that we do not test in this book. See e.g. Nye 2005 on soft power, and Manners 2002 on the prospect of a "normative power Europe."

[61] See e.g. the arguments in Vogel 1995; and Shaffer 2000.

[62] Young 2003: 458.

incremental elaboration of the traditional US system rather than any regulatory overhaul in the direction of the EU's approach.

With regard to commercial adaptation, US farmers and growers' associations have based their decisions on which crops to plant at least in part on the regulatory standards of the EU and other important markets such as Japan and Canada. Many farmers, for example, have concentrated production of corn and soybeans in those GM varieties that have been approved for marketing in the EU, and concern about the reception of GM crops in Europe has also led the leading agricultural biotechnology company, Monsanto, to defer marketing of its genetically modified "Roundup Ready" wheat. We also find some evidence of US farmers avoiding even the use of EU-approved GM crops, in order to appeal to the EU market for GM-free foods and avoid having to comply with the EU's increasingly strict labeling and traceability requirements. The commercial prospects for new GM foods and crops in the United States, therefore, remain unclear. On the one hand, US farmers have showed little inclination to abandon established GM varieties, such as soybeans, cotton and corn, use of which continues to grow in the United States. On the other hand, GM production in the United States has increasingly concentrated on these three crops, while notification of new varieties and commercial acceptance of other GM crops has decreased from the rapid pace of the late 1990s.

With regard to political mobilization, the evidence suggests that media coverage of the US/EU dispute, together with certain domestic scandals such as the 2000 Starlink controversy (in which a GM corn approved only for animal feed was found in corn chips and other food products), provided opportunities for US consumer and environmental groups to mobilize in opposition to GM foods and crops. This mobilization has so far been unsuccessful in the US (unlike in Europe), and there is little evidence that US public opinion shares the deep distrust toward GMOs felt by European publics. Polls show relatively high levels of trust in federal regulators such as the FDA and little support (much less intensive political pressure) for stricter regulation of GM foods in the United States.

At the level of federal regulation, there have been debates among US legislators and regulators about possible reforms of the US regulatory process, but the US Congress

has not produced any significant changes to the statutory basis for US biotechnology regulation. In the absence of legislative action, the most important regulatory developments have come from government regulators such as the FDA, which conducted various hearings and studies to consider administrative changes to the existing regulatory system, including the possibility of introducing mandatory labeling or pre-market approvals of new GM varieties. These hearings led the FDA to make some changes to its procedures, including the issuing of guidelines for companies to undertake voluntary notification to the FDA of new GM foods, as well as guidelines for companies wishing to voluntarily label their products as having been made with, or without, the use of bioengineering. Nevertheless, the agency declined to follow the EU practice of requiring mandatory prior approval of all GM foods and crops, nor did it endorse mandatory provisions for the labeling and traceability of GMOs. Reform of the US regulatory system remains on the US agenda, with the USDA having announced a review of its own regulatory procedures, but such reforms are likely to be piecemeal and relatively modest in comparison with Europe's regulatory requirements. Overall, US use of GM soybeans, cotton and corn continues to rise. While in the EU, we found there has been much reform with little or no fundamental change, in the US we find *change without reform* of the regulatory framework.

In both cases, moreover, we find striking evidence of increasing returns, inertia, and path-dependent development. In the US case, the early adoption of a welcoming regulatory framework in the 1980s contributed to the growth of a strong biotech industry and the widespread acceptance of GMOs among farmers and (to a lesser extent) public opinion, creating a powerful constituency for the new technology from below. At the same time, US institutional rules privilege the status quo, in which GMOs continue to be regulated under the two-decades-old Coordinated Framework, which has changed only at the margins in the absence of significant new Congressional legislation. In the EU case, by contrast, the early adoption of a highly restrictive regulatory framework, together with the food-safety crises of the mid-1990s, discouraged farmers from planting GM crops, prompted retailers to resist selling GM foods, and led to a flight of biotech investment from Europe, all of which undermined political support for GM foods and crops. Furthermore, the EU's supermajoritarian legislative rules, requiring a qualified majority

among disparate states in the Council of Ministers as well as a majority in the European Parliament, has created a huge institutional hurdle to any fundamental reform of the EU regulatory framework.

The story of GM crops and foods is an ongoing one, and there could be more convergence in the future in response to increasing understanding by regulators of the risks of GM foods and crops, or to exogenous shocks such as a future food safety or environmental crisis. We conclude that indeed, the period since 2000 has seen changes in US and European regulatory procedures and market behavior. Some elements of these changes can be interpreted as responses to external pressures, and as modest steps by each side toward some move that accommodates the other. Yet despite these changes, we find at best limited evidence of fundamental convergence between the two systems. The contemporary EU regulatory system continues to regulate strictly GM foods and crops on account of the process by which they were produced, rather than the product characteristics, and allows regulatory decisions to be based on "other legitimate factors" besides scientific risk assessments, both elements that distinguish it sharply from the US system. The US regulatory system, for its part, remains one in which relatively independent federal agencies regulate GM foods and crops according to the characteristics of the product rather than the process of genetic modification, with no requirement for pre-market authorization of new GM varieties and no mandatory rules for traceability or labeling of GM foods and crops. Notwithstanding around a decade of negotiations, deliberations, and disputes, the differences between the US and EU regulatory systems have proven to be robust and enduring. The main effect of the EU system within the US has not been a regulatory one, but rather been on decisions by US farmers not to adopt new GM varieties, such as for wheat and rice, even where they have US regulatory authorization. The pressure for the US to do something about extraterritorial market effects of the EU system correspondingly rose.

1.5 The Peril, and Promise, of WTO Adjudication

Transatlantic tensions over the regulation of GM foods and crops built steadily over the course of the late 1990s and into the following decade, yet for much of this period, the United States chose not to avail itself of options within its preferred

international forum, the WTO. During this period, the US government came under increasing pressure from agricultural producers to bring a case before the WTO's Dispute Settlement Body. US biotech firms joined agricultural associations in arguing that the EU's strict regulation of GMOs, and in particular its unofficial moratorium on the approval of new GM varieties, damaged US interests and violated the provisions of WTO law. Despite these pressures, the Clinton administration, and for a time the George W. Bush administration, resisted the temptation to bring a legal complaint against the EU at the WTO. Notwithstanding its considerable sympathy with the complaints of US producers, both US administrations feared that a WTO case could be counter-productive, increasing European resistance to GMOs being "forced" on consumers by the WTO, and possibly exporting European concerns about GM foods and crops to American consumers. The mass demonstrations at the 1999 WTO ministerial meeting in Seattle magnified these concerns, showing the extent of popular opposition to the WTO among activist environmental and other groups. Following Seattle, US officials were wary that such a complaint – whatever the outcome – could undermine support not only for GM foods and crops, but for the WTO regime itself and, in particular, the prospect of a new round of trade negotiations that were to have been launched in Seattle.

In May of 2003, however, the Bush Administration's forbearance gave way for a number of reasons, and the United States, joined by Canada and Argentina, brought a WTO complaint against the European Union, alleging that the Union's de facto moratorium on new approvals, as well as the national bans on approved varieties, constituted a violation of the SPS Agreement. In Chapter 6, we examine the reasons for the US decision to bring a complaint before the WTO, analyze the legal issues raised in the US complaint, and weigh the possibility that the case, despite its obvious risks, might have a beneficial impact by clarifying the parties' legal obligations under WTO law, stabilizing the conflict, and encouraging greater transparency and accommodation in GM regulation on both sides of the Atlantic. In short, we analyze the potential role of international legal processes, and especially third-party dispute resolution, in resolving intractable regulatory disputes.

By 2003, we argue, the Bush administration had come to believe that the costs of bringing a WTO case (backlash against GMOs in Europe, spread of the anti-GMO

movement to the US) had partially abated, while the global stakes of the debate, and thus the potential benefits of a WTO case, had substantially increased. During this period a number of advanced industrialized countries had followed the EU's lead in requiring special approval and labeling procedures for GM foods and crops, while some less developed countries in Africa had gone so far as to reject the provision of GM corn offered as food aid. If the US failed to act promptly, Bush administration officials feared, these policies could become entrenched beyond Europe, and difficult to change later. At the same time, however, the number of countries growing significant acreage of GM crops had grown to include major agricultural producers such as Argentina, Brazil, Canada, China and India, and, though to a much less extent, even Spain and Germany within the EU (see Table 6). In this context, the United States had a strong incentive to try to arrest the spread of the EU's precautionary approach, as well as a growing number of allies that shared Europe's views.

Significantly, the United States and other complainants did not challenge the EU's legislative framework for GM approvals as such, nor did it challenge (despite loud complaints from producers) the EU's more recently adopted labeling and traceability provisions. Instead, the complaints focused on the EU's implementation of that regulatory framework, challenging three specific EU actions: (1) the EU's de facto "general moratorium" on new approvals; (2) "product-specific moratoria," or failure to approve particular GM varieties found to be safe by EU scientists; and (3) the persistent use of "safeguard provisions" by individual EU member states to ban GM varieties that, once again, had been approved as safe by the Union's own scientific experts. In all three cases, the complainants argued, the Union had failed to base its regulatory decisions on scientific risk assessments as required under Article 5.1 of the SPS Agreement, and those decisions were therefore inconsistent with EU obligations under WTO law. The EU, by contrast, denied the existence of any moratorium, noting that new approvals were pending the completion of the EU's regulatory framework, and argued further that the SPS Agreement did not apply to the regulation of GMOs, which was concerned primarily with the protection of the environment and therefore fell under the rubric of the EU's preferred forum, the Cartagena Biosafety Protocol.

In September 2006, the WTO dispute-settlement panel issued its decision, which

was over one thousand pages in text. The panel expressly avoided deciding (or in its words, "examining") many crucial issues, and most particularly the question "whether biotech products in general are safe or not" and "whether the biotech products at issue in this dispute are 'like' their conventional counterparts." The panel found in favor of the United States, but largely on procedural and not substantive grounds. It found only that the EU engaged in "undue delay" in its approval process in violation of Article 8 and Annex C of the SPS Agreement, and in this way, avoided determining whether the EU had based a decision on a risk assessment or whether the assessments showed actual risks or greater risks than for conventional plant varieties. By deciding that the EU had not yet taken an "SPS measure," the panel, which took almost three years to issue a decision (in a process that was not to exceed nine months), further delayed having to make any substantive determination itself. Regarding safeguards enacted by EU member state safeguards, in contrast, the panel found that all of them were SPS "measures" that violated the EU's substantive obligations under article 5.1 of the SPS Agreement because they were "not based on a risk assessment." It noted in particular that the EU's "relevant scientific committees had evaluated the potential risks… and had provided a positive opinion." Thus, while the panel refrained from making a substantive determination on decisions at the EU level, it expressly found that the member state bans were inconsistent with the EU's substantive WTO commitments. Since the European Commission already was opposed to such member state safeguards and member state delay in the approval process, the WTO panel decision effectively reconfirmed the Commission's position in intra-EU politics, and thereby potentially could lead to greater transatlantic accommodation.

In Chapter 6, we assess how the evident risks of politicization and/or noncompliance with WTO "judicial" decisions have to be weighed against the potential benefits of legal clarification and potential accommodation that such a decision can bring. The WTO judicial system, while striving toward objectivity in its rulings and deploying highly legalistic analysis, is necessarily concerned with the acceptance of its decisions by WTO members and with compliance by the parties to a dispute. Even before the panel's GMO decision, the jurisprudence of the Appellate Body has indicated a willingness to provide significant discretion to domestic regulators in determining the appropriate level

of risk for the members of their society. For this reason, we argue, the WTO dispute settlement panel has left discretion to the EU in determining the level of acceptable risk, while spelling out the procedural decision-making requirements that it must meet before implementing trade-restrictive measures on GM foods and crops.

More generally, we suggest, the WTO judicial process, while undertaken by unelected officials operating far from the purview of ordinary citizens, may nevertheless play a positive role in helping to correct the narrow parochialism of national decision-making. WTO decisions, while frequently controversial and contested, have already pressed national decision-makers to make decisions that better take account of the impacts on foreigners while still meeting their regulatory objectives, and to justify those decisions in a transparent manner, knowing that they are potentially subject to scrutiny and review before the WTO dispute settlement system. We do not advocate that WTO panels impose their *substantive* regulatory preferences on member countries, but we do suggest that the WTO can hold its member states to a *procedural* standard whereby all members must rationally justify their decisions, take into account the impact of their decisions on outsiders, and regulate in a transparent fashion. Put differently, WTO rulings are unlikely explicitly to require substantive convergence of US and EU approaches to risk regulation (and so far, have not done so), but they may spell out the minimum obligations that states have towards each other when seeking to protect their own societies from the various risks of modern life. In doing so, they can lead to greater accommodation of divergent regulatory systems in at least two ways. First, procedural obligations based on the use of public reason, building from scientific risk assessments, can empower certain actors in domestic processes that lead to different substantive decisions on particular matters. Second, where challenged regulatory decisions are held to have met the procedural requirements and are thus found to be consistent with WTO obligations, then the WTO legal process may lead to greater acceptance of the foreign decision by the other side. In both ways, the WTO dispute settlement system can facilitate accommodation of divergent regulatory decisions. Nonetheless, as we will see, where social and regulatory approaches to technology and its risks are deeply engrained, the impact of the WTO or any other international or transnational body on substantive regulatory convergence, at least in the shorter term, is significantly constrained.

During this study an important new factor arose—the emerging role of large developing countries in the struggle over genetically modified crops. China and India are rapidly adopting GM cotton for textiles. Brazil and Argentina have adapted GM soy. With the rise of these countries as players in the world economy and in its governance, other developing countries may look to them when making their own choices over GM varieties. We therefore conclude the book, in Chapter 7, by reviewing our overall findings, assessing the implications of our findings for the study of international law and politics, and examining how the US/EU dispute has affected developing countries, and arguing that the future of agricultural biotechnology will rest, at least in part, on the decisions and the actions of less developed countries in a dispute that is no longer purely transatlantic but increasingly global in scope.