

When Cooperation Fails



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The International Law and Politics
of Genetically Modified Foods

Mark A. Pollack and Gregory C. Shaffer

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For Rita, Cameron and Fiona
Mark Pollack

For Michele, Brook and Sage
Gregory Shaffer



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Acronyms

APHIS	Animal and Plant Health Inspection Service, US Department of Agriculture
BIO	Biotechnology Industry Association
BRS	Biotechnology Regulatory Service (of APHIS)
CBD	Convention on Biodiversity
Coreper	Committee of Permanent Representatives (EU)
DNA	deoxyribonucleic acid
EC	European Community
EFSA	European Food Safety Authority (EU)
EIS	environmental impact statement
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
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

Acronyms

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

Acknowledgements

The transatlantic dispute over the regulation of genetically modified (GM) foods and crops has been troubling us almost as long as it has troubled the United States and the European Union. Back in 1999, we—a lawyer (Shaffer) and a political scientist (Pollack) at the University of Wisconsin-Madison—began a joint project on transatlantic governance, which we saw as an ambitious, if flawed, effort to facilitate and oversee the operation of a transatlantic marketplace in the absence of formal transatlantic institutions. More concretely, we saw the United States and the European Union building increasingly close links and engaging in joint governance at three levels: the intergovernmental level of high-level contacts between Washington and Brussels; the transgovernmental level of direct agency-to-agency links among lower-level officials in day-to-day domestic regulation; and the transnational level of direct civil-society cooperation among American and European businesses, labor unions, environmentalists, and consumer advocates. We were impressed, back then, by the depth of day-to-day cooperation in areas like competition policy, yet we also recognized that some areas were proving more resistant to joint, technocratic governance, and we undertook a preliminary case study of GMO regulation to understand why some issue-areas seemed more difficult to govern jointly than others. Put simply, we knew back then that GMOs posed a tough issue for transatlantic cooperation, one in which the US and EU regulators were protective of their respective regulations and regulatory frameworks, and in which interest groups and civil society could be easily mobilized to set limits on any cooperative efforts upon which regulators might agree.

Almost a decade later, we see the transatlantic dispute over GMO regulation not simply as a tough nut to crack, but as a remarkable case study of the failure of cooperation. The United States and the European Union, two long-time democratic allies, have continued and in some cases deepened their economic integration and efforts at regulatory cooperation during the past decade across a range of issue-areas (despite US-European political differences, such as over the invasion of Iraq). Yet in the case of GMOs we have seen ongoing stark differences in regulatory standards and regulatory frameworks; stillborn efforts at bilateral regulatory cooperation; persistent battles and logjams in multilateral regimes like the World Trade Organization (WTO) and the Convention on Biodiversity; and finally a so-far unsuccessful effort to litigate a resolution of the problem through the WTO dispute settlement process. Why, we wanted

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to know, had cooperation repeatedly failed? Why were the US and the EU so implacably opposed? Why couldn't US and EU regulators come to a meeting of the minds in their frequent joint meetings? Why didn't multilateral regimes facilitate cooperation, as regime theorists would have predicted? Could litigation resolve the issue by deciding clearly in favor of one side or the other, or would it backfire, prompting a backlash against both GMOs and the WTO itself? Is there any sign of convergence between the two sides, or is the now decade-old conflict likely to continue and spread to the rest of the world—and if so, how will this affect the dynamics of the conflict? What law and policy lessons, in sum, can we draw?

These are the questions that we address in this book, and our core arguments are spelled out briefly in Chapter 1, and elaborated in detail in the chapters that follow. We shall come to these arguments presently, but, as one might suspect in a project that is a decade in the making, we have many thanks to offer to many people. This project began in Madison, Wisconsin, where our efforts were funded and encouraged by the University of Wisconsin's European Union Center of Excellence, funded by a generous grant from the European Commission, where we held a conference on GMO regulation organized by Gregory Shaffer who was then the Center's Director.

We have both since left Madison, and we have received additional encouragement, and good advice, from a number of friends and colleagues—many of whom, we fear, we are forgetting. We are particularly grateful to Tim Büthe, Sungjoon Cho, Jeffrey Dunoff, Emilie Hafner-Burton, Ronald Herring, Christian Joerges, Neil Komesar, Ambassador Richard Morningstar, Daniel Naurin, Kal Raustiala, Adam Sheingate, David Vogel, Helen Wallace, Alasdair Young, four anonymous reviewers, as well as participants at conferences and workshops at the Council of European Studies (2005), Princeton University (2006), the University of Wisconsin (2006), the European Union Studies Association (2007), Hebrew University (2007), London School of Economics (2007), the Global Administrative Law conference in Viterbo, Italy (2007), the American Branch of the International Law Association (2007), Northwestern Law School (2007), University of Georgia Law School (2008), and the Law and Society annual meetings in Las Vegas (2005) and Berlin (2007), for their comments on earlier versions of portions of the manuscript. We also thank Mario Bifano, Erin Chalmers, Rebecca Estelle, Matt Fortin, Geoff Seufert, Timo Weishaupt, and Anna Woodworth for their excellent research assistance. Mark Pollack would like to thank the College of Liberal Arts at Temple University and the BP Chair in Transatlantic Relations at the European University Institute for funds to undertake research on the project in Washington and Brussels. Gregory Shaffer would like to thank the University of Wisconsin, Loyola University Chicago School of Law and the University of Minnesota Law School for their research and research travel support. He would also like to thank the Fulbright European Union Scholar-in-Residence Program for its semester of funding during his stay in Rome, as well as the Legal Office of

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We would also like to thank the dozens of government officials, international civil servants, and representatives of business and non-governmental organizations, who have met and shared their views with us in Washington, Brussels, Paris, Rome, Geneva and elsewhere. Many of these practitioners, we note in Chapter 1, have requested anonymity, and we have honored that request in each case, identifying those individuals only by broad institutional affiliation, city and date of interview, although some officials have been willing to be identified by name, and in those cases we do so. As social scientists we have tried to rely as far as possible on replicable, publicly available sources—yet given the sensitivity of GMO regulation as an issue, it was inevitable that we would rely on interviews with practitioners for some facts of the case, for context, and, quite often, as a detailed corrective to the big-picture views and predictions offered by theories of international law and politics. If we have come close to getting the details of our story right, the credit goes largely to the many participants who shared with us their time and insights, and, whether named in these pages or not, they have our heartfelt thanks.

Oxford University Press, and in particular our editor, Dominic Byatt, have been supportive of our efforts, patient with our occasional delays and constant updates in covering a moving target, and efficient as ever in moving the manuscript from review to revisions to publication. We also wish to thank Louise Sprake and Lizzy Suffling at OUP and Kay Clement for their care and diligence with the editing and production.

If we had been worried about the dangers of interdisciplinary cooperation when the project began, any such doubts have long been dispelled. We have, throughout this project, learned from each other, addressed issues that we would otherwise have ignored, and indeed discovered issues that our two disciplines both considered important, but often while using different terminology and involving scholarly literatures that often took little or no notice of the other. We hope to have built bridges across these two disciplines, and we ourselves would have great difficulty in establishing paternity over any given idea in this volume, on which we worked equally and collaboratively (with the exception of Chapter 5, which is based primarily on Shaffer's legal analysis). The order of names on the cover, we hasten to add, is solely alphabetical, and the intellectual partnership of the volume is entirely equal.

Finally, it goes without saying that the burden of traveling to foreign capitals for research, and of writing and editing on nights and weekends, has fallen not just on the two of us but on our families, who have been endlessly patient and supportive of our efforts. We dedicate this book, with love and thanks, to them.



1

Introduction and Overview: Biotechnology, Risk Regulation, and the Failure of Cooperation

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 US. 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 60 per cent of the processed foods available in US grocery stores were derived from transgenic varieties, more popularly referred to as genetically modified organisms (GMOs).¹ By the end of 2003, the estimate had risen to "between 70 and 75 per cent of all processed foods available in US grocery stores."² By 2007, approximately 89 per cent of soybeans, 83 per cent of cotton, and 61 per cent of corn grown in the US consisted of genetically modified varieties, and these figures have been rising annually.³ US farmers also grow genetically engineered canola, potatoes, tomatoes, papaya, squash, and sunflowers among other foods, although to much lesser degrees.

By contrast with the US embracing agricultural biotechnology, European Union (EU)⁴ regulators and the public have taken a far more cautious approach to GMOs, treating genetically modified foods and crops as different from their conventional counterparts, and adopting increasingly strict and complex regulatory procedures for their approval and marketing. Unlike in the US, 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 GM foods to markets in Europe. They also face greater social resistance, with activists campaigning against GM foods and ripping up GM crops from fields, and public opinion far more mobilized over GM foods than in the US.

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In an age of increasing international trade and economic interdependence, these sharp and persistent regulatory differences have resulted in ongoing transatlantic and now global disputes where economic interests and social values clash, in what some political scientists have called “system friction.”⁵ 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, first from the US and then from other agricultural producers. A potential international trade war loomed. More broadly, the regulatory systems of the two largest and most powerful markets on earth came into conflict.

Throughout the past decade, US and EU representatives have concurrently duelled and attempted to find some common ground, or at least 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 joint consultation and efforts to coordinate, where possible, their distinct approaches.⁶ 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 and its Biosafety Protocol. Despite these efforts, the two transatlantic partners have failed, either bilaterally or in multilateral regimes, to reach any fundamental agreement on the regulation of agricultural biotechnology. After considerable internal debate and delay, the Bush administration finally filed a legal complaint before the WTO in May 2003, joined by Canada and Argentina, 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 adopted by the WTO Dispute Settlement Body in November 2006. Even after the WTO ruling, however, the fundamental differences between the US and EU regulatory systems remained deeply entrenched and resistant to change and the fate of GM foods and crops remained deeply contested and uncertain.

The transatlantic GMO dispute has brought into conflict two longtime allies, economically interdependent democracies with a long record of bilateral and multilateral cooperation in both economics and security. Yet the dispute has developed into one of the most bitter and intractable transatlantic and global conflicts, resisting efforts at resolution in bilateral networks and multilateral regimes alike, and resulting in a bitterly contested legal battle before the WTO. Indeed, our account, with its emphasis on the intractability of the GMO dispute and the strikingly limited contribution of bilateral networks and multilateral regimes, contrasts sharply with most other books and articles about international cooperation, which are essentially optimistic

accounts of how cooperation under anarchy is possible and can be facilitated by international regimes. The general form of such studies falls into what might be called a Home Depot theory of international cooperation: “You can do it, we can help.”⁷

Our account of agricultural biotech regulation, by contrast, emphasizes the difficulties, the limits, and in many instances the outright failure of international cooperation in regulating GMOs. How can we explain the origins of this dispute, its intractability, and the repeated failures of cooperation? What happens to international law and to international regulatory institutions when the two economic powers clash? Just as importantly, what role, if any, can international regimes play when cooperation fails? What domestic legal, administrative and commercial responses take place in the face of prolonged diplomatic stalemate? To answer these questions, we argue, analysts need to focus on multiple levels: on the domestic sources of the dispute, on the international efforts at bilateral and multilateral cooperation, and at the interaction between the domestic and international levels. This book specifically addresses the following questions:

- *What are the domestic sources of international disputes?* Starting at the domestic and EU levels, we ask what explains the different policies on agricultural biotechnology in the US and EU. What are the respective roles of interests, institutions, and ideas in explaining these differences? Do these differences reflect deep philosophical divisions between Europeans and Americans about the regulation of risk to their societies? How deeply entrenched or path-dependent have their policies become?
- *What are the obstacles to cooperation and to “deliberation” at the bilateral level?* In light of the considerable externalities that each side’s policies had on the other in a global economy, and the prospects of a potential trade war, many scholars and practitioners placed their hope in the promise of informal transatlantic networks to deliberate jointly and identify the best policies for biotech regulation. What evidence is there of deliberation in these encounters, and why has joint deliberation failed to resolve the dispute?
- *What are the obstacles to cooperation at the multilateral level?* What happens within multilateral regimes when bilateral cooperation between powerful states fails? What strategies do powerful states use to attempt to export their policies internationally, such as forum shopping among international institutions in a fragmented international law context? How does distributive conflict affect the functioning of institutions, including the interaction among them? What happens to the interaction of hard (binding) and soft (voluntary) international law regimes?
- *What role can the WTO play when cooperation fails?* In light of the failures of both bilateral and multilateral cooperation, the US and the EU

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became embroiled in WTO litigation. How does the WTO judicial process attempt to exercise influence in managing such a conflict, in the face of entrenched differences between the WTO's two most powerful members? Can the WTO facilitate a resolution of such a dispute, or will it only exacerbate the conflict and create a public-opinion backlash to its own legitimacy?

- *Finally, what influence do international political, legal, and market pressures have on the domestic laws and policies of each side? Do we find evidence that the US is “trading up” to the EU’s more precautionary standards, or has WTO pressure led the EU to liberalize or “trade down” its restrictive policies? Or, alternatively, are each side’s policies too entrenched to be changed significantly even in the face of intense international pressure?*

In this book, we investigate these challenges—the obstacles to reconciling regulatory differences through international cooperation, and what happens when cooperation fails—through the prism of the US–European dispute over the regulation of agricultural biotechnology or GMOs. The book addresses the dynamic and reciprocal interactions of domestic law and politics, trans-governmental and transnational networks, international regimes, and global markets, through a theoretically grounded and empirically comprehensive analysis of the governance of GM foods and crops.

Crucially, while the primary focus of our analysis alternates between the domestic and international levels in the various chapters of the book, we do not analyze these two levels in isolation, but examine the interactions between them. Thus, for example, we demonstrate that the deeply politicized, entrenched and path-dependent nature of GMO regulation in the US and the EU has fundamentally shaped negotiations and decision-making at the international level, limiting the prospects for deliberation and providing incentives for both sides to engage in hard bargaining and to “shop” for favorable international forums. In addition to this bottom-up perspective, however, we also take a top-down approach, examining the impacts and the limits of transnational and international pressures on domestic laws and politics. Both foreign market pressures and international regimes, we argue, have exerted pressures for change in the US and the EU, empowering some actors and weakening others within domestic political and legal processes; yet the impact of these international pressures has been blunted by deeply entrenched, path-dependent patterns of interests and institutions on both sides of the Atlantic.

In this introduction and in the subsequent chapters of the book, we offer five inter-related arguments, five sets of answers to the above questions about the origins of the transatlantic and global disputes, the obstacles to resolving these disputes both bilaterally and multilaterally, the risks and potential rewards of legal recourse to the WTO, and the impact of international and transnational developments on domestic regulatory systems in the US, the EU

and other countries. 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.

First, at the domestic level, we ask (in Chapter 2) why the US and EU systems for the regulation of GM foods and crops look so different, and we survey theories of comparative law and politics that attribute differences in domestic regulation to differences in organized interests, political institutions, culture and ideas, and contingent events, respectively. Although multiple factors contributed to the polarization of US and EU regulatory approaches, we show why the best explanation for the differences lies neither 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 capitalize on preexisting cultural and institutional differences, with an important role played by contingent events such as the European food-safety scandals of the 1990s. We ask, in particular, 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 the change only at the margins. 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 strongly resistant to change. The friction between them has led to increasing trade conflicts and legal disputes, spurring calls for greater transatlantic and international coordination, to avoid, in particular, the threat of a transatlantic and global trade war.

Second, 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 transnational networks, with a particular emphasis on the prospect of “deliberation” as a form of decision-making in which governmental and nongovernmental actors put aside fixed positions and negotiating tactics in favor of a collective search for better understanding and better policy. We find, however, 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 and civil-society groups.⁸ Although we find a wealth of transatlantic governmental, scientific, business, and civil society networks arising to address the regulation of GMOs (examined in Chapter 3), the record of US–EU regulatory cooperation on agricultural biotechnology has shown only limited evidence of genuine deliberation, particularly deliberation with concrete 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

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biotechnology have all prevented US and EU policymakers from engaging in a joint deliberative search for the best policy in this area.

Third, we argue that the record of multilateral cooperation (undertaken within overlapping 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, imposing most of the costs of adaptation to new global norms on others. We find (in Chapter 4) that cooperation has been frustrated in practice by the existence of severe distributive conflicts between the two sides (involving both economic and political costs), which has given rise to overlapping and (sometimes purposefully) inconsistent regimes for trade, the environment, and food safety. Although a growing amount of scholarship has addressed the roles of “soft” law (which is formally non-binding) and “hard” law (which is formally binding and enforceable) as complementary and mutually reinforcing means for international problem solving, we find that hard and soft law regimes can constrain each other’s operations, at least as they were initially intended to function. Our study shows how “soft” law regimes such as the Codex Alimentarius can become “hardened” because of the implications of their decisions in “hard” law regimes, while “hard” law regimes such as the WTO can become “softened” and less certain when they seek means to avoid substantively deciding contentious issues. The interaction of “hard” and “soft” law regimes, rather than progressively moving toward a new consensus, may instead perpetuate the substantive deadlock in member-state preferences, undermining the effectiveness of both types of regimes in the process.

Fourth, we suggest that despite considerable risks, the US’s complaint before the WTO Dispute Settlement Body has offered the prospect of some clarification and mutual accommodation that had hitherto eluded the two sides in other bilateral and multilateral fora. In Chapter 5, we apply a comparative institutional analytic framework to examine the radically different institutional implications of the interpretive choices that the WTO judicial panel faced in the *EU-Biotech* case. We demonstrate how interpretive choices by a WTO judicial body can attempt to allocate decision-making to different institutional processes in which constituencies of different countries, with varying priorities, perceptions, and abilities to be heard, participate to varying and always imperfect degrees. At the same time, we show how these choices are themselves constrained by challenges to powerful members’ acceptance of WTO judicial decisions, which, in turn, can inform those decisions. While we pay close attention to the WTO legal texts, the optic here is to see the WTO judicial process through the lens of *governance* and not through a judio-centric perspective focused on judicial interpretation and review. 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 retaliate aggressively and unilaterally against Europe, which might have occurred had there been no WTO. We find that the WTO panel took a procedural approach in its decision, refusing to articulate a single substantive standard on GMO regulation, but instead insisting on certain procedural requirements that all states must observe in adopting their own domestic regulations. In the process, we contend, the WTO has empowered domestic political actors (such as the European Commission) with an interest in complying with WTO law, and as a result, has encouraged regulators on both sides of the Atlantic to operate more transparently, taking into greater account the effects of their actions on third parties.

Finally, we return to the domestic level to assess whether several decades of discussion, negotiation, and litigation have resulted in significant reform and/or convergence of the two regulatory systems. We demonstrate that, despite some domestic changes on each side, the US and EU regulatory systems for agricultural biotechnology show few, if any, signs of convergence toward a common regulatory model, but continue to differ fundamentally in their respective approaches to the regulation of GM foods and crops. 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. In the EU, 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. On the US side, meanwhile, regulators have increased the 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 on 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 both the US and the EU, however, these developments have been profoundly path-dependent, taking place at the margins of regulatory systems that remain unchanged in their fundamental approaches. These developments reflect long-standing adaptations to existing regulations by actors on either side of the Atlantic who have managed to impede significant reforms even in the face of considerable pressures for change. In some ways, in Europe we have seen much *regulatory reform without fundamental change* in outcomes, and in the US, some mostly market-driven *change without regulatory reform*.

In sum, the story of the transatlantic GMO conflict is largely one of failed attempts at bilateral and multilateral cooperation. The GMO story is, therefore, particularly interesting as a case study of the many obstacles—both domestic and international—to successful cooperation. These obstacles include the politicization and path-dependence of domestic policies which stymie

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deliberation and mutual accommodation, as well as the existence of transnational distributive conflicts and the strategic opportunities provided by overlapping international regimes. The result is frequent stalemate, fragmentation of international law, and conflict between soft and hard law regimes. Examining those obstacles and showing them in operation is one of the major contributions of the book. Yet our account is not a counsel of despair, for in addition to examining how and why cooperation fails, we also address ways in which states and regimes can facilitate the ongoing management of regulatory conflict, and, over time, together with transnational market forces, influence national regulatory and commercial practices in a (somewhat) more accommodating manner.

The final chapter of the book offers a summary of our findings, examining the implications of our study for the future of agricultural biotechnology, in particular for developing countries, as well as the study's broader implications for the prospects and limits of international cooperation in other areas. 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 will become sites where underlying conflicts manifest themselves. We show the severe limits of international political and legal regimes where domestic policies are strongly path-dependent, and powerful members have conflicting distributive stakes. In these contexts, international hard and soft law regimes do not progressively lead to harmonized mutually beneficial outcomes, but rather can constrain and even undermine each other's operations. Yet, even here, we find roles for international law and international institutions. While international institutions have been demonized by some and dubbed irrelevant by others, we show how, even with highly politicized issues over which state representatives engage in strategic maneuvering and little deliberation, they can channel political conflict into legal processes, and in this way diffuse conflict and bide time. We show, as well, how they can empower domestic actors in domestic playing fields, leading (potentially over time) to some accommodation of difference and some convergence of practice. We conclude the book by offering our prediction that, in the end, the technology is likely to be gradually accepted in most regulatory jurisdictions, but within significant market and regulatory 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 address the importance of these countries' responses to agricultural biotechnology for its future.

The rest of this introductory chapter lays out the essential elements of our arguments, chapter by chapter, regarding the reasons for US and EU regulatory difference, the resulting difficulties of bilateral and multilateral cooperation, the interactions of fragmented international legal orders, the deeply disputed role of the WTO in helping to resolve the dispute, the lack (thus far) of fun-

damental US/EU convergence, and the implications of the US–EU conflict for developing countries and the future of agriculture.

1.1. The regulatory context: Agricultural biotechnology and risk regulation

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. In Chapter 2, we introduce the technology of genetic engineering and address the arguments of both its advocates and its skeptics. Supporters of agricultural biotechnology consider genetic manipulation to be merely the latest step in an ongoing process of human intervention in nature to stabilize and increase crop yields and improve the nutritional quality, appearance, and taste of plant varieties. Biotechnology's skeptics, by contrast, raise concerns over food safety, environmental harm, agribusiness power, ethics, and broader cultural concerns.

Advocates and opponents of the technology, as in many debates over risk regulation, argue over the applicability of the key concepts of “risk” and “uncertainty.” Advocates of the technology, who have been more successful in the US, focus on cost-benefit approaches to risk, weighing the probability and magnitude of harm against prospective benefits, in this case in relation to conventional plant varieties. Opponents and skeptics, who have been more successful in the EU, in contrast, focus on the concept of uncertainty which belies the measurability of risks, in particular as regards long-term effects. They thus call for the exercise of greater precaution before approving GM varieties, pursuant to application of a rather open-ended precautionary principle. We review these broader concepts and their use in the specific arguments raised about the benefits and opportunities offered, and the risks and uncertainties posed, by the technology.

We also examine the key concepts of “risk assessment” and “risk management” and their application in regulatory systems. Risk assessment refers to the technical assessment of the risks in question. Risk management, in contrast, concerns the policy responses to these assessments. These two concepts are ideal types, as completely segregating risk assessment and risk management determinations is difficult (and some contend impossible) in practice. We will see how deliberation over risk assessment principles and approaches has been more fruitful in various international fora, while bilateral and multilateral consultations and negotiations over the appropriate risk management approach to the technology have resulted in hard bargaining, strategic maneuvering, and frequent stalemate.

Regulators have applied a range of risk management policies over time, including product bans, setting standards to minimize risks “to the extent

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feasible,” enacting requirements to eliminate “significant risk,” and engaging in cost-benefit analysis. A number of scholars contend that, while the US took a lead in risk regulation from the 1960s to the mid-1980s, there has since been a switch, with Europe becoming the more stringent regulator since the 1990s.⁹ Although there is countervailing evidence that the level of precaution exercised in the US and Europe varies with the regulatory sector (from nuclear energy to chemicals and novel foods), we focus on the evidence as to how and why Europe and the US have taken starkly different approaches to the regulation of agricultural biotechnology, with the EU taking a much more stringent regulatory approach.

1.2. The domestic sources of the conflict

In the US, the basic regulatory framework for biotechnology was set in 1986 by 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 was 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 GMOs. The Coordinated Framework established a division of responsibility among three primary US regulators, with the 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.¹⁰

By comparison with the US, EU regulation of biotechnology was far more decentralized, and the EU adopted a decision-making process in which the key decisions were taken not by a specialized regulatory agency such as 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 (as amended and elaborated by subsequent legislation), all GM 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 by 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 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 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 approaches to the technology 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 specialized 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 this theoretical backdrop, we argue that the very different approaches to GMO regulation that we observe between the US and the EU, were not determined in any straightforward way by either the institutions, 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 preexisting 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 substantially equivalent to their conventional counterparts. In doing so, they were able to draw upon a supportive institutional and cultural context, including a regulatory system featuring strong, specialized government agencies, 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 responsibilities to the USDA and FDA at the expense of the more precautionary EPA.

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In Europe, by contrast, pro-GMO interests were weaker, with a smaller biotech sector and an agricultural community that did not take up GM crops in light of consumer responses to US imports and thus, never emerged as a champion of the new technology. Pro-GMO interests in Europe encountered an institutional and cultural framework that provided multiple veto points (and in particular at the member-state level where national governments exercised considerably more regulatory authority than states in the US federal context) and multiple sources of opposition (on environmental, food-safety, and ethical grounds) to GMOs, resulting in the more demanding, politicized, and process-oriented, multi-level 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 food-safety scandals of the 1990s which undermined public support for the technology and trust in regulators at a crucial time for the introduction of GM foods and crops.

Neither the US nor the EU, then, was preordained by its interest-group, institutional or cultural characteristics to adopt the precise regulatory framework that it did. By the same token, however, once the respective US and EU regulatory frameworks were adopted, they proved 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 critical junctures can persist or become “locked in,” thereby shaping and constraining the actors later in time. Political institutions and public policies, in this view, are subject to “positive feedback,” insofar as those institutions and policies generate incentives for actors to stick with and not abandon the existing laws and institutions, adapting them only incrementally to changing political environments. These positive feedbacks 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.¹¹

Insofar as political institutions and public policies are, in fact, characterized by positive feedbacks, regulatory politics will be characterized by *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 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 an institution or a policy bolsters its societal support base, making it more difficult to change and more stable in the face of external shocks over time.¹²

In this context, we argue that the US and EU regulatory frameworks for agricultural biotechnology, while not themselves determined by preexisting institutional constraints, have since generated significant positive feedback, 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 case of the US, the critical juncture occurred in the mid-1980s, when the introduction of agricultural biotechnology and of GM foods and crops presented policymakers 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 EU with a relatively weakly organized biotech industry, diverse preferences among EU governments, and a decision-making system with a large number of veto points (involving key roles for member states demanding increasingly strict EU-level requirements), 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 half of the 1990s in the EU, when various 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 in the following decade.

Just as importantly, in each case, the regulatory frameworks adopted have generated positive feedback, both by creating institutional rules that could be changed only with difficulty and by generating adaptations among interest groups and public opinion that contributed to the stability of the two respective frameworks. In the US, the early adoption of a relatively welcoming regulatory framework contributed to significant investment, 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 EU, 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 interest-group and 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 fundamental reform of the EU regulatory

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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. In response, 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 and regulatory disputes, reflective of conflicts over divergent regulatory approaches that we will continue to see in the future.

We conclude Chapter 2 by adapting a two-level (and in the EU case, three-level) game from international relations theory to assess how national and international politics and law interact. According to Robert Putnam's "two-level games" model, all international negotiations take place simultaneously at two levels.¹³ At the international level (Level 1), negotiators (also known as statesmen, chiefs-of-government or COGs) bargain with their foreign counterparts in an effort to reach mutually beneficial agreements, while at the domestic level (Level 2), the same negotiator engages in bargaining with domestic constituencies, who must ultimately accept the contents of any agreement struck at Level 1.

In such two-level games, we demonstrate, the bargaining power and the ultimate outcomes of political cooperation depend not only on the preferences of COGs—in our case, the US federal government and the European Commission negotiating on behalf of the EU—but also on the nature and intensity of preferences among their respective political constituencies. As we shall see, the intense, highly mobilized, and increasingly entrenched preferences of interest groups and publics on both sides of the Atlantic act as a source of bargaining power for both COGs, who can claim that their "hands are tied" by intense domestic pressures over the issue of GMO regulation. Those same domestic constraints, however, also decrease the "win-sets" of each side and hence the likelihood of successful cooperation, by making it difficult for either COG to engage in genuine deliberation or in significant concessions to the other side, for fear of having the resulting agreement rejected "back home." As we shall also see, much of the past decade has witnessed an effort to overcome these obstacles, through deliberation, negotiation, and, ultimately, litigation.

1.3. The promise and failure of transatlantic deliberation

The relationship between the US and the EU is not, of course, purely conflictual, despite the real and significant differences between 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 EU remain each other's largest trading partner and source 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 harmonized 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, for 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, without the need for a hierarchical political or legal order at the international level. In practice, however, both of these routes—bilateral cooperation between US and EU regulators, as well as multilateral cooperation in various international regimes—have proven disappointing, providing as yet no clear accommodation of the fundamental differences between the two sides' approaches.

International relations and international legal scholars have pointed to the prospect of international governance through the so-called “transgovernmental networks” of lower-level government officials cooperating directly on a day-to-day basis with their counterparts in other jurisdictions.¹⁴ By contrast with the image of two-level games, in which high-level international negotiators (COGs) monopolize the representation of domestic interests abroad, transgovernmental networks raise the promise of direct interactions between technocratically oriented domestic regulators, who might be expected to work pragmatically and deliberatively to solve common problems.

Transgovernmental networks are now commonplace in the European Union, where national regulators have established formal and informal EU-wide networks in most areas of policy-making, from competition policy, financial services, and environmental policy to utilities regulation. By the turn of the twenty-first century, Anne-Marie Slaughter has 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.¹⁵ 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

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directly and fruitfully, despite their differences, in areas such as competition policy and data privacy protection.¹⁶

Some scholars have gone 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. 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.¹⁷ 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.¹⁸

Habermas and his followers concede that genuine communicative action or argumentative rationality is 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 certain specific conditions, including a “common lifeworld” among the participants, provided by “a high degree of international institutionalization in the respective issue-area”; “uncertainty of interests and/or lack of knowledge about the situation among the actors”; and “international institutions based on nonhierarchical relations enabling dense interactions in informal, network-like settings.”¹⁹ 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.

Faced with a situation of growing economic interdependence, US and EU policymakers in the 1990s onward engaged in extensive efforts at bilateral cooperation, enlisting networks of scientists, civil-society groups, business representatives, 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 gradual convergence of regulatory approaches to GM foods and crops. 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 a 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 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 an 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 toward 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. Because of this, US and EU regulators declined to invest significant resources in bilateral regulatory cooperation, but rather brought their clashing perspectives and demands to multilateral fora.

1.4. The move to multilateral regimes

The regulation of agricultural biotechnology did not 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 the US and European positions. Both sides, therefore, sought to advance their interests through a variety of multilateral regimes such as the WTO and its Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), which address 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 technological issues among advanced industrialized countries; and the Codex Alimentarius Commission, which sets “voluntary” food-safety standards for conventional as well as GM 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 interrelated reasons.

First, many issue-areas in international politics are characterized by stark disputes about the *distribution* of costs and benefits from cooperation. While

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all parties to a regime may agree about the *desirability* of cooperation, they may and often do disagree about the *terms* of cooperation, which may result in unequal benefits and costs for the parties.²⁰ International regimes can 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 US, the EU, and other countries share a common interest in avoiding a global trade war, but they differ sharply in their preferred solutions. Each side has sought to promote international standards and international cooperation *on its own terms*. For this reason, within each of the various multilateral fora that we examine in Chapter 4, the US has sought to promote what it terms a “science-based” approach to biotechnology regulation, while the EU has sought to secure international recognition for its more “precautionary” approach. We do find some evidence of deliberative decision-making on agricultural biotechnology within multilateral regimes, most notably within the OECD and the Codex Alimentarius Commission. Such deliberation is most likely, we find, where negotiations focus on issues of scientific risk assessment, where the negotiators are themselves scientific and technical experts, and where network deliberations are insulated from domestic public opinion. By contrast, however, where the subject turns from risk assessment to risk management, where international trade negotiators and trade concerns play a key role in negotiations, and where negotiations take place in the shadow of domestic public opinion, negotiators typically revert to a logic of consequentiality, bargaining from essentially fixed positions and seeking international codification and support for their established domestic positions. Deliberative decision-making, therefore, is by no means impossible, but it is challenging and relatively rare in the deeply politicized sphere of GMO regulation.

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, the states frequently engage in “forum shopping,” favoring the specific regime or forum most likely to produce their preferred outcomes.²¹ The existence of multiple overlapping regimes with no clear hierarchy in a fragmented international legal system, moreover, tends to produce legal inconsistencies among regimes reflective of underlying differences among powerful actors, further clouding the prospects for successful cooperation. This phenomenon of regime complexes, moreover, is related to the problem of distribution, insofar as distribu-

tive conflict provides the states with incentives to forum-shop among different regimes within a regime complex, or to create new regimes deliberately to support their own positions and undermine those of the other side.

This is indeed the pattern we find in the case of agricultural biotechnology. Both the US and EU sought to promulgate global standards for agricultural biotechnology that reflected their own domestic standards, protecting their own carefully negotiated regulatory standards and exporting the costs of adjustment to the other side.²² In the process, both sides also shopped actively for the international forum most likely to support their respective efforts. We find that the US demonstrates a clear preference for the WTO forum, with its emphasis on trade and its disciplines on the use of non-tariff barriers, while the EU 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 more than 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 formally 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 been “softened,” made more flexible and less predictable, as the WTO’s judicial process has sought 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 “hardened” because of concerns over the possible implications of Codex decisions in WTO dispute settlement, as large states have sent trade delegates along with food-safety technical experts to discuss the adoption of new “voluntary” standards and principles. For this reason, we argue, Codex, which earlier was more deliberative in its standard-setting processes, is more frequently characterized by the same disputes, coalitions, and hardball bargaining that characterize negotiation and litigation before the WTO. Hence, we find that hard and soft law regimes do interact, as previous scholars have argued, but they do so in ways that can also undermine, rather than take advantage of, their respective strengths.

Yet, we also maintain that these tensions among international law regimes should not necessarily be lamented. The conflicts reflect underlying differences among states and state constituencies (and in particular, powerful ones) in a diverse, pluralist world. Overlapping regimes, involving “hard” and “soft”

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law mechanisms, can also provide a service to each other, signaling the states and international decision-makers to tread softly in applying their particular rules by taking account of related international developments.

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 US 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. In May 2003, however, the Bush administration's forbearance gave way, and the US, joined by Canada and Argentina, brought a WTO complaint against the EU, 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 5, we examine the reasons for the US decision to bring a complaint before the WTO, analyze the legal issues before the WTO panel in terms of their broader institutional implications, and weigh the possibility that the case, despite its obvious risks, might have a beneficial impact by clarifying the parties' obligations under WTO law, stabilizing the conflict, and encouraging greater transparency and accommodation in GMO regulation on both sides of the Atlantic.

By 2003, we argue, the Bush administration had come to believe that the costs of bringing a WTO case (further 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, and instituted moratoria on GM plantings, 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 increased to include major agricultural producers such as Argentina, Brazil, Canada, China, and India, and though to a relatively minor extent, even Spain and

Germany within the EU.²³ In this context, the US had a strong incentive to try to arrest the spread of the EU's precautionary approach to a growing number of countries that might share Europe's views.

Significantly, the US and other complainants did not challenge the EU's legislative framework for GM approvals as such, nor did they 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 its 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 the relevant EU scientific bodies; and (3) the persistent use of "safeguard provisions" by individual EU member states to ban GM varieties that 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, maintaining that new approvals needed to wait until after the completion of the EU's regulatory framework. It further argued that the SPS Agreement did not apply (or applied only in part) to the regulation of GMOs, since the EU was concerned with the protection of its environment which fell outside of the SPS Agreement's scope. The EU contended that the legal claims should thus be assessed under other WTO and non-WTO agreements, including that 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 of text. The panel expressly avoided examining many crucial issues and most particularly the questions "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 ruled primarily in favor of the US, but largely on procedural and not substantive grounds. It first found that the SPS Agreement applied to all of the legal claims. It then held that the EU had engaged in "undue delay" in its approval process in violation of Article 8 and Annex C of the SPS Agreement, and thus had yet to take an "SPS measure." In this way, the panel 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, because these SPS Agreement obligations only applied to "SPS measures." Ironically, by deciding that the EU had engaged in undue delay before taking an "SPS measure," the panel which took almost three years to issue a decision (in a legal process that was not to exceed nine months), itself avoided making any substantive evaluation.

Regarding safeguards enacted by EU member states, in contrast, the panel found that all of them were "SPS measures" that violated the EU's substantive

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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 substantively evaluating 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 was already 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 could potentially lead to greater transatlantic accommodation.

In Chapter 5, we apply a framework of comparative institutional analysis to assess the WTO panel’s interpretive choices in terms of their institutional implications. This framework allows us to see how the WTO judicial process can attempt to allocate power structurally from one institution and one level to another, thus affecting who participates and how they participate in deciding which substantive policies to pursue. We examine and evaluate five radically different institutional alternatives available to the panel through its interpretation of the relevant WTO texts, ranging from deference to national law-making, to “judicial balancing,” to allocation of decision-making to international political processes or to international markets. By shifting authority among institutional alternatives, the WTO judicial process alters relations between the decision-makers and the affected public. The optic here is to see the WTO judicial process through a broader lens of governance and not through a judiciocentric perspective focused solely on judicial interpretation and review. We show how, in the end, the panel chose to focus on the *procedures* of the EU approval process, and in this way effectively deferred to substantive decision-making in the EU, although subject to internationally imposed procedural constraints. We further show the similarities and differences of our comparative institutional approach with analytic frames currently used in the legal academy, such as global constitutionalism, conflict of laws/legal pluralism and global administrative law.

We then examine the WTO panel decision in light of the sociological legitimacy constraints confronting the WTO. In this way, we assess how national legal contexts reciprocally affect WTO legal decisions in an interactive process. The WTO judicial system, while striving toward objectivity in its rulings and deploying highly legalistic analysis, is necessarily concerned with compliance by the parties to the dispute and the general acceptance of its decisions by WTO members, especially those on whom the WTO’s effectiveness depends. Even before the panel’s GMO decision, the jurisprudence of the Appellate Body indicated a willingness to provide significant discretion to domestic regulators in determining the appropriate level of risk for the members of their society. In this case, we argue, the WTO dispute-settlement panel again 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 contend, the WTO judicial process, while undertaken by unelected officials operating far from the purview of ordinary citizens, may nevertheless play a positive role, although subject to real constraints that we address. To start, it can help to manage trade conflicts by channeling them into a legal process. In our case, for example, it has helped US officials counter pressures to retaliate unilaterally against the EU's measures, which might well have occurred in the absence of WTO dispute resolution. In addition, the WTO judicial process can help clarify members' procedural obligations to justify their decisions to other members who may be adversely affected, including by reference to a scientific risk assessment. In this way, the WTO judicial process can help to correct the parochialism of national decision-making. WTO decisions, while frequently controversial and contested, have arguably 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.

Put differently, WTO rulings have not required *substantive convergence* of US and EU approaches to risk regulation, but they have spelled out *procedural obligations* that members have toward 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 (such as the European Food Safety Authority, the European Commission and the European Court of Justice, in our case) 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, 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.

1.6. 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, whether through joint

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deliberation or as a result of pressures exerted by international organizations such as 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 WTO, might move toward what the US calls a more “science-based” and less “politicized” system of regulation which would, in turn, facilitate the approval of 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 US, which might become more precautionary in its own regulations and thus more accommodating of European regulatory choices.

In Chapter 6, 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 both cases, we find, pressures from international markets and international institutions have provided some incentives for domestic change, but the impact of these pressures has been limited and channeled by the entrenched and path-dependent nature of interests and institutions on both sides of the Atlantic.

In the EU, 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 coexistence of GM and conventional crops, and new rules on the approval and cataloging 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, in the middle of the WTO case, 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 twelve new member states that joined the Union since 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 found are not supported by scientific evidence, the Commission's efforts were repeatedly rebuffed by the Council, where a large number of member states opposed the initiation of a legal challenge by the Commission.²⁴ Moreover, other aspects of the revised EU legislative framework, such as its labeling and traceability provisions, represent a further move *away* from the more accommodating US model, so that the EU system has actually gotten worse for many US growers. 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 decade, remains, as it has been, a strict and highly precautionary system. It continues to regulate GM foods and crops stringently in terms 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 of GM foods and crops 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.²⁵ In sum, we argue that while the EU regulatory system has been overhauled, EU policies and 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 something of a Potemkin village. The *de jure* regulatory system, with its many procedures for consultation, looks impressive on the surface. But for many non-EU constituencies the system appears to be largely a sham to meet formal WTO requirements, as key member-state veto players ensure that no GM crops or foods are marketed, regardless of scientific risk assessments. The result, in their view, is lots of costly show, but with a predetermined outcome. We call this *reform without change*.

In the US, 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 US might "trade up" to the precautionary and process-based European approach.²⁶ These pressures took the form of three

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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 regulatory practices, whether to protect Americans from risks or to reassure foreign markets and foreign governments of the safety and content of US products.²⁷ 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 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 Korea. Many farmers, for example, have concentrated production of corn and soybeans in those GM varieties that have been approved for marketing in the EU, while resisting the introduction of new GM wheat or rice varieties not approved for use in the EU. We also find some evidence of US farmers avoiding the use of US-approved and even 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 US, therefore, remain unclear. On the one hand, US farmers have showed little inclination to abandon established GM varieties, such as soybeans, cotton, canola, and corn, the use of which continues to grow in the US. On the other hand, GM production in the US has increasingly concentrated on these four crops, while notification of new varieties and commercial acceptance of other GM crops have 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 the European public. Polls show relatively high levels of trust in federal regulators such as the FDA, and much less support (and even less intensive political pressure) for stricter regulation of GM foods in the US.

At the level of federal regulation, finally, 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 and the USDA, which conducted various hearings and studies to consider administrative changes to the existing regulatory system, including the possibility of introducing mandatory labeling or premarket 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 being organic and thus produced without the use of GM varieties. 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. In addition, some farm groups have asked the USDA to take account of administrative authorizations of GM varieties in key export markets before permitting their planting in the US because of the difficulty of segregating grains to ensure they meet that market's requirements, but so far it has not been done. Reform of the US regulatory system thus remains on the US agenda, with the USDA also undertaking reviews of its regulatory procedures, but such reforms are likely to be piecemeal and relatively modest in comparison with Europe's regulatory requirements. Hence, by comparison with the EU, where we found much reform with little or no fundamental change, in the US we find some, primarily market-oriented, *change without reform* of the regulatory framework.

In both cases, moreover, we find striking evidence of positive feedback, self-reinforcing systems, 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 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, have created a huge institutional hurdle to any fundamental reform of the EU regulatory framework.

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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 or benefits of GM foods and crops, or to exogenous shocks such as a future food-safety or environmental crisis, or to a change in the framing of the issues in light of developments in large developing countries such as Brazil, China, and India. We conclude that indeed, the period since 2000 has seen some 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 movement that accommodates the other. Yet despite these changes, we find at best limited evidence of fundamental convergence between the two systems. Notwithstanding more than a decade of negotiation, deliberation, and dispute, the differences between the US and EU regulatory systems have proven to be robust and enduring.

1.7. Conclusions

In the conclusion (Chapter 7), we draw out a series of five policy lessons from our study. We find in particular that the transatlantic dispute over transgenic foods and crops is unlikely to be *resolved* in the near future, whether by bilateral deliberation, multilateral negotiation, gradual market-driven convergence, or international litigation. Yet, we argue, the dispute can and should be *managed* through a combination of these and other methods. Bilateral consultations have thus far failed to live up to the high expectations of deliberative decision-making. Yet, we do find evidence of deliberation among scientific experts over risk assessment, and this effort to establish scientific (if not political) consensus is worth pursuing, preferably within multilateral regimes like the OECD and Codex, which have the additional advantage of including third parties who engage in the regulation and trade of GM products. Multilateral regimes, while subject to distributive conflicts and to forum-shopping and inconsistency across regimes, also have a potentially positive role to play, by lowering the transaction costs of negotiations, providing a common vocabulary for discussing GMO regulation, clarifying at least some of the mutual obligations of the parties, and contributing to regulatory knowledge and capacity-building. We find that the WTO, while treading relatively lightly in a deeply politicized area, can have—and has already had—a positive impact on the conflict, by channeling the dispute into legal processes, clarifying the procedural obligations of both sides, and catalyzing the pressure to increase the transparency of domestic regulatory processes.

During our study, an important new factor arose—the emerging role of large developing countries in the struggle over genetically modified crops. China and India have adopted GM cotton for textiles, and Brazil and Argentina

have adopted 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 about GM varieties. We therefore also conclude the book by examining how the US–EU dispute has affected the developing countries, and the role that these countries may play in shaping the future of agricultural biotechnology in a dispute that is no longer purely transatlantic but increasingly global in scope.

Not surprisingly, in light of the many domestic and international pressures on developing-country policy, and in the absence of a generally accepted global standard, developing countries have adopted a wide range of regulatory stances toward agricultural biotechnology, running the gamut from US-style acceptance and widespread commercialization to strict rejection of the new technology. Looking across the developing world, we nonetheless see two broad and somewhat contradictory trends in the regulation and commercial adoption of GM foods and crops. On the one hand, cross-national surveys of GMO regulation indicate that with a few exceptions, the general trend in regulation has been toward greater stringency. A growing number of countries have enacted new regulatory approval and monitoring requirements, as well as more restrictive rules for the importation and labeling of GM foods and crops, reflecting in part transnational capacity-building efforts catalyzed by the Cartagena Biosafety Protocol. At the same time, however, studies on GMO cultivation and commercialization reveal impressive increases in the adoption of GM crops, with the greatest growth rates in the developing world. Indeed, it seems likely that larger developing countries such as Brazil, China, and India will continue to invest in GM technology, cultivating a select group of GM crops, and most others will agree to import at least some GM products.

In sum, if we extrapolate from current trends, it seems likely that agricultural biotechnology will be increasingly accepted over time, albeit within significant market and regulatory constraints for GM foods directly consumed by humans. Nonetheless, the development of GM foods and crops, their regulation and commercialization, are also likely to continue to be shaped, for good or ill, by future contingent events. A major food-safety or environmental crisis involving GM foods and crops is, in our view, unlikely in light of over a decade of experience—yet such a crisis, if it occurred, would likely have a profoundly negative impact on the commercial acceptance and future regulation of GM foods and crops around the world. In contrast, the development and adoption in developing countries of second-generation GM crops that significantly benefit the world's poor could also help swing public opinion, markets, and regulators in favor of agricultural biotechnology around the world. To the extent that a resolution of the conflict is possible, it is most likely to be catalyzed neither in the courtroom nor at a negotiating table, but in the laboratory and in the fields.

1.8. A note on methods and theoretical implications

Finally, before proceeding in the next chapter to the challenges of risk regulation and genetic engineering, we close this chapter with a brief discussion about the nature of our chosen topic, the generalizability of our findings, and the research methods we have employed. We have chosen to delve deeply into a particular policy area in which political and legal institutions at multiple levels interact within a global market context, rather than address multiple issue-areas, as we have done in earlier work.²⁸ 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, decided to focus on this case for three reasons.

First, the regulation of GM foods and crops is an area 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 for farmers and biotech companies that produce GM foods and crops, but also to each of us, for whom it will affect the food we eat, the clothes we wear, and the environment we inhabit. 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 conflicts between the US and EU will facilitate or impede the adoption of agricultural biotechnology, and in this way, will shape the future of agriculture.²⁹

Second, we believe that the GMO conflict is emblematic of issues that will arise in the future, in an economically globalized world characterized by rapid technological changes having uncertain effects. Current disputes over Europe's new legislation for chemicals, and potential future ones over nanotechnology are two examples. 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 protection, poverty eradication, human rights such as food security, the ethics of new research, the relative roles of scientific and political oversight of regulatory 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 in the face of risk, is therefore, a crucial step in understanding the regulatory challenges to be faced in a rapidly changing world in the years to come.

Third, and most generally, the GMO case is one in which two large, market-oriented and democratic actors have attempted repeatedly to cooperate

in an area that would traditionally have been characterized as “low politics” in international relations, and in which a plethora of bilateral networks and multilateral regimes stood ready to facilitate cooperation. Yet, such efforts at cooperation have failed repeatedly, leading us to believe that a careful understanding of the GMO case would reveal both the impediments to successful cooperation and the contributions that international institutions and international law might nevertheless make when cooperation fails.

Throughout the book, therefore, our aim is not only to investigate and offer a definitive empirical account of the transatlantic GMO dispute—although we hope we have done just that—but also to draw on a series of “mid-range” theories that address the various aspects and stages of the dispute, and to engage in the testing and further elaboration of those theories. Hence, in Chapter 2, we elaborate the theories of comparative public policy-making, path-dependence, and two-level games; in Chapter 3, theories of deliberation and persuasion; in Chapter 4, theories of distributive bargaining, regime complexes, and forum-shopping; in Chapter 5, legal theories of international judicial decision-making; and in Chapter 6, theories of international-domestic law and policy interaction. In one sense, therefore, this book represents “applied theory,” drawing on theories of politics and law to analyze and think critically about one of the vital public-policy issues of our day.³⁰ 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 insights and hypotheses about the workings of international “regime complexes,” the interaction of hard and soft laws, and the role of international courts and tribunals when cooperation fails. We, thus, make no attempt to develop any “grand theory” of the GMO conflict, but rather seek, in this book, to borrow from theoretical literatures on each of these topics, while also aiming to make contributions back to those literatures, identifying the implications and lessons of our findings for the study of international relations and international law more generally.

In methodological terms, this study is based on more than eight years of joint empirical investigation, drawing on a wealth of primary and secondary sources, including official documents from the US and the EU, as well as non-governmental organizations and the many multilateral regimes that have dealt with one or another aspect of the conflict. Crucially, moreover, we have cross-checked our findings from these written sources against interviews with a wide range of European and US government regulators, international civil servants, scientists, representatives of business, farmers associations, anti-GMO activists, and other stakeholders holding different ideological and policy orientations about the dispute. In many cases, these individuals have requested anonymity in making their comments, and in those cases we have identified these subjects by their institutional affiliations and the date of the

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interview; where subjects have agreed to allow it, we have identified them by name. In addition, we have attempted, wherever possible, to corroborate information gleaned from interviews in other sources, to minimize our own and the reader's reliance on non-replicable interview data. Throughout the book we have attempted to process-trace³¹ our hypotheses and claims at both the national and international levels, triangulating on our subject using all available sources, whether primary or secondary, quantitative or qualitative, written or interview-based, and we have documented our sources as fully as possible in the footnotes and references to the book.

Although the empirical story of GM foods and crops is a moving target, we hope that this study provides an accurate and insightful analysis of the domestic sources of international regulatory conflict; the attempts at and impediments to cooperation through deliberation and bargaining in transnational networks and multilateral regimes; the roles that international law, international regimes and international markets can nonetheless play, albeit within severe limits that we identify, in domestic systems; and ultimately what happens to international law, international regimes and markets, when cooperation fails.